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
June 13, 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	**167-176**
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:	
• March 21, 2023, Special Conference Committee	**3-4**
• March 30, 2023, Full Board Meeting	**5-12**
• March 30, Public Hearing	**13-14**
• March 30, 2023, Formal Hearing	**15-16**
• April 21, 2023, Formal Hearings	**17-19**
• April 28, 2023, Special Conference Committee	**20-22**
• May 4, 2023, Telephone Conference Call	**23-24**
• May 9, 2023, Special Conference Committee	**25-26**
• May 18, 2023, Innovative Pilot Program Committee	**27-28**
• May 23, 2023, Regulation Committee	**29-34**
• May 24, 2023, Special Conference Committee	**35-38**
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	**39-41**
• Report of Regulation Committee Meeting:	
o Recommendation to amend Guidance Document 110-45 *Approved Chemicals for use as Hydrocarbon or Other Flammable Solvents by Pharmaceutical Processors*	**42-57**
o Recommendation to adopt Guidance Document 110-50 *Cannabis Product Packaging Requirements*	**58-59**
o Reconsider amendment of 18VAC110-20-555 regarding exemption of ADDs stocked solely with stat-use or emergency drugs	**60-75**
o Discussion regarding number and location of pharmacy permits in recent years	**76-79**
o Recommendation of 2024 legislative proposals:	**80-106**
▪ Pharmacy technicians accepting refill authorizations for Schedules III-VI prescriptions and clarification of quantity/refills for Schedule VI prescriptions	

        - Requiring federal criminal background check for resident and nonresident wholesale distributors and third-party logistics providers
        - Clarifying compounding of essentially copies of commercially available drug product
    - Recommendation to amend Guidance Documents 110-36 and 110-9 regarding USP revisions **107-147**
    - Recommendations regarding discussion of monetary penalties in Guidance Document 110-9
    - Recommendation to accept outsourcing facility inspections performed by California and Florida **148-166**
- Adoption of exempt regulations – addition of chemicals from Schedule I **167-176**
- Adoption of proposed regulations – implementation of 2022 legislation for pharmacists initiating treatment **177-191**
- Amend Naloxone Protocol **192-218**
- Adoption of exempt regulatory changes pursuant to 2023 scheduling actions of the General Assembly **219-234**
- Adoption of fast-track regulatory action to amend 18VAC110-20-735 **235-237**

New Business:

- Elections of Chairman and Vice-Chairman, July 1, 2023 through June 30, 2024
- Schedule 2024 meeting dates **Handout**

Reports:

- 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 **238**
- Report on Nonresident Facilities – Beth O'Halloran, RPh **239**
- Report on Inspection Program – Melody Morton, Inspections Manager, Enforcement Division **Handout**
- Report on Pharmaceutical Processors – Annette Kelley, M.S., C.S.A.C. **240**
- Report on Disciplinary Program – Ellen B. Shinaberry, PharmD **241**
- Executive Director's Report – Caroline D. Juran, RPh **242**

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

Adjourn

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

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, March 21, 2023
Commonwealth Conference Center
Second Floor
Board Room 3

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 11:08 am.
PRESIDING:	Kristopher Ratliff, Committee Chair
MEMBERS PRESENT:	Wendy Nash, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Rose DeMatteo, Compliance Case Manager Jess Weber, DHP Adjudication Specialist
CVS/Pharmacy #2315 Permit No. 0201-004463	Sharita L. Holmes, Pharmacist-in-Charge of CVS/Pharmacy #2315, Ashley Jones, Quality Assurance Technician, and Joseph Levino, Senior Legal Counsel for Regulatory Affairs, appeared as representatives of CVS/Pharmacy #2315 to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the December 6, 2022 Notice. They were represented by Nathaniel Brand, III, Esquire and Margaret Hardy, Esquire.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of CVS/Pharmacy #2315. Additionally, she moved that Mykl Egan and Rose DeMatteo attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Nash and duly seconded by Mr. Ratliff, the Committee unanimously voted to issue a monetary penalty to CVS/Pharmacy #2315 and order additional terms and conditions placed on the Pharmacy.
ADJOURNED:	3:35 p.m.

_____ _____

Kristopher Ratliff, Chair

Mykl D. Egan
Discipline Case Manager

_____ _____

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

Thursday, March 30, 2023

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

CALL TO ORDER:	A full board meeting was called to order at 9:10AM.
PRESIDING:	Dale St. Clair, PharmD, Chairman
MEMBERS PRESENT:	William Lee, DPh Kristopher Ratliff, DPh Patricia Richards-Spruill, RPh Cheri Garvin, RPh Larry Kocot, JD Ling Yuan, PharmD Sarah Melton, PharmD Wendy Nash, PharmD
STAFF PRESENT:	Caroline D. Juran, RPh, Executive Director James Rutkowski, Senior Assistant Attorney General Erin Barrett, JD, DHP Director of Legislative and Regulatory Affairs Arne Owens, DHP Director (arrived approx. 10AM) James Jenkins, Jr., DHP Chief Deputy Director Ellen Shinaberry, PharmD, Deputy Executive Director Ryan Logan, RPh, Deputy Executive Director Annette Kelley, MS, CSAC, Deputy Executive Director Beth O'Halloran, RPh, Deputy Executive Director (departed approx. 11AM) Sorayah Haden, Executive Assistant
PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:	
QUORUM:	With all members present, a quorum was established.
APPROVAL OF AGENDA:	**An amended agenda was provided as a handout. The amended agenda was adopted as presented.**

APPROVAL OF PREVIOUS BOARD MEETING MINUTES	Draft minutes for meetings held between November 21. 2022 and February 16, 2023 were presented.
MOTION:	**The Board voted unanimously to adopt the minutes for the meetings held between November 21, 2022 and February 16, 2023 as presented. (motion by Garvin, seconded by Ratliff)**
PUBLIC COMMENT:	Christine Barrille, VPhA, provided public comment informing the board of two bills VPhA sponsored regarding Medicaid provider status for pharmacists and test and treat initiation by pharmacists which were recently passed during the 2023 General Assembly. She stated the position of the Department of Labor and Industry on pharmacy technician training programs in high schools is a significant barrier, and she thanked staff for attending the recent VPhA Annual Meeting.
DHP DIRECTOR'S REPORT:	James Jenkins, Jr., RN, DHP Chief Deputy Director presented the Director's Report on behalf of Arne Owens. Jenkins informed the Board that all four of DHP's submitted bills were passed during the 2023 General Assembly. DHP is working with the Healthcare Workforce to continue to provide survey reports for the Commonwealth. He acknowledged several at DHP are currently working on the Governor's Right Help, Right Now initiative.
NEW BUSINESS:	
ADOPTION OF 2022 PHARMACISTS AND PHARMACY TECHNICIAN WORKFORCE SURVEY REPORTS:	Dr. Barbara Hodgdon provided a PowerPoint presentation of highlights of the draft 2022 Pharmacists and Pharmacy Technician Healthcare Workforce Survey Reports.
MOTION	**The Board voted unanimously to adopt the 2022 Pharmacist and Pharmacy Technicians Workgroup Survey Reports as presented. (motion by Melton, seconded by Kocot)**
ACTION ITEM:	**The Board requested staff to tabulate the number of current active pharmacy permits and closed permits annually for the last several years to potentially identify any trends or access shortages for patients across the Commonwealth.**
LEGISLATIVE/ REGULATORY/GUIDANCE:	
REPORT OF THE 2023 GENERAL ASSEMBLY	Erin Barrett referenced the legislative report included in the agenda packet regarding relevant bills considered or passed by the 2023 General Assembly.

CHART OF REGULATORY ACTIONS

Erin Barrett briefly reviewed the chart in the agenda packet and provided updated information.

ADOPTION OF EXEMPT FINAL REGULATIONS TO PLACE CERTAIN CHEMICALS IN SCHEDULE I

Pursuant to 54.1-3443(D), the Board considered the adoption of exempt regulations regarding the addition of chemicals into Schedule I.

MOTION:

The Board voted unanimously to adopt the exempt changes to 18VAC10-20-322 to place certain chemicals in Schedule I as presented below:

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 compounds.

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

b.N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (other name: para-fluoroacetyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 1-[1-(3-fluorophenyl)cyclohexyl]piperidine (other names: 3-fluoro Phencyclidine, 3F-PCP), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 2-(ethylamino)-2-(2-fluorophenyl)-cyclohexanone (other names: 2-fluoro-2-oxo PCE, 2-fluoro NENDCK), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Central nervous system stimulant.

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

The placement of drugs listed in this subsection shall remain in effect until [September 30], 2024, unless enacted into law in the Drug Control Act. (motion by Yuan, seconded by Garvin)

ADOPTION OF EXEMPT FINAL REGULATIONS TO CONFORM DRUG SCHEDULES TO FEDERAL SCHEDULING ACTION

Pursuant to 54.1-3443 (E), the Board considered the adoption of the exempt final regulations to conform drug schedules to recent federal scheduling actions. It was stated the Board must make a motion to adopt or deny the exempt changes to 18VAC110-20-323 pursuant to federal scheduling changes.

MOTION:

The Board voted unanimously to adopt the exempt changes to 18VAC110-20-323 to conform drug schedules to recent federal scheduling actions as presented below:
31. Adds N-methyl-1-(thiophen-2-yl)propan-2-amine (other name: methiopropamine) to Schedule I;
32. Adds N -phenyl- N′-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5- yl)carbamimidate (other name: mesocarb) to Schedule I;
33. Adds 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol (other name: zipeprol) to Schedule I;
34. Adds 7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid (other name: amineptine) to Schedule I; and,
35. Deletes Fenfluramine from Schedule IV.
(motion by Richards-Spruill, seconded by Lee)

ADOPTION OF FINAL REGULATIONS FROM 2021 PHARMACISTS INITIATING TREATMENT LEGISLATION

The Board considered the adoption of final regulations pertaining to the implementation of 2021 legislation for pharmacists initiating treatment. Two comments in support were received during the recently open public comment period.

MOTION

The Board voted unanimously to adopt the final regulatory changes to 18VAC110-21-46 pertaining the implementation of 2021 legislation for pharmacists initiating treatment as presented. (motion by Melton, seconded by Yuan)

ADOPTION OF PROPOSED REGULATIONS FOLLOWING PERIODIC REVIEW OF CHAPTER 30

The Board considered the adoption of proposed regulations to Chapter 30 following periodic view.

MOTION

The Board voted unanimously to adopt the proposed regulatory changes to 18VAC110-30-21, 18VAC110-30-55, and 18VAC110-30-80 as presented. (motion by Garvin, seconded by Richards-Spruill)

ADOPTION OF PROPOSED REGULATIONS FOR EXEMPTION OF ADDs STOCKED SOLELY WITH STAT-USE OR EMERGENCY

The Board considered the adoption of proposed regulatory changes to exempt ADDs exclusively stocked with emergency or stat-use medications from certain requirements. This action resulted from a petition for rulemaking received in 2022.

DRUGS

MOTION	**The Board voted 8-0 to adopt the proposed regulatory action as presented to amend 18VAC110-20-555 to exempt the requirement for pharmacist review of the prescription order and electronic authorization of a drug stored in an automated dispensing device (ADD) when the ADD is stocked exclusively with emergency or stat-use medications. (motion by Garvin, seconded by Kocot; St.Clair abstained,)**
ADOPTION OF FAST-TRACK ACTION TO REPEAL 18VAC110-21-140 AND 18VAC110-21-150	The Board considered the adoption of fast-track regulatory changes to remove provisions no longer effective based on delayed enactment of the educational requirements when the statutory language regarding pharmacy technician trainees was first passed.
MOTION	**The Board voted unanimously to adopt the fast-track regulatory change to repeal 18VAC110-21-140 and 18VAC110-21-150 as presented. (motion by Ratliff, seconded by Melton)**
AMEND GUIDANCE DOCUMENT 110-9	The Board considered the amendment of Guidance Document 110-9 to include the relatively new licensing category of pharmacy technician trainees in deficiency #4.
MOTION	**The Board voted unanimously to amend Guidance Document 110-9 as presented by inserting "pharmacy technician trainees" into Deficiency #4. (motion by Garvin, seconded by Ratliff)**
ACTION ITEM:	**The Board requested that staff compare the recommended monetary penalties in Guidance Document 110-9 to other states and that this subject be included on the next Regulatory Committee meeting agenda.**
ADOPTION OF GUIDANCE DOCUMENT 110-37 FOR ANTICIPATED SHORTENED HOURS OF PHARMACY OPERATION	To address recent concerns with patients not being able to obtain dispensed prescriptions from a pharmacy that temporarily closes unexpectedly, the Board considered the adoption of Guidance Document 110-37 regarding access to prescriptions during unanticipated shortened hours.
MOTION	**The Board voted unanimously to adopt Guidance Document 110-37 as presented and amended by changing "54.1-3316(2), (3)" to "54.1-3316(2), (13)". (motion by Ratliff, seconded by Garvin)**
ADOPTION OF GUIDANCE FOR PHARMACY ADMINISTRATION RECORDS	To address recent concerns when a drug is administered by someone other than the pharmacist listed on the dispensing record, the Board considered the adoption of Guidance Document 110-50 regarding pharmacy administration records.
MOTION	**The Board voted unanimously to adopt Guidance Document 110-50 as**

presented. (motion by Garvin, seconded by Lee)

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

At the request of VDH to include reference to a new formulation with a higher concentration of naloxone, the Board considered the revision of Guidance Document 110-44 pertaining to the protocol for the prescribing and dispensing of Naloxone. Staff provided a handout of 110-44 that contained an additional revision for Board consideration.

MOTION

The Board voted unanimously to amend Guidance Document 110-44 as presented by inserting "or 5mg" into both charts under "Auto-Injector" and on page 5, inserting the phrase "* Only those DBHDS-approved trainers who have successfully completed DBHDS-approved training on proper drug administration with, and disposal of hypodermic needles and syringes, and who are otherwise authorized to dispense injectable naloxone through a standing order issued in compliance with this protocol, and whose organizations has first obtained a controlled substances registration from the Board of Pharmacy may dispense injectable naloxone with hypodermic needles and syringes." which was inadvertently removed during a previous revision. (motion by Kocot, seconded by Garvin)

AMEND STATEWIDE PROTOCOLS FOR VACCINES FOR ADULTS AND MINORS

Ms. Juran informed the Board that staff had received feedback following the December board meeting that the adopted language requiring 20 hours of training for pharmacy technicians and pharmacy interns was inconsistent with requirements in the PREP Act. The Board considered an amendment of the statewide protocols for vaccines for adults and minors three years and older to align the educational requirements with the PREP Act.

MOTION

The Board voted unanimously to adopt the amended statewide protocols for vaccines for adults and minors as presented. (motion by Melton, seconded by Richards-Spruill)

ADOPTION OF EMERGENCY REGULATIONS AND NOIRA PURSUANT TO 2023 PHARMACISTS INITIATING TREATMENT LEGISLATION

Staff provided a handout regarding the adoption of emergency regulations and NOIRA pursuant to 2023 pharmacists initiating treatment legislation.

MOTION

The Board voted unanimously to adopt the emergency regulations and NOIRA pursuant to 2023 legislation regarding pharmacist initiation of treatment as presented. (motion by Ratliff, seconded by Melton)

REPORTS:

CHAIRMAN'S REPORT

Dale St.Clair presented the Chairman's report. He stated he would attend the

upcoming NABP 119th Annual Meeting in Nashville, TN, along with Ms. Juran, Ms. Garvin, and Dr. Melton. He will also serve as the District 2 representative on the NABP Resolutions Committee. It was noted that Dr. Melton will have two pharmacy students with her in attendance who were chosen for the poster session and will highlight the Board's adoption of Guidance Document 110-32 regarding Possible Drug Interactions with Cannabis.

BOARD OF HEALTH PROFESSIONS

Dr. Sarah Melton indicated that the Board of Health Professions has not met since the previous Board meeting. The next meeting is scheduled to be held in May 2023.

LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES

Ryan Logan, Deputy Executive Director, presented the Licensing Report of Individuals and In-State Facilities which included data from August 2021 to March 2023. As of March 6, 2023, the Virginia Board of Pharmacy has a total of 41,968 current active in-state and individual licensees.

LICENSURE OF NONRESIDENT FACILITIES

Ryan Logan, Deputy Executive Director, presented the Licensing Report of Nonresident Facilities on behalf of Beth O'Halloran, Deputy Executive Director which included data from August 2021 through February 2023. As of February 21, 2023, the Virginia Board of Pharmacy has 2,524 current active nonresident facility registrants.

INSPECTION PROGRAM

Timothy Reilly, DHP Pharmacist Inspector presented the Inspections Report on behalf of Melody Morton which included data from October 2022 through December 2022. The report included statistics regarding the number of inspections completed, identified deficiencies, and the rate of deficiency occurrences.

PHARMACEUTICAL PROCESSORS

Annette Kelley, Deputy Executive Director, presented the Pharmaceutical Processors Report. She noted a recent change to the report included in the agenda packet in that there are now 14 cannabis dispensing facilities in Virginia as four additional facilities have been permitted during the last quarter. The Board has seen a 98% decrease in patient applications due to the change in the registration requirements as of July 1, 2022. There is an anticipated transition date of the medical cannabis program to the Virginia Cannabis Control Authority of January 1, 2024. As of the March 7, 2023, the medical cannabis program consists of the following registrations: 881 registered practitioners, 28,958 registered patients, 130 registered parents/guardians, 154 registered agents, and 2,627 registered cannabis oil products.

DISCIPLINARY PROGRAM

Dr. Ellen B. Shinaberry, Deputy Executive Director presented the Disciplinary Program Report. She highlighted a recent change to the report

included in the agenda packet in that there are now 364 open cases.

EXECUTIVE DIRECTOR'S REPORT

Ms. Juran presented the Executive Director's report. Mrs. Juran reviewed upcoming meetings and meetings recently attended by her and/or board members. She stated that the reference to an upcoming meeting for VPhA on her report in the agenda packet should have read VSHP. Also, she reported that her role as Chairman of the National Association of Boards of Pharmacy will end in May 2023.

CONSIDERATION OF CONSENT ORDERS, SUMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS

Dr. Shinaberry presented a request from OptumRX (0214-000508) to amend a recent Order.

CLOSED MEETING

Upon a motion by Garvin and duly seconded by Nash, 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 OptumRX (0214-000508). Additionally, she moved that Caroline D. Juran, James Rutkowski, Dr. Ellen B. Shinaberry, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE

Upon a motion by Garvin, and duly seconded by Yuan, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

DECISION

Upon a motion by Ratliff, and duly seconded by Nash, the Board voted 8-0 to deny the request for OptumRX (0214-000508). (Kocot abstained)

MEETING ADJOURNED: 1:25pm

_____ _____

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING OF SCHEDULING OF CHEMICALS IN SCHEDULE I AND CONFORMING SCHEDULES TO FEDERAL SCHEDULING ACTIONS

Thursday, March 30, 2023
Commonwealth Conference Center
Second Floor
Board Room 4

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

CALL TO ORDER: At 9:06AM, the Board of Pharmacy ("Board") convened two public hearings to consider the scheduling of certain chemicals in Schedule I and conforming drug schedules to recent federal scheduling actions.

PRESIDING: Dale St.Clair, PharmD, Chairman

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

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

PUBLIC COMMENT

Dr. St.Clair invited members of the public to offer comment on the subject of placing certain chemicals into Schedule I upon recommendation from the Department of Forensic Science and in accordance with subsection D of 54.1-3443. The five chemicals under consideration were:

1. Synthetic compounds.

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

b.N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (other name: para-fluoroacetyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 1-[1-(3-fluorophenyl)cyclohexyl]piperidine (other names: 3-fluoro Phencyclidine, 3F-PCP), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 2-(ethylamino)-2-(2-fluorophenyl)-cyclohexanone (other names: 2-fluoro-2-oxo PCE, 2-fluoro NENDCK), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Central nervous system stimulant.

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

Robyn Weimer, Chemistry Program Manager, Division of Technical Services, DFS provided public comment in support of the action. No other public comment was offered.

Dr. St.Clair invited members of the public to offer comment on the subject of conforming certain drug schedules to recent federal action in accordance to subsection E of 54.1-3443.

No public comments were offered.

MEETING ADJOURNED

The Public Hearings adjourned at 9:10am.

Caroline D. Juran, Executive Director

Date

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

Thursday, March 30, 2023
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 2:25 PM.

PRESIDING: Dale St. Clair, PharmD, Chair

MEMBERS PRESENT:
Patricia Richards-Spruill, RPh
Larry Kocot, J.D.
Kristopher Ratliff, DPh
William Lee, DPh
Sarah Melton, PharmD
Wendy Nash, PharmD
Ling Yuan, PharmD
Cheri Garvin, RPh

STAFF PRESENT:
Caroline D. Juran, RPh, Executive Director
James Rutkowski, Senior Assistant Attorney General
Ellen B. Shinaberry, PharmD, Deputy Executive Director
Sorayah Haden, Executive Assistant

QUORUM: With 9 members of the Board present, a panel of the board was established.

Mazdak Sagheb Tehrani
0202-213044

A formal hearing was held in the matter of Mazdak Sagheb Tehrani to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia and to act on his request for reinstatement of his pharmacist license.

Jess Weber, DHP Adjudication Specialist, presented the case for the Commonwealth of Virginia.

Mazdak Sagheb Tehrani testified on his own behalf and was not represented by counsel.

Katie Land, Sr. Investigator, DHP testified in person on behalf of the Commonwealth.

Farzina Azphenia testified on behalf of Mazdak Sagheb Tehrani.

CLOSED MEETING:	Upon a motion by Lee, and duly seconded by Richards-Spruill, the Board voted unanimously, 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 Mazdak Sagheb Tehrani. Additionally, he moved that Caroline D. Juran, James Rutkowski, Ellen B. Shinaberry, and Sorayah Haden attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Lee, Seconded by Richards-Spruill)
DECISION:	Upon a motion by Garvin and duly seconded by Kocot, the Board unanimously voted to accept the Findings of Fact and Conclusions of Law as presented by the Commonwealth and amended by the Board. Upon a motion by Ratliff and duly seconded by Lee, the Board unanimously voted that with the evidence presented, to deny the reinstatement application of Mazdak Sagheb Tehrani.
ADJOURN:	With all business concluded, the meeting adjourned at 4:46pm.

Caroline D. Juran
Executive Director

Date

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

Friday, April 21, 2023

Department of Health Professions
Drury Plaza Hotel – Chickahominy Room
11049 West Broad Street
Henrico, Virginia 23060

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:15AM.

PRESIDING: Dale St. Clair, Chair

MEMBERS PRESENT:
William Lee
Wendy Nash
Cheryl Garvin, RPh
Larry Kocot, JD

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

QUORUM: With 5 members of the Board present, a panel of the board was established.

CYNTHIA GLOVER
PHARMACY TECHNICAN TRAINEE
APPLICANT

A formal hearing was held in the matter of Cynthia Glover to discuss allegations that she has violated certain laws and regulations governing the practice of pharmacy in Virginia and approve or deny the pending Pharmacy Technician Trainee application.

David Robinson, Assistant Attorney General for the Commonwealth, presented the case. Mr. Robinson was assisted by Christine Andreoli DHP Adjudication Specialist.

Cynthia Glover was not represented by counsel.

Joyce Johnson, DHP Senior Investigator testified in person on behalf of the Commonwealth.

Cynthia Glover testified on her own behalf.

CLOSED MEETING:	Upon a motion by Dr. Lee, and duly seconded by Ms. Garvin, the Board voted unanimously, 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 Cynthia Glover. Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, and Sorayah Haden attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Lee, Second by Garvin)
DECISION:	Upon a motion by Dr. Lee and duly seconded by Dr. Nash, the Board unanimously voted that with the evidence presented, to deny the Pharmacy Technician Trainee registration of Cynthia Glover.
BOARD MEMBER DEPARTURE	Chairman St Clair departed at the conclusion of the formal hearing for Cynthia Glover.
PRESIDING:	William Lee, Vice Chair
MEMBERS PRESENT:	Wendy Nash Cheryl Garvin, RPh Larry Kocot, JD Patricia Richards-Spruill
STAFF PRESENT	Caroline Juran, Executive Director James Rutkowski, Assistant Attorney General Ellen B. Shinaberry, Deputy Executive Director Sorayah Haden, Executive Assistant
FALLS CHURCH PHARMACY PHARMACY, 0201-003833	A formal hearing was held in the matter of Falls Church Pharmacy to discuss allegations that they have violated certain laws and regulations governing the practice of pharmacy in Virginia. David Robinson, Assistant Attorney General for the Commonwealth, presented the case. Mr. Robinson was assisted by Christine Andreoli, DHP Adjudication Specialist.

Falls Church Pharmacy was not represented by counsel.

Victoria McGhee, DHP Sr. Inspector, testified in person on behalf of the Commonwealth.

Thu Anh Bui testified on behalf of Falls Church Pharmacy.

CLOSED MEETING: Upon a motion by Ms. Garvin, and duly seconded by Mr. Kocot, the Board voted unanimously, 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 Falls Church Pharmacy. Additionally, she moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, and Sorayah Haden attend the closed meeting.

RECONVENE: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Garvin, Second by Nash)

DECISION: Upon a motion by Ms. Garvin and duly seconded by Mrs. Richards-Spruill, the Board unanimously voted that with the evidence presented, to revoke the Pharmacy permit of Falls Church Pharmacy.

ADJOURN: With all business concluded, the meeting adjourned at 1:55pm.

Caroline D. Juran, Executive Director

Date

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Friday, April 28, 2023

Drury Plaza Hotel
Shenandoah Room
11049 West Broad Street
Glen Allen, VA 23060

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:16 am.
PRESIDING:	Patricia Richards-Spruill, Committee Chair
MEMBERS PRESENT:	Ling Yuan, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Case Specialist Jess Weber, DHP Adjudication Specialist
JENNIFER BRASSER ATKINS, PHARMACIST License No. 0202-205797	Jennifer B. Atkins, pharmacist, appeared to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacist as stated in the November 18, 2022, Notice, which was continued by letter dated March 14, 2023. She was represented by Mark J. Passero, Esq.
Closed Meeting:	Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Jennifer B. Atkins. Additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to issue Ms. Atkins a REPRIMAND and order her to comply with one term and condition.
LYNDON LEITNER, PHARMACIST APPLICANT	Lyndon Leitner, pharmacy applicant, appeared to discuss his application for a pharmacy license by endorsement and to discuss allegations that grounds may exist to deny his application as stated in the January 27, 2023, Notice. He was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Lyndon Leitner. Additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to GRANT the application of Mr. Leitner for licensure by endorsement to practice pharmacy.
SELENA CARTER PHARMACY TECHNICIAN TRAINEE APPLICANT	Selena Carter, pharmacy technician trainee applicant appeared to discuss her application as a pharmacy technician trainee and to discuss allegations that grounds may exist to deny her application as stated in the March 14, 2023, Notice. She was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to

Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Kennedy Donkor. Additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision: Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill the Committee unanimously voted to DENY the application of Ms. Carter for registration as a pharmacy technician trainee.

ADJOURNED: 4:00 p.m.

_____

Mykl D. Egan
Discipline Case Manager

_____

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, May 4, 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 May 4, 2023, at 8:04 AM, to consider the summary suspensions in case nos. 194996 and 226117.

PRESIDING: Dale St. Clair, Chair

BOARD MEMBERS PRESENT:
Larry Kocot
Cheri Garvin
Patricia Richards-Spruill
William Lee
Wendy Nash
Kristopher Ratliff

STAFF PRESENT:
Mykl Egan, Discipline Case Manager
Caroline Juran, Executive Director
James Rutkowski, Senior Assistant Attorney General
Sean J. Murphy, Assistant Attorney General
Anne G. Joseph, DHP Adjudication Consultant

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 seven (7) members participating and two (2) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

HONOR M. MONTGOMERY License No. 0202-208010	Sean Murphy, Assistant Attorney General, presented a summary of the evidence in case nos. 194996 and 226117 regarding the pharmacy license of Honor M. Montgomery. Mr. Murphy was assisted by Anne G. Joseph, DHP Adjudication Consultant
DECISION:	Upon a motion by Mr. Ratliff and duly seconded by Mrs. Richards-Spruill, the Board unanimously voted (7-0) that, with the evidence presented, the practice as a pharmacist by Honor M. Montgomery poses a substantial danger to the public; and therefore, the registration of Ms. Montgomery shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Ms. Montgomery for the suspension of her license, with the suspension being stayed under certain terms and conditions.
ADJOURN:	With all business concluded, the meeting adjourned at 8:18 AM.

_____
Mykl Egan, Discipline Case Manager

_____
Date

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, May 9, 2023
Commonwealth Conference Center
Second Floor
Board Room 3

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:26 am.
PRESIDING:	Kristopher Ratliff, Committee Chair
MEMBERS PRESENT:	Ling Yuan, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Case Specialist Jess Weber, DHP Adjudication Specialist
CVS/Pharmacy #3794 Permit No. 0201-003379	Jacob Ozan, Quality Assurance Technician, and Joseph Lavino, Senior Legal Counsel for Regulatory Affairs, appeared as representatives of CVS/Pharmacy #3794 to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the January 27, 2023, Notice and continued by letter dated February 21, 2023. They were represented by George Parcells, Esquire and Margaret Hardy, Esquire.
Closed Meeting:	Upon a motion by Dr. Yuan, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of CVS/Pharmacy #3794. Additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Yuan and duly seconded by Mr. Ratliff, the Committee unanimously voted to issue a monetary penalty to CVS/Pharmacy #3794 and order additional terms and conditions placed on the Pharmacy.
ADJOURNED:	1:40 p.m.

_____
Mykl D. Egan
Discipline Case Manager

_____
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INNOVATIVE PILOT PROGRAM COMMITTEE

Thursday, May 18, 2023
Commonwealth Conference Center
Second Floor
Board Room 4

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

CALL TO ORDER:	A meeting of a Special Conference Committee (Innovative Pilot) of the Board of Pharmacy was called to order at 9:07 AM.
PRESIDING:	Dale St. Clair, Committee Chairman
MEMBER PRESENT:	Cheri Garvin, Committee Member
STAFF PRESENT:	Caroline D. Juran, Executive Director Mykl Egan, Discipline Case Manager Jess Weber, DHP Adjudication Specialist Ellen B. Shinaberry, Deputy Executive Director
BRIGHTVIEW, LLC Brightview's Remote Pharmacist Verification	Terri Scarpulla, RPh, Brightview Manager of OTP Compliance, and Tracia Knight, Brightview VP of OTP Compliance, appeared in person to discuss the proposed innovative pilot program "Brightview's Remote Pharmacist Verification" as stated in the May 12, 2023 Notice.
DISCUSSION:	Representatives of Brightview presented information related to the proposed pilot "Brightview's Remote Pharmacist Verification"in an opioid treatment program.
DECISION:	Upon a motion by Ms. Garvin, and duly seconded by Dr. St. Clair, the Committee voted unanimously to approve the innovative pilot program for three years with certain terms and conditions.
ADJOURN:	With all business concluded, the meeting adjourned at 12:11 PM.

Cheryl Nelson Committee Chairman	Caroline D. Juran Executive Director
Date	Date

1. DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

Tuesday, May 23, 2023
Commonwealth Conference Center
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:05AM.
PRESIDING:	Kristopher Ratliff, DPh, Committee Chairman
MEMBERS PRESENT:	Patricia Richards-Spruill, RPh Wendy Nash, PharmD Ling Yuan, PharmD Larry Kocot, JD
MEMBER ABSENT:	Bill Lee, DPh
STAFF PRESENT:	Caroline Juran, RPh, Executive Director Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP Ellen B. Shinaberry, PharmD, Deputy Executive Director Beth O'Halloran, RPh, Deputy Executive Director Ryan Logan, RPh, Deputy Executive Director Annette Kelley, MS, CSAC, Deputy Executive Director Sorayah Haden, Executive Assistant
QUORUM:	With 5 committee members present, a quorum was established.
APPROVAL OF AGENDA:	Agenda was approved as presented.
PUBLIC COMMENT:	No public comment was offered.
UPDATE ON REGULATORY ACTIONS	Ms. Barrett reviewed the chart of regulatory action found on pages 2-4 of the agenda packet.
UPDATE ON TRANSFER OF MEDICAL CANNABIS PROGRAM TO VIRGINIA CANNABIS CONTROL AUTHORITY	Ms. Barrett provided a verbal update for the transfer of the medical cannabis program to the Virginia Cannabis Control Authority (VCCA) which will occur on January 1, 2024. Ms. Kelley and other staff members of the Board are routinely meeting with VCCA staff to ensure a smooth transition. Both agencies are waiting for legal advice from the Office of the Attorney General regarding the handling of the Request for Application for a pharmaceutical processor permit in Health Service Area I. Ms. Barrett indicated the Board will vote to repeal its regulations in December,

effective January 1, 2024. Board staff is working with VCCA staff who will address the required regulatory changes from 2023 legislation and incorporate the proposed regulatory changes from 2022 legislation that remain under administrative review.

AMEND GUIDANCE ON HYDROCARBON SOLVENTS

Becky Hobden, Lab Director, Green Analytics Virginia provided a PowerPoint presentation entitled "Residual Solvents Testing in Cannabis". The slides of the presentation were included on pages 21-29 of the agenda packet. In December 2022, the Board adopted the guidance without butane and propane because the solvents are not explicitly listed in Table 12 of the American Herbal Pharmacopeia Cannabis Inflorescence, 2014. Ms. Hobden highlighted that the Table is pulled from the International Conference on Harmonization (ICH) for the establishment of solvents and limits which is not an exhaustive list. She provided information regarding numerous states that have authorized the use of butane and propane and the associated limits for exposure as a residual solvent in cannabis products. She indicated that tests do exist for assessing residual levels of butane and propane and therefore, would comply with 18VAC110-60-300(G)(6) and 18VAC110-60-281.

MOTION:

The committee voted unanimously to recommend to the full board that it amend Guidance Document 110-45 found on page 6 of the agenda packet by inserting butane and propane as a class 3 solvent with a permissible daily exposure of 50mg/day. (motion by Nash, seconded by Richards-Spruill)

ADOPT GUIDANCE REGARDING CANNABIS ADVERTISING REGULATIONS AS APPLIED TO PACKAGING

Ms. Juran explained that staff will occasionally seek direction from members of the Board when reviewing cannabis product applications for approval. Dr. Nash and Ms. Garvin had recently suggested to staff that input from the Board may be appropriate when considering the approval of cannabis product names and packaging. Ms. Kelley stated that the guidance would assist the industry as well when preparing applications for product approval. The committee reviewed the draft guidance included in the agenda packet regarding cannabis product packaging requirements. Mr. Kocot recommended that product names not be associated with "social media influencers" as well.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the guidance document entitled "Cannabis Product Packaging Requirements" as presented and amended by inserting "social media characters" into the sentence for which brand names may not be associated. (motion by Yuan, seconded by Kocot)

RECONSIDER AMENDMENT OF 18VAC110-20-555

Ms. Barrett reminded the Committee that the Board adopted a proposed regulatory action in March 2023 resulting from a petition for rulemaking to exempt requirements in 18VAC110-10-555 for pharmacist review of a prescription/order and electronic authorization for accessing a drug when

the automated dispensing device is solely stocked with drugs for stat or emergency use. She and Ms. Juran indicated board counsel recently advised that the proposed regulatory action appears to violate federal requirements and therefore, may be inconsistent with the requirement in 18VAC110-20-555 (13) which requires a pharmacy to comply with a written policy and procedure for complying with federal regulations related to the storage and dispensing of controlled substances. This advice appeared to be based on a 2016 letter from DEA to ASCP and the 2022 DEA Pharmacist's Manual. The Committee expressed a desire to hear more from board counsel and Dr. St. Clair at the upcoming full board meeting before deciding on the matter.

MOTION:

The committee voted unanimously to defer the reconsideration of amendment of 18VAC110-20-555 to the full board meeting in June. (motion by Richards-Spruill, seconded by Yuan)

DISCUSSION OF NUMBER AND LOCATION OF PHARMACY PERMITS IN RECENT YEARS

The committee reviewed an excerpt from the 2022 DHP Biennial Report in the agenda packet regarding the number of current active pharmacy permits between 2012 and 2022. A geo-map of current active pharmacy permits was provided as a supporting handout. On June 30, 2012, there were 1,754 pharmacies in Virginia. As of June 30, 2016, the number of pharmacy permits grew by 100. Between June 30, 2016 and June 30, 2022, the number of pharmacy permits in Virginia declined by 86 for a total of 1,768 pharmacies in Virginia. Staff noted that the population census increased by 8.5% between April 1, 2010 and July 1, 2022. Ms. Juran reminded the Committee that the Board issues only one type of pharmacy permit and therefore, it's difficult to know how many different types of pharmacies exist in Virginia. Dr. Nash and Dr. Ratliff inquired if staff could request pharmacies to self-identify its practice setting upon renewal. The Committee indicated they would possibly like to share this information with other agencies or entities in the future, if helpful, to ensure patient access.

ACTION ITEM:

Staff will research with the IT Department the Board's ability to have pharmacies self-identify its practice setting during the renewal process and for this information to auto-populate in the licensing database.

LEGISLATIVE PROPOSALS:

- Pharmacy technicians accepting refill authorizations or Schedule III-VI prescriptions and clarification of quantity/refills for Schedule VI

The committee reviewed draft legislative proposals for the 2024 General Assembly session.

prescriptions.
- Requiring federal criminal background check for resident and nonresident wholesale distributors and third-party logistics providers
- Clarifying compounding of essentially copies of commercially available drug product.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the three legislative proposals as presented. (motion by Nash, seconded by Richards-Spruill)

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

The committee reviewed draft amendments to Guidance Documents 110-36 and 110-9 based on revisions to Chapters <795> and <797> of the United States Pharmacopeia effective November 2023.

MOTION

The committee voted unanimously to recommend to the full board that it amend Guidance Document 110-36 as presented. (motion by Kocot, seconded by Yuan)

The Board further discussed the proposed question and answer #3 within Guidance Document 110-36 and confirmed that all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, should pass a media-fill test at each pharmacy prior to performing sterile compounding. Staff informed the Committee that USP has confirmed that this is not a requirement of USP and therefore, the originally proposed "must" in the agenda packet should be changed to read "should".

The Committee voted unanimously to recommend to the full Board that it adopt Guidance Document 110-36 as presented and amended by changing the proposed answer to question #3 to read, "Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, should pass a media-fill test at each pharmacy prior to performing sterile compounding." (motion by Kocot, seconded by Richards-Spruill)

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

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

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

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

ACTION ITEM

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

DISCUSSION OF ACCEPTANCE OF OUTSOURCING FACILITY INSPECTIONS PERFORMED BY OTHER STATES

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

MOTION:

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

ADJOURN: With all business concluded, the meeting adjourned at 1:52PM.

_____
Caroline D. Juran, RPh,
Executive Director

_____
DATE

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, May 24, 2023
Commonwealth Conference Center
Second Floor
Board Room 3

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:05 am.
PRESIDING:	Cheryl Garvin, Committee Chair
MEMBERS PRESENT:	Wendy Nash, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Jess Weber, DHP Adjudication Specialist
DEYONA WATKINS, Pharmacy Technician Trainee Applicant Registration No.	Deyona Watkins appeared to discuss her application for registration as a pharmacy technician trainee and to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy that could lead to the denial of her application as stated in the March 3, 2023 Notice. Ms. Watkins was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Deyona Watkins. Additionally, she moved that Mykl Egan attend the closed meeting because his presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to GRANT Ms. Watkins' application to practice as a pharmacy technician trainee.
VICTORIA TRABULSIE, Pharmacy Technician Trainee Registration No. 0245-003362	Victoria Trabulsie did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 10, 2023 Notice. Ms. Trabulsie was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Victoria Trabulsie. Additionally, she moved that Mykl Egan attend the closed meeting because his presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to refer the matter to a formal administrative hearing.
AMANDA WHITMAN Pharmacist Applicant License No.	Amanda Whitman, pharmacy applicant, did not appear to discuss her application for a pharmacy license by endorsement and to discuss allegations that grounds may exist to deny her application as stated in the March 22, 2023, Notice. She was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of

	deliberation to reach a decision in the matter of Amanda Whitman. Additionally, she moved that Mykl Egan attend the closed meeting because his presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee voted unanimously to DENY Ms. Whitman's application for licensure as a pharmacist.
KIRTESH PATEL, Pharmacist License No. 0202-012322	Kirtesh Patel, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the April 14, 2023, Notice. He was represented by Greg Habib, Esq.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Kirtesh Patel. Additionally, she moved that Mykl Egan attend the closed meeting because his presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee voted unanimously to DISMISS the case.

PRESTON GROBES, Pharmacist License No. 0202-011659	Preston Grobes did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 28, 2023, Notice. Mr. Grobes was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Preston Grobes. Additionally, she moved that Mykl Egan attend the closed meeting because his presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Nash and duly seconded by Ms. Garvin, the Committee voted unanimously to assess a monetary penalty against Mr. Grobes.
ADJOURNED:	12:58 p.m.

Cheryl Garvin, Chair	Mykl D. Egan Discipline Case Manager
Date	Date

Board of Pharmacy
Current Regulatory Actions
As of May 30, 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 1,833 days; 6.2 years since submission for executive branch review	Addresses a patient safety concern.
18VAC110-20	Emergency/ NOIRA	Pharmacy working conditions	2/27/2023	Governor 92 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 422 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 422 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 272 days	Permits centralized warehousers or wholesale distributors to verify Schedule VI drugs for ADDs in hospitals
18VAC110-20	Final	Implementation of 2021 legislation for pharmacists initiating treatment	5/8/2023	Secretary 22 days	Final regulatory action to replace 2021 emergency regulations for pharmacists initiating treatment

At DPB/OAG

VAC	Stage	Subject Matter	Date submitted*	Office; time in office	Notes
18VAC110-20	Exempt/ Final	March 2023 scheduling of chemicals in Schedule I	4/18/2023	OAG 42 days	Adds chemicals to Schedule I per DFS recommendation
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	5/2/2023	OAG 28 day	Scheduling action pursuant to federal changes
18VAC110-21	Emergency/ NOIRA	2023 pharmacists initiating treatment	4/18/2023	OAG 42 days	Changes in pharmacists initiating treatment pursuant to legislation

18VAC110-21	Fast-track	Repeal of outdated sections	4/18/2023	OAG 42 days	Repeals outdated regulations regarding pharmacy technician registration
18VAC110-30	Proposed	Implementation of 2021 periodic review	4/18/2023	OAG 42 days	Implements changes identified during the periodic review process
18VAC110-60	Exempt/ Final	Pharmaceutical processor regulations	10/5/2022	OAG 237 days	Implements changes to processor regulations pursuant to 2022 legislation

* Date submitted to current location

Recently effective or awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date
18VAC110-21	Emergency	2022 pharmacists initiating treatment	3/13/2023	2/21/2023

Agenda Item: Revision of previously adopted, but not yet effective, guidance document on hydrocarbon solvents

Included in your agenda package are:

- Draft amendments to Guidance Document 110-45 recommended by the Regulatory Committee;
- Board-adopted regulations regarding use of hydrocarbon solvents;
- Correspondence between Becky Hobden, Lab Director, Green Analytics Virginia; and
- Excerpt from American Herbal Pharmacopeia.

Staff Note: Regulatory Committee recommended that the Board amend Guidance Document 110-45 to include butane and propane with a daily exposure of 50mg/day.

Action needed:

- Motion to accept the Regulatory Committee's recommendation to amend Guidance Document 110-45.

Virginia Board of Pharmacy

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

Pursuant to 18VAC110-60-281(H) and 18VAC110-60-300(G)(6), the Board approves the following chemicals for use as hydrocarbon or other flammable solvents in the cultivation, extraction, production, or manufacturing of cannabis products. These approvals are based on the availability of testing for residual material of individual solvents.

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

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

Project 7283 - Final

Board of Pharmacy

Pharmaceutical processor regulation changes pursuant to 2022 legislation

18VAC110-60-281. Use of hydrocarbon-based solvents or other flammable solvents.

A. The following words and phrases used in this section have the following meaning:

1. "Closed-loop system" means machinery in which volatile hydrocarbon substances are self-contained without the loss or escape of those substances.

2. "Flammable solvent" means a liquid that has a flash point below 100 degrees Fahrenheit. Flammable solvents include, but are not limited to, hydrocarbon-based solvents.

3. "Hydrocarbon-based solvent" means a type of solvent composed of hydrogen and carbon compounds, such as N-butane, isobutene, propane, or any isomer or combination thereof.

B. Hydrocarbon-based solvents may be used in the cultivation, extraction, production, or manufacturing of cannabis products provided that:

1. A pharmaceutical processor complies with all requirements in this section.

2. A pharmaceutical processor using hydrocarbon-based solvents in general industrial use as promulgated by the Occupational Safety and Health Administration and published in 29 C.F.R. § 1910 or any subsequent regulation governing such use, including, but not limited to, regulations governing:

a. ventilation requirements;

b. air contaminants; and

c. hazard communication.

3. A pharmaceutical processor using hydrocarbon-based solvents shall comply with any requirements issued by the Virginia Department of Labor and Industry regarding use of hydrocarbon-based solvents.

4. A pharmaceutical processor using hydrocarbon-based solvents shall comply with any requirements issued by the Virginia Department of Environmental Quality regarding use of hydrocarbon-based solvents.

5. A pharmaceutical processor using hydrocarbon-based solvents maintains sole responsibility for any adverse outcomes or violations of federal or Virginia state laws or regulations caused by such use.

6. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that all equipment, counters, and surfaces used in the cultivation, extraction, production, or manufacturing of cannabis products are food-grade and do not react adversely with any hydrocarbon solvent used. All counters and surface areas shall be constructed in a manner that reduces the potential development of microbials, molds, and fungi and can be easily cleaned.

7. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that any room in which hydrocarbon-based solvents will be used contains an emergency eye-wash station.

8. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that a professional grade, closed-loop extraction system capable of recovering solvent is used in the cultivation, extraction, production, or manufacturing of cannabis products.

a. Closed-loop extraction systems must be commercially manufactured and bear a permanently affixed and visible serial number.

b. A pharmaceutical processor using a closed-loop extraction system must obtain a certification from a licensed engineer that certifies that the system was commercially manufactured, is safe for its intended use, and built to codes of recognized and generally accepted good engineering practices, such as: (i) the American Society of Mechanical Engineers ("ASME"); (ii) American National Standards Institute ("ANSI"); (iii) Underwriters Laboratories ("UL"); or (iv) the American Society for Testing and Materials ("ASTM").

c. The certification must contain the signature and stamp of a professional engineer and include the serial number of the extraction unit certified.

9. A pharmaceutical processor using hydrocarbon-based solvents shall obtain a safety data sheet for each hydrocarbon-based solvent used and store such data sheet on the premises. All such records shall be subject to inspection by the board.

10. A pharmaceutical processor using hydrocarbon-based solvents shall develop standard operating procedures, good manufacturing practices, and a training plan prior to using such solvents. Standard operating procedures shall specifically address the following:

a. Safe and proper handling and use of hydrocarbon-based solvents;

b. Safe and proper operation of machinery and equipment;

c. Adequate cleaning and maintenance of machinery and equipment;

d. Incident reporting for any instances where the operator does not follow the stated standard operating procedures which identifies: (i) the operator's name; (ii) the date and time of the incident; (iii) the supervising employees to which the incident report will be sent; and (iv) an incident summary, which includes whether any cannabis products or other substances escaped from the closed-loop system, the amount of

escaped material, whether the material was destroyed, and how the incident was resolved; and

e. Safe and proper disposal of waste created during processes using hydrocarbon-based solvents.

11. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that any person using such solvents in a closed-loop system:

a. Is fully trained on how to use the system;

b. Has direct access to applicable material safety data sheets; and

c. Handles and stores the solvents safely.

C. If a pharmaceutical processor intends to use a flammable solvent, then a designated industrial hygienist or professional engineer that is not an employee of the pharmaceutical processor must:

1. Establish a maximum amount of flammable solvents and other flammable materials that may be stored within the pharmaceutical processor facility in accordance with applicable laws and regulations;

2. Determine what type of electrical equipment must be installed within the room or rooms in which flammable solvents are to be stored in accordance with applicable laws and regulations;

3. Determine whether a gas monitoring system must be installed within the room in which flammable solvents are to be used or stored, and, if required, the system's specifications in accordance with applicable laws and regulations;

4. Determine whether a fire suppression system must be installed within the room in which the flammable solvents are to be used or stored, and, if required, the system's specifications in accordance with applicable laws and regulations; and

5. Determine whether a fume vent hood or exhaust system must be installed within the room or rooms in which a flammable solvent will be used, and, if required, the system's specifications in accordance with applicable laws and regulations.

D. If a pharmaceutical processor makes a material change to its use of flammable solvents in any part of the manufacturing process, a designated industrial hygienist or professional engineer that is not an employee of the pharmaceutical processor must re-certify the standard operating procedures for use of flammable solvents determined under subsection C.

E. A pharmaceutical processor shall maintain copies of all reports generated by or received from the designated industrial hygienist or professional engineer for inspection by the board.

F. A pharmaceutical processor shall not store an amount of flammable solvents on site which exceeds the maximum amount allowable as identified by the designated industrial hygienist or professional engineer.

G. A pharmaceutical processor shall ensure that all appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each employee handling a flammable solvent.

H. The board shall approve chemicals for use as hydrocarbon or other flammable solvents in the cultivation, extraction, production, or manufacturing of cannabis products based on availability of testing for residual material of individual solvents.

Re: Residual Solvents Testing for Hydrocarbons

Becky Hobden <becky.hobden@greenanalyticsllc.com>
Wed 3/22/2023 10:07 AM

To: Juran, Caroline (DHP) <Caroline.Juran@DHP.VIRGINIA.GOV>
Cc: Barrett, Erin (DHP) <Erin.Barrett@dhp.virginia.gov>;Kelley, Annette (DHP) <Annette.Kelley@dhp.virginia.gov>

3 attachments (1 MB)
oha-8964-technical-report-marijuana-contaminant-testing.pdf; ICH_Q3C-R8_Guideline_Step4_2021_0422_1 (3).pdf; USP 467.pdf;

Hi Caroline, Annette, and Erin,

Hope you are all enjoying the start of Spring! I am following up on the questions Caroline sent last week. May 23 is on my schedule to present an overview and answer any questions from the BOP.

The table that I sent you in the previous email addresses the specific question that was brought up at the Dec 6, 2022, full Board of Pharmacy meeting regarding what other states that have marijuana programs (medical and/or recreational) allow the use of butane and/or propane in their production. The concern from the BOP was that butane and propane are not specifically listed on Table 12 in the AHP, which references the International Conference on Harmonization (ICH) for the establishment of the solvents and limits. The table from my previous email came from looking at other states' lists of permissible solvents and their limits to highlight that most, if not all, other states with cannabis programs do allow butane and propane in their production.

Often, as in Table 12, you will see the listed solvents and their Permissible Daily Exposure (PDE), rather than Acceptable Concentration/Limits (ppm). The conversion from PDE (mg/day) to Acceptance Limits is found USP <467> (attached), which is referenced in the ICH, Section 3.3 (pg. 3):

The dose of 10g/day is used as a conservative maximum daily dose. As a reference point, Virginia has a limit of 10mg of THC per dose. A patient would have to consume 1000 doses in one day to reach a 10g dose.

For example, a solvent like ethanol (and all other Class 3 solvents), which has a PDE of 50mg per day, the calculation for acceptable concentration in a product is below:

Acceptance Limit (ppm) = (1000 x 50mg per day) / 10 g per day
Acceptance Limit (ppm) = 5000ppm

This calculation is also referenced, perhaps more succinctly, in a Technical Report from the Oregon Health Authority titled "Oregon Health Authority's Process To Determine Which Types of Contaminants to Test For in Cannabis Products, and Levels for Action" (attached to this email). Pages 9-10 give a good description of solvents use and limits in cannabis production and speaks specifically to butane and propane giving a justification for considering them a Class 3 solvent with a PDE of 50mg/day and an Acceptance Limit of 5000ppm:

"Butane, propane… are short-chain alkanes similar to pentane. Pentane falls into a class of solvents designated as class 3 by ICH Q3C. Class 3 solvents are less toxic and default to a health-based action level of 5,000 ppm for butane [and] propane"

I am not sure why some states have chosen other Acceptance Limits. Speaking with my colleagues in Massachusetts, where the limits are very low, there is significant on-going efforts to increase those limits.

Because butane and propane both fall into the definition in the ICH for a Class 3 solvent, my recommendation is to include them in the VA list of permissible solvents with the limits of a Class 3 solvent (5000 ppm).

To address the question of setting separate limits for inhalable products, the Oregon Technical Report addresses this question as well on pg.10, second bullet point, which states "… the ICH Q3C does assume 100% absorption by any exposure route. This covers inhalation, which is how some pharmaceuticals are administered".

Hope that helps, let me know if you have additional questions.

Thanks,
Becky Hobden
Lab Director
Green Analytics Virginia
540-682-3765 (lab)
828-279-2765 (direct)

On Fri, Mar 10, 2023 at 4:51 PM Juran, Caroline (DHP) <Caroline.Juran@dhp.virginia.gov> wrote:

> Hi, Becky -
>
> Circling back around to this issue. Greatly appreciate your providing us with your research below but I do have a few questions.
>
> 1. Would you be willing to provide a brief overview of the subject and answer board member questions at the May 23rd Regulation Committee meeting? I think this subject is going to require a deeper dive to ensure the board is educated and comfortable with the decision-making.
> 2. I'm trying understand your chart compared to Table 12 in the AHP Cannabis Inflorescence document. I noticed the table for Class 3 solvents uses a header of "Permissible Daily Exposure: 50mg/day", but your chart appears to reference Parts per Million. How do I compare or reconcile PDE to PPM?
> 3. Do you have a specific recommendation for limits? I see that most states have adopted 5,000 for both butane and propane but other states have landed on several different limits, and I note that Colorado with its longstanding cannabis program has set 1,000 as its limit for both solvents. What's the rationale for why the limits vary from 500 to 5,000? I read the pertinent sections of the National Academies of Science document you previously forwarded but some of the states' numbers feel somewhat arbitrary.
> 4. Do you recommend separating out limits for inhaled products vs. non-inhaled products as three states have done?
>
> Thank you, again, for your assistance with this subject. Have a nice weekend.
>
> Best,
> Caroline
>
> Caroline D. Juran, RPh
> Executive Director
> Virginia Board of Pharmacy
>
> **From:** Becky Hobden <becky.hobden@greenanalyticsllc.com>
> **Sent:** Tuesday, December 20, 2022 5:17 PM
> **To:** Juran, Caroline (DHP) <Caroline.Juran@DHP.VIRGINIA.GOV>

Cc: Kelley, Annette (DHP) <Annette.Kelley@dhp.virginia.gov>; Barrett, Erin (DHP) <Erin.Barrett@dhp.virginia.gov>
Subject: Re: Residual Solvents Testing for Hydrocarbons

Hi Caroline, Erin, and Annette,

Continuing the conversation about butane and propane, I did a thorough search of regulations around residual solvents in states where cannabis is regulated. I could find a list for almost all states either written in the regulations or as guidance documents from the regulatory body in the state. Almost all states test for butane and propane and I have included the limits in the table below. Many of these state regulations reference the *American Herbal Pharmacopoeia on Cannabis* and/or the *International Conference on Harmonization*, which is the guiding document for the AHP on residual solvents testing.

I would like to present this to the Board of Pharmacy and whatever additional documentation is needed to get the list updated to include butane and propane. Those hydrocarbons are widely used in cannabis production and are often preferred solvents because of their ability to retain the terpenes, which benefits patients and processors. We can currently test for both of those solvents. Let me know if you have any questions and the best path forward to amending the guidance document from the BOP.

Happy Holidays!

Becky Hobden
Lab Director
Green Analytics Virginia
540-682-3765 (lab)
828-279-2765 (direct)

State	Status	Butane	Propane
Alaska	medical & recreational	800	not tested
Arizona	medical & recreational	5000	5000
Arkansas	medical	5000	5000
California	medical & recreational	5000	5000
Colorado	medical & recreational	1000	1000
Connecticut	medical & recreational	residual solvents not tested at all	residual solvents not tested at all
Florida	medical	800	2100
Hawaii	medical	800	not tested
Illinois	medical & recreational	10	10
Louisiana	medical	800	not tested
Maine	medical & recreational	5000	5000
Maryland	medical & recreational	5000	5000
Massachusetts	medical & recreational	1	1
Michigan	medical & recreational	800 (inhaled products); 5000 (non-inhaled)	2100 (inhaled products); 5000 (non-inhaled)
Minnesota	medical	800 (inhaled products); 5000 (non-inhaled)	2100 (inhaled products); 5000 (non-inhaled)
Mississippi	medical	5000	5000
Missouri	medical & recreational	800 (inhaled products); 5000 (non-inhaled)	2100 (inhaled products); 5000 (non-inhaled)
Montana	medical & recreational	5000	5000
Nevada	medical & recreational	500	500

New Hampshire	medical	500	500
New Jersey	medical & recreational	5000	5000
New Mexico	medical & recreational	800	800
New York	medical & recreational	5000	5000
North Dakota	medical	5000	5000
Ohio	medical	5000	5000
Oklahoma	medical	1000	1000
Oregon	medical & recreational	5000	5000
Pennsylvania	medical	5000	not tested
Rhode Island	medical & recreational	5000	5000
South Dakota	medical	800	2100
Utah	medical	5000	5000
Vermont	medical & recreational	5000	5000
Washington	medical & recreational	5000	5000
Washington, DC	medical & recreational	5000	5000
West Virginia	medical	5000	5000
Alabama	medical	could not find limits	could not find limits
Delaware	medical	could not find limits	could not find limits

On Tue, Dec 6, 2022 at 8:44 AM Juran, Caroline (DHP) <Caroline.Juran@dhp.virginia.gov> wrote:

Becky -

Thank you for the additional information.

Caroline D. Juran, RPh
Executive Director
Virginia Board of Pharmacy

From: Becky Hobden <becky.hobden@greenanalyticsllc.com>
Sent: Tuesday, December 6, 2022 7:42 AM
To: Juran, Caroline (DHP) <Caroline.Juran@DHP.VIRGINIA.GOV>
Cc: Kelley, Annette (DHP) <Annette.Kelley@dhp.virginia.gov>; Barrett, Erin (DHP) <Erin.Barrett@dhp.virginia.gov>
Subject: Re: Residual Solvents Testing for Hydrocarbons

Hi Caroline,

Thanks for your email. The list of solvents in the AHP was pulled directly from the International Conference on Harmonization (ICH) in their published document I*CH Harmonised Guidelines*, *Impurities: Guidelines for Residual Solvents Q3C.* I've attached the most recent version (8) of that document to this email. In the 'Introduction' of that document, it states that the list presented is not exhaustive.

> The lists [of Class 1, 2, and 3 solvents] are not exhaustive and other solvents can be used and later added to the lists. Recommended limits of Class 1 and 2 solvents or classification of solvents may change as new safety data becomes available. Supporting safety data in a marketing application for a new drug product containing a new solvent may be based on concepts in this guideline or the concept of qualification of impurities as expressed in the guideline for drug substance (Q3A, Impurities in New Drug Substances) or drug product (Q3B, Impurities in New Drug Products), or all three guidelines. (pg. 7)

In a precursory review of safety data for butane and propane, there is a good amount of published data available. The National Library of Medicine has published data in A*cute Exposure Guideline Levels for Selected*

Airborne Chemicals: Vol. 12 that includes acute exposure data for butane (pg. 13-47) and propane (pg. 288-315). That document is attached.

Butane and Propane are often preferred solvents in cannabis production because of their ability to retain the cannabis terpenes, a benefit to patients and processes alike. They are widely used in other states safely and effectively. One example of this is Maryland where in the Maryland Medical Cannabis Commission's Testing Regulations published June 2019, they refer specifically to the same ICH guidelines and include in their list of acceptable solvents both butane and propane. They are listed as Class 3 solvents with a limit of 5,000 ppm.

Becky Hobden
Lab Director
Green Analytics Virginia
540-682-3765 (lab)
828-279-2765 (direct)

On Mon, Dec 5, 2022 at 4:01 PM Juran, Caroline (DHP) <Caroline.Juran@dhp.virginia.gov> wrote:

Becky -

Thank you for the email, however, I don't think we can include butane and propane in the guidance document. Regulation 18VAC110-60-300(G)(6) states "6. For the purposes of the residual solvent test, a sample of the cannabis oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopia for Cannabis Inflorescence." Butane and propane do not appear to be listed in the AHP.

Please let me know if I am overlooking something.

Kindest regards,
Caroline

Caroline D. Juran, RPh
Executive Director
Virginia Board of Pharmacy

From: Becky Hobden <becky.hobden@greenanalyticsllc.com>
Sent: Thursday, December 1, 2022 8:09 AM
To: Kelley, Annette (DHP) <Annette.Kelley@dhp.virginia.gov>; Barrett, Erin (DHP) <Erin.Barrett@dhp.virginia.gov>; Juran, Caroline (DHP) <Caroline.Juran@DHP.VIRGINIA.GOV>
Subject: Re: Residual Solvents Testing for Hydrocarbons

Dear Caroline, Erin, Annette, and Members of the Board of Pharmacy,

Thank you for taking into consideration the public comments addressing residual solvents testing that were submitted by Green Analytics Virginia during the recent comment period for the Proposed Regulations Governing Pharmaceutical Processors. The regulation for approving hydrocarbons “based on availability of testing for residual material of individual solvents” ensures all potential residual solvents left from processing are detectable before product approval.

In addition to the solvents approved by the VA Board of Pharmacy, Green Analytics has the capability to test for butane and propane. These hydrocarbons are widely used in cannabis production and have proven to be effective, efficient, and safe technologies. Green Analytics is currently testing for propane and butane for our customers in other states where they are not restricted. Including butane and propane in the list of approved hydrocarbons would be within the boundaries of the regulations.

Thank you for your time and consideration in this matter. Please reach out with any questions.

Becky Hobden
Lab Director
Green Analytics Virginia
540-682-3765 (lab)
828-279-2765 (direct)

American Herbal Pharmacopoeia®

Cannabis Inflorescence

Cannabis spp.

Standards of Identity, Analysis, and Quality Control

Revision 2014

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Table 11 Metal limits recommended for herbal products in the US

Contaminating metal	Limit, µg/daily dose
Inorganic arsenic	10
Cadmium	4.1
Lead	6
Methyl mercury	2.0

Source: AHPA (2008).

ents have broad use sites that could allow for their use on cannabis. Additionally, some states, (e.g., Massachusetts, Washington, and Colorado) are formulating guidelines for pesticide use in cannabis cultivation, whose ingredients are approved in that state for organic production, or are listed by the Organic Materials Review Institute (OMRI). Use of unapproved pesticides in those states that allow for OMRI-listed or exempt pesticides represents a public safety license violation and can result in the cancellation of a cannabis producer's license. State allowance for pesticide use on cannabis may be in conflict with federal pesticide regulations.

Presence and Testing of Pesticides in Cannabis

Specialty agricultural supply stores for the cannabis industry, have proliferated across the US, many of which are categorized as "hydroponic". This aspect of the industry lacks any meaningful regulation or guidance. Products found in such stores have been reported to contain banned substances, and often fail to accurately disclose ingredients or provide adequate information for proper use. For example, the California Department of Food and Agriculture (CDFA) in 2011 issued cease and desist orders against the sale of a number of popular cannabis cultivation products due to their inclusion of a number of banned plant growth regulators including daminozide (Alar) and paclobutrazol (CDFA 2011). A number of these products are labeled as "organic" though they may not be compliant under the National Organics Program of the United States Department of Agriculture (USDA).

The use of such agents on cannabis crops is widespread. Daley et al. (2013) compiled a list of 148 pesticide products used in cannabis cultivation, based on a survey of California growers. Insecticides and miticides are often used on cannabis grown indoors, while fungicides are used on both indoor and outdoor crops. Inappropriate use of insecticides, miticides, and fungicides (such as improper product selection, application rate, concentration, and/or timing) can lead to pests becoming resistant and/or medical users being exposed to inappropriate residue levels.

Appropriate testing methodologies, as recommended by the Environmental Protection Agency (EPA Residue Analytical Methods [RAM]) or those of the Food and Drug Administration (FDA Pesticide Analytical Manual [PAM]), should be employed when appropriate. However, as these tests were developed for commodity food products, the amount of sample needed may be prohibitive to apply to the cannabis industry. Alternatively, The food testing QuEChERS screen uses smaller quantities and may be more applicable to a variety, though not all, of cannabis products (Schoen 2013, personal communication to AHP, unreferenced).

In the cannabis industry today, the most commonly used screening technology for organophosphates, organochlorines, carbamates, and ethylenediaminetetraacetic acid (EDTA) are immunoassays (e.g., enzyme-linked immunosorbent assays [ELISA]) and broad spectrum field tests that may or may not be validated for use on cannabis. Similarly, immunoassays for a broad range of PGRs and fungicides commonly used in cannabis cultivation are not available. Because of their relative inexpense, immunoassays are routinely used by analytical labs specializing in cannabis testing and are at high risk of not detecting pesticide residues and reporting samples to be "pesticide-free" or "non-detected". Before commercial use, any immunoassay should be validated against a standard testing methodology.

Table 10 provides a list of the most common pesticides (including acaricides, insecticides, fungicides, and plant growth regulators) used in cannabis production.

Solvent Residues

Limits on solvents used in the manufacture of botanical products are established by the International Conference on Harmonization (ICH) (ICH 2011), with exceptions made for ethanol and acetic acid in products formulated to contain these substances (e.g., tinctures and vinegars). According to the ICH guideline, solvents are categorized in 3 classes. Class 1 includes known carcinogens, toxic substances, and environmental hazards such as benzene, carbon tetrachloride, 1,2-dichloroethane, 1,1-dichloroethene, and 1,1,1-trichloroethane. These are to be avoided in the manufacture of herbal and/or pharmaceutical products. Class 2 and 3 solvents (Table 12) are distinguished based on their relative toxicity level. Limits established for permissible daily exposures (PDE) are determined individually for Class 2 solvents. Limits for Class 3 solvents are set at a general limit of 50 mg/day. In addition, the ICH guideline lists solvents for which no adequate toxicological data was found (Table 13) and requires manufacturers of pharmaceutical products that choose to use these solvents to supply justification for residual levels of these solvents in their final products. Petroleum ether, found in this group, is reportedly used in the production of hash oil (UNODC 2009).

Solvent extracted products made with Class 3 or other solvents, are not to exceed 0.5% residual solvent by weight or 5000 parts per million (PPM) per 10 gram of solvent-based product and are to be quantified according to the United States Pharmacopeia (USP <467>), Residual Solvents, Option 1. Higher concentrations may also be acceptable provided they are realistic in relation to safety, manufacturing, and good manufacturing practices.

Table 12 Permissable and restricted solvents in the manufacture of cannabis preparations

Class 2 solvents		Class 3 solvents Permissible daily exposure: 50 mg/day
Solvent	Permissible daily exposure, mg/day	
Acetonitrile	4.1	Acetic acid†
Chlorobenzene	3.6	Acetone
Chloroform*	0.6	Anisole
Cyclohexane	38.8	1-Butanol
1,2-Dichlorothene	18.7	2-Butanol
Dichloromethane*	6.0	Butyl acetate
1,2-Dimethoxyethane	1.0	tert-Butylmethylether
N,N-Dimethylacetamide*	10.9	Cumene*
N,N-Dimethylformamide	8.8	Dimethyl sulfoxide
1,4-Dioxane*	3.8	Ethanol*†
2-Ethoxyethanol	1.6	Ethyl acetate
Ethyleneglycol	6.2	Ethyl ether
Formamide	2.2	Ethyl formate
Hexane	2.9	Formic acid
Methanol*	30.0	Heptane
2-Methoxyethanol	0.5	Isobutyl acetate
Methylbutyl ketone	0.5	Isopropyl acetate
Methylcyclohexane	11.8	Methyl acetate
N-Methylpyrrolidone*	5.3	3-Methyl-1-butanol
Nitromethane*	0.5	Methylethyl ketone
Pyridine*	2.0	Methylisobutyl ketone
Sulfolane	1.6	2-Methyl-1-propanol
Tetrahydrofuran	7.2	Pentane
Tetralin	1.0	1-Pentanol
Toluene*	8.9	1-Propanol
1,1,2-Trichloroethene	0.8	2-Propanol
Xylene	21.7	Propyl acetate

* Listed as chemicals known to the state of California to cause cancer or reproductive toxicity under Proposition 65 (CAEPA 2013).
Source: AHPA (2008); CAEPA (2013); ICH (2011); United States Pharmacopeia (USP 30-NF 25 2007).

Table 13 Solvents for which no adequate toxicological data was found

1,1-Diethoxypropane	Methylisopropyl ketone
1,1-Dimethoxymethane	Methyltetrahydrofuran
2,2-Dimethoxypropane	Petroleum ether
Isooctane	Trichloroacetic acid
Isopropyl ether	Trifluoroacetic acid

Source: ICH (2011).

Agenda Item: Adoption of new Guidance Document 110-50 regarding cannabis product packaging requirements

Included in your agenda package is:

- Proposed Guidance Document 110-50, as recommended by the Regulation Committee.

Action needed:

- Motion to accept the Regulatory Committee's recommendation to adopt Guidance Document 110-50; or

- Take no action.

Virginia Board of Pharmacy

Cannabis Product Packaging Requirements

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

Packaging should not:

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

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

References:

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

Agenda Item: Reconsider amendment of 18VAC110-20-555

Included in your agenda package are:

- NOIRA and public comments received;
- Proposed regulatory changes adopted by the Board in March 2023;
- 2016 DEA letter to ASCP; and
- Excerpt from 2022 DEA Pharmacist's Manual.

Staff Note: Board counsel has advised that the proposed regulatory action appears to violate federal requirements and, therefore, may be inconsistent with the requirement in 18VAC110-20-555(13), which requires a pharmacy to comply with a written policy and procedure for complying with federal regulations related to the storage and dispensing of the controlled substances.

The Regulatory Committee considered this issue and did not issue a recommendation. The Committee wished the full Board to consider this matter.

Action needed:

- Motion to withdraw or amend the March 2023 adoption of the proposed regulatory amendment of 18VAC110-20-555.

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Exemption of automated dispensing devices stocked solely with emergency or stat use medications from certain requirements of 18VAC110-20-555
Date this document prepared	June 6, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation.

In response to a petition for rulemaking, the Board is issuing a Notice of Intended Regulatory Action to consider an amendment to section 555 to exempt an automated dispensing device ("ADD") from the requirements of 18VAC110-20-555 when that ADD is exclusively stocked with certain drugs that may be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency use.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

ADD = automated dispensing device

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for change is a petition for rulemaking requesting an amendment to regulations for ADDs stocked solely with stat or emergency use drugs. As presented by the petitioner, it would be more secure for such drugs to be stored in an ADD than a "tackle-box" style mechanism which is currently used.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The Board determined that the petitioner correctly identified a potential hazard in storage of stat or emergency use only medications under 18VAC110-20-540 or 18VAC110-20-550. Stat or emergency use drugs stored in an ADD would contain an electronic record of access to those drugs, while the current tackle-box style storage systems do not. For some facilities, such as nursing homes, ADDs are not used because the only drugs stored on the premises are stat or emergency use medication. Patient and drug security may be increased through utilization of ADDs when exempted from certain requirements that would unacceptably delay the administration of life-saving drugs for patients.

Substance

Briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

An amendment to 18VAC110-20-555 would exempt ADDs exclusively stocked with drugs that would be kept in an emergency drug kit pursuant to 18VAC110-20-540 or a stat-drug box pursuant to 18VAC110-20-550 and are solely administered for stat or emergency use from the requirements of 18VAC110-20-555(1), (4)(a), and (4)(b).

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

The Board of Pharmacy regulates both the use of ADDs and the use of emergency or stat drugs. There is no alternative to regulation to create this exemption.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Erin Barrett, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233, erin.barrett@dhp.virginia.gov, or by fax at (804) 915-0382. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

Commenter: Ben Traynham, Hancock, Daniel & Johnson, P.C.

Comments by PharmScript, LLC

Dear Mr. St. Clair:

Please accept this letter on behalf of PharmScript, LLC as comments on the proposed rulemaking to exempt automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555. PharmScript supports the rulemaking because it will eliminate a hurdle to speedy patient care and ultimately lower risk of patient harm.

PharmScript is one of several long-term care pharmacy services companies who provide remote pharmacy services such as distributing and dispensing emergency and stat-use pre-packaged drugs via automated dispensing devices (ADDs) to nursing homes in Virginia.

18VAC110-20-555 presents an issue that is unique to our operation in Virginia, and that is the required extra-step pharmacist authorization (PV1 order verification) of stat-drugs being dispensed from an ADD. Requiring the pharmacist to review and electronically authorize each stat-drug *prior* to administration is a time-consuming and unnecessary task during a critical period in patient care when the patient needs medication.

PharmScript operates in twenty-three states and the District of Columbia, and Virginia is the only jurisdiction that requires this authorization prior to administration. Other states, including neighbors DC, Maryland, Tennessee, and North Carolina, allow for the pharmacist verification of stat drugs (also referred to as "starter drugs" or "emergency drugs") after administration, usually within 24 hours.

Stat-drugs, synonymous and used as a term interchangeable with emergency drugs, are drugs that should be administered immediately to avoid or reduce patient harm. Stat-drug boxes contain pre-packaged drugs that are ready for administration. The risk of improper administration by the caregiver accessing the ADD is extremely low to nonexistent as there are many safeguards, including electronic controlled access, already built into the ADD system.

In short, the net effect of this requirement is delayed patient care. Delayed care increases the risk of harm to the patient. The increased risk of harm due to delayed care significantly outweighs any potential risk associated with eliminating the PV1 authorization prior to removing stat drugs from an ADD.

Accordingly, PharmScript strongly supports the proposed rulemaking as it would provide patients faster access to the medication they need while reducing potential risk of harm. Please feel free to contact me if you or any Board member wishes to discuss the operational effect of this regulation further.

Sincerely,

John Camperlengo
Chief Legal Officer, PharmScript LLC
CommentID: 206471

12/7/22 1:42 pm

Commenter: Brad McDaniel, Virginia Society of Health-system Pharmacists

Emergent Medication Access vis ADCs

VSHP supports the access to medications that are required in emergent circumstances and waiting for a pharmacist to review the order could adversely impact the patient's condition. The Institute for Safe Medication Practice's "Guidelines for the Safe Use of Automated Dispensing Cabinets" includes that such circumstances would include antidotes, rescue agents, and reversal agents, life-sustaining medications, and urgent comfort medications such as managing acute pain or intractable nausea and vomiting.

Condition 1. VSHP requests that the Board consider the following exemptions to support timely access to medications outside of pharmacy service hours, when access to medications from a STAT box is needed:

- Outside of pharmacy service hours

- Nurse removes the medication under a patient profile (meaning that the ADC is configured as a "profiled" machine) – this is called an "override" function in the ADC

- Medications provided for this indication are for emergent use (such as criteria outlined in ISMP's guidelines)

- Overrides are assessed periodically by the pharmacy provider for appropriate use of emergent medications

We believe these exemptions will support after-hours emergent access to medications and still allow for pharmacist review and verification of orders during pharmacy service hours.

Conditions 4(a) and 4(b) are appropriate exemptions to accomplish this objective.

Brad McDaniel, PharmD, MBA, BCCCP

Chair, Legislative Affairs Committee

Virginia Society of Health-systems Pharmacists

Project 7251 - Proposed

Board of Pharmacy

Exemption of automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555

Chapter 20

Regulations Governing the Practice of Pharmacy

18VAC110-20-555. Use of automated dispensing devices.

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.

3. For facilities not required to obtain a controlled substance registration, access to the automated dispensing device shall be restricted to a licensed nurse, pharmacist, or prescriber, or a registered pharmacy technician for the purpose of stocking or reloading.

4. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:

a. ~~A drug, including a drug that would be stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550,~~ Except for automated dispensing devices exclusively stocked with drugs that would be stored in an emergency drug kit or stat-drug box for emergency or stat administration, a drug may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.

d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

5. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

6. Prior to the removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device, which shall include the date; drug name, dosage form, and strength; quantity; nursing home; a unique identifier for the specific device receiving drugs; and initials of the pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

7. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

8. At the time of loading, the delivery record for all Schedules II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

9. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or the proper reporting of a loss.

10. The PIC of the provider pharmacy or his designee shall conduct at least a monthly audit to review distribution and administration of Schedules II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his

designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedules II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

11. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

12. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

13. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system,

accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

14. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedules II through V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 14 a and 14 b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained offsite or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

NOV 30 2016

Arnold E. Clayman, PD, FASCP
Vice President of Pharmacy Practice & Government Affairs
American Society of Consultant Pharmacists
1321 Duke Street
Alexandria, Virginia 22314-3563

Dear Mr. Clayman:

This responds to your letter dated June 9, 2016, to the Drug Enforcement Administration (DEA), which was submitted as a follow-up to a meeting between the DEA and the American Society of Consultant Pharmacists (ASCP) on May 25, 2016, regarding the use of electronic emergency kits in Long Term Care Facilities (LTCFs). In your letter, you ask whether electronic emergency kits at LTCFs require a separate registration. The DEA appreciates the opportunity to address your inquiry.

As your letter points out, DEA issued a policy statement in 1980 addressing the use of emergency kits in LTCFs. 70 FR 24128 (April 9, 1980). In that document, DEA took the position that an emergency kit containing controlled substances may be placed in a "non-federal registered" LTCF if certain conditions were met. As DEA has not issued any Federal Register document rescinding that policy statement, it remains effective.

Your letter also refers to the DEA regulations relating to an Automated Dispensing System (ADS). As set forth in 21 CFR § 1301.27, a retail pharmacy that installs and operates an ADS at an LTCF must maintain a separate registration at that location.

All emergency kits – whether or not they are electronic – remain subject to the 1980 policy statement (and thus need not be separately registered), *provided they satisfy the criteria of the 1980 policy statement at all times.* Among other things, it is crucial to bear in mind that an emergency kit is only an emergency kit if it is used *exclusively for emergencies*. It also bears emphasis that, in accordance with the CSA and DEA regulations, a controlled substance may only be dispensed for emergency purposes (or otherwise) pursuant to a valid prescription. Thus, where, as in the scenario described in your letter, the kit is maintained at the LTCF by a pharmacy, controlled substances may not be dispensed from the kit for emergencies prior to receipt by the pharmacist of a valid prescription in accordance with the requirements of in 21 CFR §§ 1306.11 and 1306.21. As these sections of the regulations indicate, such prescription may, depending on the circumstances, be issued in writing (paper or electronic in accordance with part 1311), orally, or by fax. In addition, as you know, to be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice, and the pharmacist bears a corresponding responsibility therefor. 21 CFR § 1306.04(a).

If, at any time, a kit is used to administer or dispense controlled substances for a purpose other than an emergency, the kit thereafter ceases to be an emergency kit and, as a result, the separate registration requirement applies.

We trust this letter adequately addresses your inquiry. For information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Liaison and Policy Section at (202) 307-7297.

Sincerely,

Louis J. Milione
Assistant Administrator
Diversion Control Division

United States Department of Justice

Drug Enforcement Administration
Diversion Control Division

www.DEAdiversion.usdoj.gov

Pharmacist's Manual

An Informational Outline of the Controlled Substances Act

Revised 2022[1]

1 This manual replaces all previous editions of the Pharmacist's Manual issued by the Drug Enforcement Administration, both hard copy and electronic. Previous Version EO-DEA154, DEA-DC-046.

registered sites at the retail pharmacy or other approved central location. 21 CFR 1304.04(a)(2) and (b)(1).

DEA registered pharmacies wishing to operate an ADS at an LTCF must contact the DEA Office of Diversion Control, Registration and Program Support Section, at 1-800-882-9539 for registration instructions. An affidavit which meets the requirement of 21 CFR 1301.17(c) must also be submitted with DEA. 21 CFR 1301.27(a).

Emergency Kits for Long-Term Care Facilities

DEA has issued a policy statement which provides individual state licensing and regulatory boards with general guidelines for establishing specific rules concerning controlled substances used in emergency kits at LTCFs. 45 FR 24128 (Apr. 9, 1980) (See Appendix H, *Guidelines for Emergency Kits in Long-Term Care Facilities*.)

All emergency kits (whether or not they are electronic) remain subject to the policy statement in Appendix H, provided they satisfy the criteria of that policy statement at all times. 45 FR 24128 (Apr. 9, 1980). Among other things, it is crucial to bear in mind that an emergency kit is for use in emergencies as defined by the state. It also bears emphasis that, in accordance with the CSA and DEA regulations, a controlled substance may only be dispensed for emergency purposes (or otherwise) pursuant to a valid prescription or medical order. 21 U.S.C. 841(a)(1), 21 CFR 1306.04(a), 21 CFR 1300.01(b) ("*prescriptions*"). Thus, where the kit is maintained at the LTCF by a pharmacy, controlled substances may not be dispensed from the kit for emergencies prior to receipt by the pharmacist of a valid prescription in accordance with the requirements of 21 CFR 1306.11, 1306.21. As these sections of the regulations indicate, such prescriptions may, depending on the circumstances, be issued in writing (paper or electronic in accordance with Part 1311), orally, or by fax. In addition, to be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice, and the pharmacist bears a corresponding responsibility therefor. 21 CFR 1306.04(a). If, at any time, a kit is used to administer or dispense controlled substances for a purpose other than in emergencies as defined by the state, the kit thereafter ceases to be an emergency kit and, as a result, the separate registration requirement applies.

Opioid (Narcotic) Addiction Treatment Programs

The Narcotic Addict Treatment Act of 1974, the Drug Addiction Treatment Act (DATA) of 2000, the Comprehensive Addiction and Recovery Act of 2016 (CARA) and the SUPPORT for Patients and Communities Act of 2018 amended the CSA with respect to the use of controlled substances in the medical treatment of opioid addiction. These laws established the procedures for approving and licensing practitioners involved in the treatment of opioid addiction as well as improving the quality and delivery of that treatment to the segment of society in need.

Agenda Topic: Number and location of pharmacy permits in recent years

Included in Agenda Packet:

- Excerpt from 2022 DHP Biennial Report regarding number of current active pharmacy permits between 2012 and 2022
- U.S. Census Data, population in Virginia in 2010 and 2022
- Geo-mapping of current active pharmacy permits (to be provided as a handout)

Action Needed:

- Discussion. In May, the Regulation Committee recommended staff research with IT if the Board could ask pharmacies to self-identify its practice setting during the renewal process and for this information to auto-populate in the licensing database.

Appendix A – Licenses

Board	Occupation	2012 30-Jun	2014 30-Jun	2016 30-Jun	2018 30-Jun	2020 30-Jun	2022 30-Jun	Percent Change 20-22
Pharmacy	Pharmacy	1,754	1,796	1,854	1,822	1,771	1,768	-0.17%
	Pharmacy Intern	1,797	2,092	2,058	1,865	1,649	1,312	-20.44%
	Pharmacy Technician	12,413	13,610	13,719	13,773	13,162	12,924	-1.81%
	Pharmacy Technician Training Program	86	103	120	143	130	126	-3.08%
	Pharmacy Technician Trainee						6,258	-
	Physician Selling Controlled Substances	500	664	666	708	626	571	-8.79%
	Physician Selling Drugs Location	-	255	222	157	174	160	-8.05%
	Pilot Programs	-	6	18	10	22	25	13.64%
	Registered Agent for Medical Cannabis					7	179	2457.14%
	Registered Practitioner For CBD/THCA Oil						873	-
	Registered Par/Guard For Medical Cannab					51	262	413.73%
	Registered Patient For Medical Cannabis					3,978	52,903	1229.89%
	Registered Product						1,566	-
	Registered Physician for CBD/THC Oil	-	-	-	-	401	-	-
	Repackaging Training Program	-	1	-	2	2	2	0.00%
	Restricted Manufacturer	77	75	69	55	44	36	-18.18%
	Third Party Logistics Provider †	-	-	-	5	6	7	16.67%
	Warehouser	46	42	47	86	112	121	8.04%
	Wholesale Distributor	112	122	120	79	65	62	-4.62%
Pharmacy Total		**30,666**	**34,398**	**35,972**	**36,968**	**41,676**	**99,376**	**138.45%**

An official website of the United States government

United States Census Bureau

QuickFacts

Virginia

QuickFacts provides statistics for all states and counties, and for cities and towns with a ***population of 5,000 or more***.

Enter state, county, city, town, or zip code | -- Select a fact -- | CLEAR | TABLE | MAP | CHART

Table

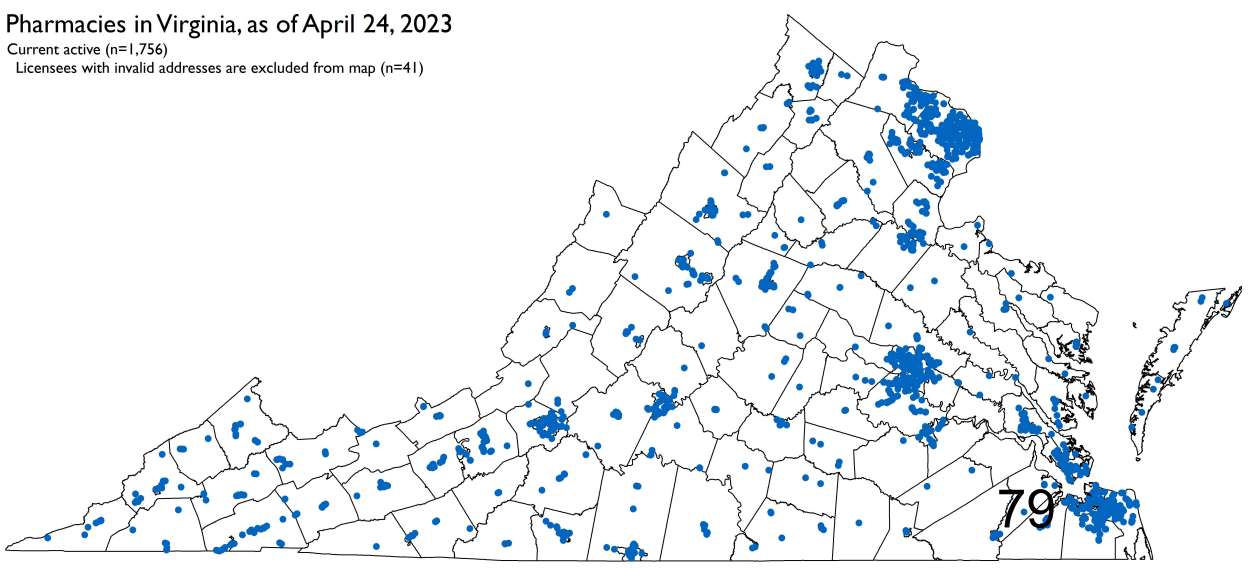
All Topics | Virginia

Population Estimates, July 1, 2022, (V2022)	**8,683,619**
PEOPLE	
Population	
Population Estimates, July 1, 2022, (V2022)	**8,683,619**
Population Estimates, July 1, 2021, (V2021)	8,657,365
Population estimates base, April 1, 2020, (V2022)	8,631,384
Population estimates base, April 1, 2020, (V2021)	8,631,384
Population, percent change - April 1, 2020 (estimates base) to July 1, 2022, (V2022)	0.6%
Population, percent change - April 1, 2020 (estimates base) to July 1, 2021, (V2021)	0.3%
Population, Census, April 1, 2020	8,631,393
Population, Census, April 1, 2010	8,001,024

Pharmacies in Virginia, as of April 24, 2023

Current active (n=1,756)

Licensees with invalid addresses are excluded from map (n=41)



Agenda Topic: 2024 Legislative proposals

- Authorization of pharmacy technicians to clarify refills and quantity of certain prescriptions
- Clarifying compounding of essentially copies of commercially available drug product
- Requiring federal criminal background check for resident and nonresident wholesale distributors and third-party logistics providers

Staff Note:

Legislative proposals for 2024 must be adopted by the Board in June for consideration by the DHP Director, Secretary of HHR, and Governor for possible inclusion in the Governor's packet of legislation introduced during the 2024 General Assembly Session.

Included in packet:

- Draft proposal regarding pharmacy technicians resulting from 2021 work group
- Draft proposal regarding compounding
- FDA guidance on compounding
- Regulation 18VAC110-50-80 requiring federal background report

Staff Note: The Regulation Committee recommended the full board adopt the legislative proposals as presented.

Action Needed:

- Vote to accept or deny the Regulation Committee's recommendation to adopt the legislative proposals as presented, or
- Vote to adopt the legislative proposals as amended.

Department of Health Professions

Authorization of pharmacy technicians to clarify refills and quantity of certain prescriptions

A BILL to amend the *Code of Virginia* by amending §§ 54.1-3320 and 54.1-3321 of the Code of Virginia relating to permissible acts of pharmacy technicians.

Be it enacted by the General Assembly of Virginia:

1. **That § 54.1-3320 and 54.1-3321 of the *Code of Virginia* are amended and reenacted as follows:**

§ 54.1-3320. Acts restricted to pharmacists.

A. Within the practice of pharmacy as defined in § 54.1-3300, the following acts shall be performed by pharmacists, except as provided in subsection B:

1. The review of a prescription, in conformance with this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title and with current practices in pharmacy, for its completeness, validity, safety, and drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, and noncompliance and duplication of therapy;

2. The receipt of an oral prescription from a practitioner or his authorized agent;

3. The conduct of a prospective drug review and counseling as required by § 54.1-3319 prior to the dispensing or refilling of any prescription;

4. The provision of information to the public or to a practitioner concerning the therapeutic value and use of drugs in the treatment and prevention of disease;

5. The communication with the prescriber, or the prescriber's agent, involving any modification other than refill authorization of a prescription or of any drug therapy in Schedules III-VI or clarification of quantity or refill of a prescription issued for a Schedule VI drug, resolution of any drug therapy problem, or the substitution of any drug prescribed;

6. The verification of the accuracy of a completed prescription prior to dispensing the prescription;

7. The supervision of pharmacy interns and pharmacy technicians; and

8. Any other activity required by regulation to be performed by a pharmacist.

B. A pharmacy intern may engage in the acts to be performed by a pharmacist as set forth in subsection A or the Drug Control Act (§ 54.1-3400 et seq.) for the purpose of obtaining practical

experience required for licensure as a pharmacist, if the supervising pharmacist is directly monitoring these activities.

C. A registered pharmacy technician, working under the direct supervision of a qualified nuclear pharmacist, as defined by regulations of the Board, may accept oral prescriptions for diagnostic, nonpatient specific radiopharmaceuticals in accordance with subsection C of § 54.1-3410.1.

D. Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more pharmacy technicians than allowed by Board regulations.

§ 54.1-3321. Registration of pharmacy technicians.

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

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

2. The preparation of prescription labels or patient information;

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

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

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

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

7. The acceptance of refill authorization of a prescription for a Schedule III-VI drug, or clarification of quantity and refills for a prescription issued for a Schedule VI drug from a prescriber or his authorized ~~agency~~ agent, so long as there is no other change to the original prescription;

8. Under the supervision of a pharmacist, meaning the supervising pharmacist is at the same physical location of the technician or pharmacy intern, and consistent with the requirements of § 54.1-3303.1, administration of the following drugs and devices to persons three years of age or older as set forth in regulations of the Board: vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

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

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

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

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

3. Evidence that he has successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.

C. The Board shall promulgate regulations establishing requirements for:

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

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

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

D. The Board shall waive the initial registration fee for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

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

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

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

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

I. A registered nurse or licensed practical nurse practicing at an opioid treatment program pharmacy may perform the duties set forth for pharmacy technicians in subsection A, provided that all take-home medication doses are verified for accuracy by a pharmacist prior to dispensing.

Board of Pharmacy

2024 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending § 54.1-3410.2, relating to the compounding of commercially available products.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3410.2 of the *Code of Virginia* is amended and reenacted as follows:

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, 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.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § 54.1-3420.2.

A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.

Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients 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.

Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA; or are manufactured by an establishment that is registered by the FDA; and

2. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product and such determination is documented on the prescription (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, or (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, ~~or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product;~~ or

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original

manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ 54.1-3301, 54.1-3304, and 54.1-3304.1 shall comply with all provisions of this section and the relevant Board regulations.

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018
Compounding

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:
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https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
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Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act
Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed in the title page.

I. INTRODUCTION AND SCOPE

To qualify for exemptions under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug product must be compounded by a licensed pharmacist or physician who does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product, among other conditions. This guidance sets forth FDA's policies regarding this provision of section 503A, including the terms *commercially available*, *essentially a copy of a commercially available drug product*, and *regularly or in inordinate amounts*.[2]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For policies pertaining to mixing, diluting, and repackaging biological products, see FDA's guidance, *Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.* For policies pertaining to repackaged drug products, see FDA's guidance, *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*.

All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

II. BACKGROUND

A. Section 503A of the FD&C Act

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 and amended by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from the following three sections of the FD&C Act:[3]

- Section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements)
- Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use)
- Section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs))

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503A of the FD&C Act is that it must be compounded by a licensed pharmacist or a licensed physician that "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product."[4]

The statute further states that "the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug."[5]

A complete list of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A appears in the FDA guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.

B. Compounding, Generally

Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, an elderly patient who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a strength that is lower than that of the commercially available product. Drug products for identified individual patients can be compounded by licensed pharmacists in state-licensed

[3] In addition, under section 581(13) of the FD&C Act, the term "product," for purposes of pharmaceutical supply chain security requirements, does not include a drug compounded in compliance with section 503A.

[4] See section 503A(b)(1)(D).

[5] See section 503A(b)(2).

pharmacies and Federal facilities and by licensed physicians operating under section 503A of the FD&C Act. Drug products can also be compounded by outsourcing facilities under section 503B of the FD&C Act for identified individual patients pursuant to prescriptions or for distribution to health care practitioners without first receiving a prescription.[6] Both sections 503A and 503B restrict compounding drug products that are essentially a copy of a commercially available drug product (section 503A) or an approved drug product (section 503B).

C. Risks Associated with Compounded Drug Products

Although compounded drugs can serve an important need, they can also pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with CGMP requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products that they compound because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint, such as a report of a serious adverse event or visible contamination.

FDA has investigated numerous serious adverse events associated with compounded drug products that were contaminated or otherwise compounded improperly, including the adverse events associated with the 2012 fungal meningitis outbreak in which contaminated injectable drug products resulted in more than 60 deaths and 750 cases of infection. FDA has also identified many pharmacies that compounded drug products under insanitary conditions such that the drug products may have been contaminated with filth or rendered injurious to health and that shipped the compounded drug products made under these conditions to patients and health care practitioners across the country, sometimes in large amounts.

D. Compounded Drugs That Are Essentially Copies of Commercially Available Drug Products

Section 503A provides exemptions from new drug approval, labeling with adequate directions for use, and CGMP requirements of the FD&C Act, so that drug products can be compounded as customized therapies for identified individual patients whose medical needs cannot be met by commercially available drug products. The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risks because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared

[6] Section 503B of the FD&C Act describes the conditions that must be met for a human drug product compounded by an outsourcing facility to qualify for exemptions from sections 505, 502(f)(1), and 582 (concerning drug supply chain security requirements) of the FD&C Act. The conditions applicable to outsourcing facilities are discussed in separate guidances applicable to those facilities.

under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available.

In addition to these immediate public health risks, section 503A's limitations on producing a drug product that is essentially a copy of a commercially available drug product protects the integrity and effectiveness of the new drug and abbreviated new drug approval processes that Congress put in place to protect patients from unsafe, ineffective, or poor quality drugs. Furthermore, sponsors may be less likely to invest in and seek approval of innovative, life-saving medications if a compounder could, after a drug is approved, compound "substitutes" that may be less expensive because they have not had to demonstrate safety and effectiveness and are not produced in accordance with CGMP requirements or labeled with adequate directions for use.

Sponsors might also be less likely to seek approval of an ANDA for a generic drug if compounders were permitted to compound drugs that are essentially copies of commercially available drugs without going through the ANDA process. An ANDA must include data to demonstrate that the drug has the same active ingredient and is bioequivalent to an approved drug. FDA also conducts premarketing inspections of proposed manufacturing facilities.

The copies restriction also protects FDA's drug monograph process. FDA has an ongoing process for evaluating the safety and effectiveness of certain over-the-counter (OTC) medications, and if the Agency determines that an OTC drug meets certain conditions and is generally recognized as safe and effective, it will publish a final monograph specifying those conditions. Products that comply with a final monograph may be marketed, but manufacturers are required to meet CGMP standards. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements.

III. POLICY

As stated above, to qualify for the exemptions under section 503A of the FD&C Act, a drug must be compounded by a licensed pharmacist or a licensed physician that does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.[7] This means that a compounded drug product is not eligible for the exemptions in section 503A if it is (1) essentially a copy of a commercially available drug product, and (2) compounded regularly or in inordinate amounts. Accordingly, and as discussed below, when evaluating whether a drug product meets the condition in section 503A regarding essentially copies, FDA intends to determine whether a compounded drug product is *essentially a copy of a commercially available drug product:* if it is, FDA intends to determine whether the drug product was compounded regularly or in inordinate amounts.[8]

[7] See section 503A(b)(1)(D).

[8] FDA is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance or rulemaking. FDA regards a health system as collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients. There is no definition of "health system" that applies to all sections of the FD&C Act.

FDA's policies with regard to the terms (1) *commercially available drug product*, (2) *essentially a copy of a commercially available drug product*, and (3) *regularly or in inordinate amounts*, are as follows:

A. Commercially Available Drug Product

For purposes of this guidance, a drug product is commercially available if it is a marketed drug product.

We do not consider a drug product to be commercially available if

- the drug product has been discontinued and is no longer marketed[9] or
- the drug product appears on the FDA drug shortage list in effect under section 506E of the FD&C Act.[10] A drug "appears on the drug shortage list in effect under section 506E" if the drug is in "currently in shortage" status (and not in "resolved" status) in FDA's drug shortage database.

Commercially available drugs are available on the market, and they are generally subject to FD&C Act requirements relating to approval, labeling, and CGMP requirements, and the copies restriction applies to all such drugs because section 503A is not intended to provide a means for compounders to produce compounded drugs exempt from the Act's requirements that are essentially copies of commercially available drug products.

B. Essentially a Copy of a Commercially Available Drug Product

1. What is Essentially a Copy?

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if:

- the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product;
- the API(s) have the same, similar, or an easily substitutable dosage strength; and

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However, this is the definition of a "health system" used in section 506F of the Act concerning hospital repackaging of drugs in shortage.

[9] FDA maintains a list of approved drug products that sponsors have indicated are not marketed in the discontinued section of the list of Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). See http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Specifically, the list includes approved drug products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined were withdrawn for safety or effectiveness reasons, or have had their approvals withdrawn for reasons other than safety or effectiveness subsequent to being discontinued from marketing.

[10] See http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

- the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug,

unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product.

The limitations in section 503A(b)(1)(D) apply to the compounding of drug products that are *essentially* copies of a commercially available drug product – not only to drugs that are exact copies or even to drugs that are nearly identical. This is to ensure that compounders do not evade the limits in this section by making relatively small changes to a compounded drug product and then offering the drug to the general public without regard to whether a prescribing practitioner has determined that the change produces for the patient a significant difference. For example, Congress contemplated that a compounded drug may be essentially a copy of a commercially available drug if "minor changes in strength (such as from .08% to .09%) are made that are not known to be significant . . ." for the patient for whom the drug was prescribed.[11]

a. Same API

With regard to the characteristics listed above, an API is the substance in a drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.[12] When a compounded drug product offers the same API as a commercially available drug product, in the same, similar, or easily substitutable dosage strength and for use through the same route of administration, we generally intend to consider such a drug product *essentially a copy*, unless a prescriber determines that there is a change, made for an identified individual patient, that will produce a significant difference for that patient.

We recognize that, for some patients, a drug product that has the same API, strength, and route of administration may include a change that produces a significant difference for a particular patient. For example, a drug product compounded without a particular inactive ingredient may produce a significant difference for a patient who has an allergy to the inactive ingredient in the commercially available drug product. However, for other patients, this change may produce no difference at all. Congress did not intend for compounders to use, for example, the fact that some patients may have allergies as a basis to compound a drug without the inactive ingredient for other patients who do not have the allergy under the exemptions in section 503A (i.e., without meeting requirements for premarket approval, labeling with adequate directions for use, or

[11] U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

[12] Section 503A refers to bulk drug substances. A *bulk drug substance* is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. It does not include intermediates used in the synthesis of the substance. This definition is the same as the definition of active pharmaceutical ingredient. See 21 CFR 207.1, 207.3.

CGMP requirements).[13] In the context of compounding and consistent with the statute, we generally intend to consider such a drug essentially a copy unless a prescriber determines that there is a change that will produce a significant difference for the patient for whom it is prescribed.

b. Same, Similar or Easily Substitutable Strength

FDA generally intends to consider two drugs to have a similar dosage strength if the dosage strength of the compounded drug is within 10% of the dosage strength of the commercially available drug product.

With regard to the concept of easily substitutable strength, in some cases, the same or similar dosage strength can be achieved by administration of fractional or multiple doses of a drug product. For example, if FDA-approved Drug X tablets have a dosage strength of 25 mg and a patient needs 50 mg of Drug X, FDA would generally consider a compounded Drug X 50 mg tablet to have an easily substitutable strength because the patient could take two Drug X 25 mg tablets to achieve the required dose.[14]

c. Same Route of Administration

Route of administration is a way of administering a drug to a site in a patient (e.g., topical, intravenous, oral).[15] In general, FDA does not intend to consider a compounded drug product with the same API and similar or easily substitutable strength to be essentially a copy of a commercially available drug product if the compounded drug product and the commercially available drug product have different routes of administration (e.g., if the commercially available drug product is oral and the compounded drug product is topical). However, if the compounded drug product has the same API and similar or easily substitutable strength as the commercially available drug product and the commercially available drug product can be used (regardless of how it is labeled) by the route of administration prescribed for the compounded drug, FDA generally intends to consider the compounded drug to be essentially a copy of the commercially available drug. In this case, the compounded drug product generally would not produce a significant difference for an identified individual patient relative to the commercially available drug product.

For example, if the commercially available drug is an injectable drug sold in a vial that is labeled for intra-muscular use, but the drug also can be drawn from the vial by a smaller needle for subcutaneous administration, a compounded drug product with the same API and similar or

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[13] *See* note 11.

[14] If a commercially available tablet must be split to achieve the prescribed dosage strength, and such tablet is not suitable for splitting, FDA would not consider the compounded drug made to the prescribed dosage strength to have an easily substitutable strength. For example, some tablets may be too small or crumble too easily when split, making splitting an inappropriate option. Information regarding tablet splitting may be printed in the "HOW SUPPLIED" section of the professional label insert and in the patient package insert of an approved drug product.

[15] See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071667.htm.

easily substitutable strength prescribed for sub-cutaneous administration would generally be considered to be essentially a copy, unless the prescriber documents on the prescription that the compounded drug product produces a significant difference for the identified individual patient.

d. Same Characteristics as Two or More Commercially Available Drug Products

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if the compounded drug product contains the same APIs as two or more commercially available drug products in the same, similar, or easily substitutable strength and if the commercially available drug products can be used (regardless of how they are labeled) by the same route of administration prescribed for the compounded drug, unless there is documentation as described in section III.B.2. Such drug products present the same kinds of concerns as drug products that have a single API and in some respects may be more dangerous because of the potential for unintended drug interactions or formulation issues. For example, if drug X and drug Y are commercially available oral drug products, FDA generally intends to consider a compounded oral drug product that combines drug X and drug Y in strengths that are within 10% of the strengths of the respective commercially available products to be essentially a copy of the commercially available drug product, unless a prescriber determination of a significant difference has been documented.

2. Statement of Significant Difference

Pursuant to section 503A(b)(2) of the FD&C Act, a compounded drug product is not essentially a copy of a commercially available drug product if a change is made for an identified individual patient, and the prescribing practitioner has determined that the change will produce a significant difference for that patient. If a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription.

FDA does not believe that a particular format is needed to document the determination, provided that the prescription makes clear that the prescriber identified the relevant change and the significant difference that the change will produce for the patient. For example, the following would be sufficient:

- "No Dye X, patient allergy" (if the comparable drug contains the dye)
- "Liquid form, patient can't swallow tablet" (if the comparable drug is a tablet)
- "6 mg, patient needs higher dose" (if the comparable drug is only available in 5 mg dose)

However, if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not

sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product.[16]

If a prescription does not make clear that the prescriber made the determination required by section 503A(b)(2), or a compounded drug is substituted for the commercially available drug product, the compounder can contact the prescriber and if the prescriber confirms it, make a notation on the prescription that the compounded drug product contains a change that makes a significant difference for the patient. The notations should be as specific as those described above, and the date of the conversation with the prescriber should be included on the prescription.[17]

It is not possible to offer exhaustive guidance about when a difference will be "significant" to an identified individual patient. At this time, FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation. However, we do intend to consider whether a prescription or notation relied upon by a compounder to establish that a drug is not essentially a copy documents that the determination was made.

If the compounder produces drugs in anticipation of receiving valid prescriptions for identified individual patients, and the compounder obtains the statement of significant difference from the prescriber when it receives the prescription for the compounded drug, prior to distribution, FDA does not intend to consider the compounded drug that is then distributed to be essentially a copy.

3. Documentation of Shortage

If the drug was compounded because the approved drug product was not commercially available because it was on the FDA drug shortage list, the prescriber or compounder should include a notation on the prescription that it was on the drug shortage list and the date the list was checked.[18]

4. Regularly or in Inordinate Amounts

A drug product is not eligible for the exemptions in section 503A if it is prepared by a pharmacist or physician who compounds "regularly or in inordinate amounts (as defined by the Secretary)" any drug products that are essentially copies of a commercially available drug

[16] Congress noted that "where it is readily apparent, based on the circumstances, that the 'significant difference' is a mere pretext to allow compounding of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from .08% to .09%) are made that are not known to be significant or instances in which the prescribing physician is receiving financial remuneration or other financial incentives to write prescriptions for compounded products." *See* the U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

[17] See section IV of this guidance.

[18] See section IV of this guidance.

product.[19] FDA interprets this to mean that, in order to be compounded in accordance with section 503A, a drug product that is essentially a copy of a commercially available drug product cannot be compounded regularly – i.e., it cannot be compounded at regular times or intervals, usually, or very often. Nor can the amounts compounded be inordinate, in light of the purpose of section 503A.

Section 503A is intended to protect patients from the public health risks of providing compounded drugs to patients whose medical needs could be met by commercially available drug products and to protect the integrity and efficiency of the drug approval process. Under the statutory scheme, only very rarely should a compounded drug product that is essentially a copy of a commercially available drug product be offered to a patient. We conclude, therefore, that a drug product that is essentially a copy of a commercially available drug product is compounded regularly or in inordinate amounts if it is compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances.

It is important to note that the regularly or in inordinate amounts provision is not implicated if the compounded drug is not essentially a copy of a commercially available drug product. For example, a compounded drug product that has the same API, dosage strength, and route of administration as a drug product on FDA's shortage list would not be considered essentially a copy of a commercially available drug because a drug product is not considered *commercially available* if it is on FDA's drug shortage list. In addition, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient.
Once it has been determined that a compounded drug is essentially a copy of a commercially available drug product as described above, the following are examples of factors that may be the basis for concluding that it has been compounded regularly or in inordinate amounts:

- The compounded drug product amounts to more than a small number of prescriptions or a small percentage of the compounded drug products that a compounder prepares.
- The compounder routinely substitutes compounded drugs that are essentially copies of commercially available drugs upon receiving prescriptions for patients.
- The compounder offers pre-printed prescription pads that a prescriber can use to write a prescription for the drug product that is essentially a copy without making a determination that there is a change that will produce a significant difference for a patient.
- The compounded drug product is not compounded on an as-needed basis, but on a routine or pre-set schedule.

The foregoing list is not intended to be exhaustive. Other factors may be appropriate for consideration in a particular case.

To focus enforcement on the most significant cases, as a matter of policy, at this time FDA does not intend to take action against a compounder for compounding a drug product that is

[19] See section 503A(b)(1)(D).

essentially a copy of a commercially available drug product regularly or in inordinate amounts if the compounder fills four or fewer prescriptions for the relevant compounded drug product in a calendar month.[20] As noted above, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient; thus, a prescription that documents such a prescriber determination would not be counted towards the four prescriptions.

Compounders may produce a limited amount of drugs in anticipation of receiving valid prescriptions for identified individual patients. See section 503A(a)(2). FDA generally intends to consider whether such drugs are essentially a copy at the time the drug is distributed rather than the time it is produced.

5. Recordkeeping

A licensed pharmacist or physician seeking to compound a drug product under section 503A should maintain records to demonstrate compliance with section 503A(b)(1)(D). For example, records should be kept of notations on prescriptions for identified individual patients that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient.

Compounders under section 503A should also maintain records of the frequency in which they have compounded drug products that are essentially copies of commercially available drug products and the number of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products to document that such compounding has not been done regularly or in inordinate amounts.[21]

FDA recommends that compounders maintain the records described above for a period of at least three years.

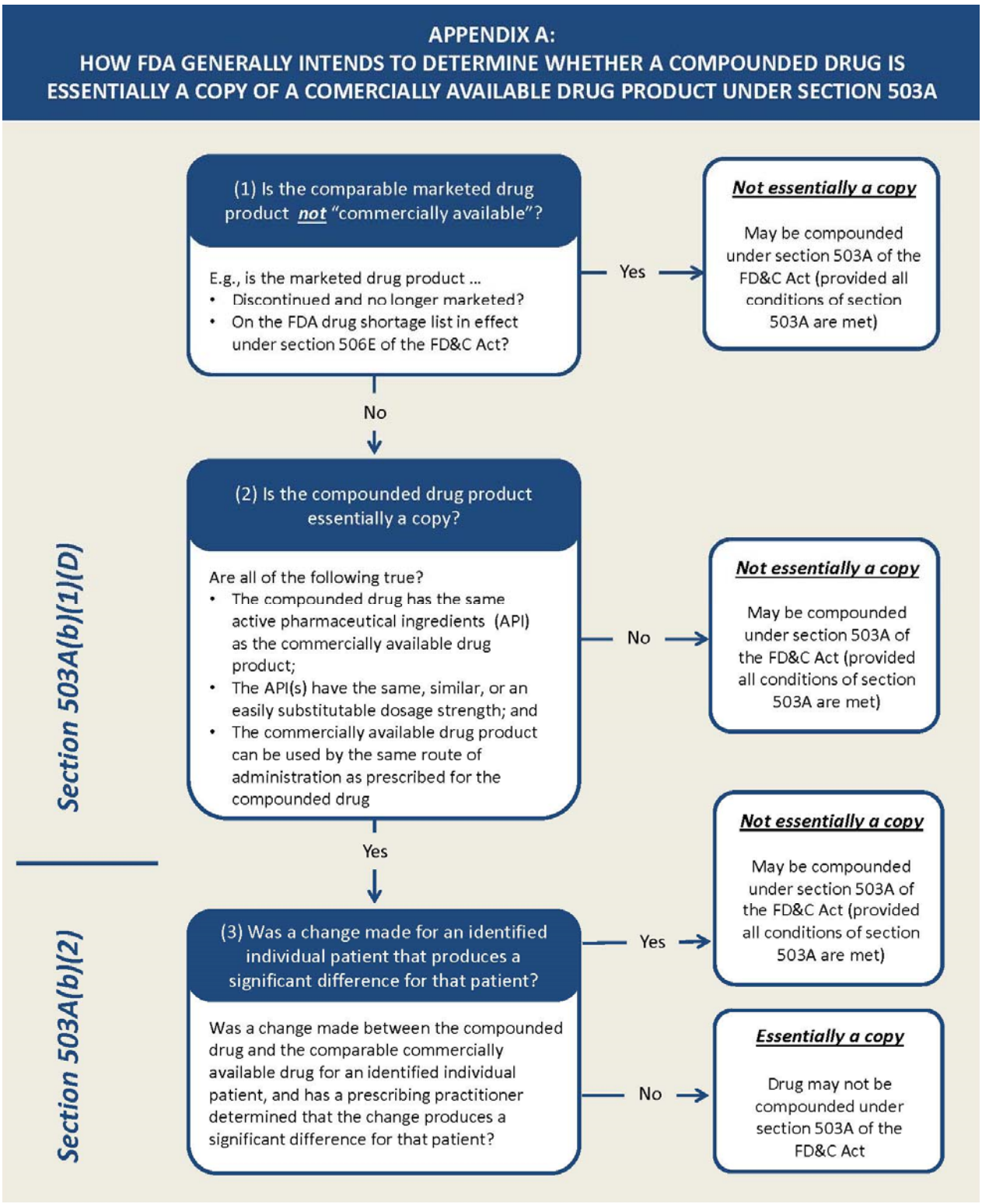
IV. PAPERWORK REDUCTION ACT

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). See footnotes 17, 18, and 21. These provisions require review and are not in effect until they display a currently valid OMB control number. The information collection provisions in this guidance have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. FDA will publish a notice in the *Federal Register* announcing OMB's decision regarding the information collection provisions in this guidance.

[20] For purposes of this policy, FDA intends to consider each refill of a prescription as an additional prescription.

[21] See section IV of this guidance.

APPENDIX A.


APPENDIX A:
HOW FDA GENERALLY INTENDS TO DETERMINE WHETHER A COMPOUNDED DRUG IS ESSENTIALLY A COPY OF A COMERCIALLY AVAILABLE DRUG PRODUCT UNDER SECTION 503A
Section 503A(b)(1)(D)
Section 503A(b)(2)
(1) Is the comparable marketed drug product not "commercially available"?
E.g., is the marketed drug product ...
• Discontinued and no longer marketed?
• On the FDA drug shortage list in effect under section 506E of the FD&C Act?
Yes
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
No
(2) Is the compounded drug product essentially a copy?
Are all of the following true?
• The compounded drug has the same active pharmaceutical ingredients (API) as the commercially available drug product;
• The API(s) have the same, similar, or an easily substitutable dosage strength; and
• The commercially available drug product can be used by the same route of administration as prescribed for the compounded drug
No
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
Yes
(3) Was a change made for an identified individual patient that produces a significant difference for that patient?
Was a change made between the compounded drug and the comparable commercially available drug for an identified individual patient, and has a prescribing practitioner determined that the change produces a significant difference for that patient?
Yes
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
No
Essentially a copy
Drug may not be compounded under section 503A of the FD&C Act

18VAC110-50-80. Minimum licensure and permitting qualifications and eligibility; responsible party.

A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors, registration of nonresident wholesale distributors or nonresident third-party logistics providers, and permitting of third-party logistics providers:

1. The existence of grounds to deny an application as set forth in § 54.1-3435.1 of the Code of Virginia;

2. The applicant's past experience in the manufacture or distribution of drugs or devices;

3. Compliance with the recordkeeping requirements;

4. Prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the manufacturing, distribution, prescribing, or dispensing of drugs by the responsible party or immediate family members of the responsible party, and owners, directors, or officers; and

5. The responsible party's credentials as set forth in subsection B of this section.

B. Requirements for the person named as the responsible party.

1. The responsible party shall be the primary contact person for the board as designated by the wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider, who shall be responsible for managing the wholesale distribution operations at that location;

2. The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor or third-party logistics provider licensed, registered, or permitted in Virginia or another state where the person's responsibilities included managing or supervising the recordkeeping, storage, and shipment for drugs or devices;

3. A person may only serve as the responsible party for one wholesale distributor license, nonresident wholesale distributor registration, third-party logistics provider permit, or nonresident third-party logistics provider registration at any one time;

4. The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor, nonresident

wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider;

5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider during normal business hours, except for time periods when absent due to illness, family illness or death, vacation, or other authorized absence; and

6. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider and all applicable state and federal laws related to wholesale distribution of prescription drugs or the legal acts of a third-party logistics provider.

C. The person named as the responsible party on the application shall submit the following with the application:

1. A passport size and quality photograph taken within 30 days of submission of the application;

2. A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed;

3. An attestation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

4. A federal criminal history record check; and

5. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven years, that manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning third-party logistics providers or wholesale distribution of prescription drugs in which such businesses were named as a party.

D. Responsibilities of the responsible party.

1. Ensuring that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs or the legal acts of a third-party logistics provider;

2. Requiring any employee who has access to prescription drugs to attest that the employee has not been convicted of a violation of any federal or state drug law or any law relating to third-party logistics providers or to the manufacture, distribution, or dispensing of prescription drugs;

3. Maintaining current working knowledge of requirements for wholesale distributors or third-party logistics providers and assuring continued training for employees;

4. Maintaining proper security, storage, and shipping conditions for all prescription drugs; and

5. Maintaining all required records.

E. Each nonresident wholesale distributor or nonresident third-party logistics provider shall designate a registered agent in Virginia for service of any notice or other legal document. Any nonresident wholesale distributor or nonresident third-party logistics provider that does not designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon whom may be served all legal process in any action or proceeding against such nonresident wholesale distributor or nonresident third-party logistics provider. A copy of any such service of legal documents shall be mailed to the nonresident wholesale distributor or nonresident third-party logistics provider by the board by certified mail at the address of record.

Agenda Item: Revision of Guidance Documents 110-36 and 110-9 based on USP revisions effective November 1, 2023

Included in your agenda package are:

- Redline of proposed changes to Guidance Document 110-36, taking USP revisions into account;
- Clean version of proposed amended Guidance Document 110-36; and
- Redline of proposed changes to Guidance Document 110-9, taking USP revisions into account.

Staff Note: Regulatory Committee recommended that the Board amend Guidance Document 110-36 and Guidance Document 110-9.

Action needed:

- Motion to accept the Regulatory Committee's recommendation to amend Guidance Documents 110-36 and 110-9 to incorporate pending USP revisions.

Guidance Document: -110-36 Revised: ~~September 25, 2019~~June 13, 2023
Effective: ~~November 28, 2019~~TBD

Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

Virginia Code § 54.1-3410.2 ~~of the Code of Virginia~~ and ~~Regulation~~ 18VAC110-20-321 require~~s~~ 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. ~~USP first published Chapter 800 in 2014. It was first published as an official standard in February 2016 with a delayed implementation date of July 1, 2018. On September 27, 2017, USP published a notification of intent to revise the effective date of chapter <800> to December 1, 2019.~~ 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

~~The terms "annually" and "semiannually" as used in USP Chapters 795 and 797 are defined to mean every 12 months and every 6 months, respectively. Records associated with annual and semiannual requirements shall be maintained in accordance with USP standards. Such records may be maintained as an electronic image that provides an exact image of the document that is clearly legible provided such electronic image is retrievable and made available at the time of inspection or audit by the Board or an authorized agent.~~

~~*NOTE: On September 23, 2019, USP published a Notice of Intent to Revise which stated Chapters 795, 797, and 825 were under appeal and that "USP's Bylaws provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, USP is postponing the official dates of the revised <795> and <797>, and the new general chapter <825> until further notice. In the interim, the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008) including the section Radiopharmaceuticals as CSPs will remain official. General Chapter <800> is*~~

~~*Originally adopted: June 8, 2004*~~
~~*Revised: September 25, 2019*~~

~~*not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable." While USP and the Board encourages utilization of <800> in the interest of advancing public health, the Board cannot legally require compliance with requirements in 800 related to compounding until the appeals of 795 and 797 are resolved and the revised chapters become effective.*~~

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. ~~"USP on Compounding: A Guide for the Compounding Practitioner" may be purchased at http://www.usp.org/store/products-services/usp-compounding This guide provides access to all compounding related General Chapters from the USP-NF and is updated with the release of each new USP-NF edition and supplement.~~

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. ***Are there specific educational and training requirements regarding personnel?***~~

   ~~Yes. In USP chapter <797>, compounding personnel are required to be adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties: perform aseptic hand cleansing and disinfection of nonsterile compounding surfaces; select and apropriately don protective garb; maintain or achieve sterility of compounded sterile products in ISO class 5 environments; identify, weigh, and measure ingredients; manipulate sterile products aseptically; sterilize high-risk level compounded sterile products and label; and, inspect the quality of compounded sterile products. Personnel must also sucessfully complete a site-specific training program as required in Regulation 18VAC110-20-111.~~

~~3. ***In the absence of sterility testing, what beyond use dates (BUDs) must be used?***~~

   ~~When sterility testing has not been performed, the assigned BUD must not exceed the following allowances:~~

	~~Controlled Room Temperature~~	~~Refrigerator~~	~~Freezer~~
~~Low-risk~~	~~48 hours~~	~~14 days~~	~~45 days~~

~~*Originally adopted: June 8, 2004*~~
~~*Revised: September 25, 2019*~~

~~Medium-risk~~	~~30 hours~~	~~9 days~~	~~45 days~~
~~High-risk~~	~~24 hours~~	~~3 days~~	~~45 days~~

~~4. *What BUD must be assigned to a single dose vial used in preparing a compounded sterile product?*~~

- ~~If the single dose vial is punctured outside of an ISO Class 5 environment, the assigned BUD shall not exceed 1 hour, unless specified otherwise by the manufacturer;~~
- ~~If the single dose vial is punctured within and stored within an ISO Class 5 environment, the assigned BUD shall not exceed 6 hours;~~
- ~~A punctured single dose vial that is removed from the ISO Class 5 environment such as for final verification purposes shall not exceed 1 hour from being removed from the ISO Class 5 environment or the originally assigned BUD of 6 hours within the ISO Class 5 environment, whichever is shorter (reference the Center For Disease Control (CDC) and USP Appendix);~~
- ~~A closed system transfer device (CSTD) should not be used to extend the BUD of a single dose vial to exceed the 1 hour BUD when punctured outside of an ISO Class 5 environment or the 6 hour BUD when punctured within and not removed from an ISO Class 5 environment.~~

~~***5. Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is assured for 90 days?***~~

~~No, it is inappropriate and a violation of law to assign a BUD which exceeds the USP default BUDs in the absence of sterility testing. Drug stability should not be confused with drug sterility.~~

~~***6. How may stability information be taken into consideration when assigning a BUD?***~~

~~Stability information for multiple drugs may be considered when combining the drugs in a compound, assuming the shortest BUD is used to assign stability to the compound. Peer-review or reference source literature shall be consulted and the professional judgement of the pharmacist exercised when assigning the BUD of a compound containing multiple drugs. Any extended BUD must also comply with the applicable USP Chapter <795> or <797>.~~

~~***7. What concepts, at a minimum, should be taken into consideration when determining drug stability?***~~

~~Pharmacists should use professional judgment to determine appropriate references of chemical stability information and note that sterile and non-sterile drug stability is formulation specific. Existing stability information may only be used when the compound has been prepared using the same formulation (USP-NF equivalent ingredients) as used in either at least one peer-reviewed article or other reliable reference source. The process used by the pharmacist to determine drug stability should be well-documented and maintained for inspector review.~~

~~Additionally, stability may be estimated for an aqueous or non-aqueous compound under the following conditions:~~

- ~~Stability information exists in peer-reviewed articles or reference sources indicating stability at a low concentration and high concentration and therefore, stability for concentrations in between could be estimated;~~
- ~~Stability of the drug is not concentration-dependent; and,~~
- ~~The drug is compounded using the same formulation (USP-NF equivalent ingredients) as used in the peer-reviewed articles or reference sources.~~

~~8. What is skip lot testing and may skip lot testing be used to perform sterility testing of compounded sterile products?~~

~~Skip lot testing is a process that only tests a fraction of the drugs compounded. It is NOT appropriate for sterility testing. It may only be used for ensuring consistency and drug strength (potency). Because skip lot testing is complex and requires a robust program, it may not be possible for a pharmacy to properly implement. Information regarding skip lot testing may be accessed at~~ http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm

~~9. How may a hospital pharmacy "batch-producing" limited quantity of CSPs for IN-HOUSE use extend the BUD past the default dating in Chapter <797>?~~

~~EACH BATCH must undergo sterility testing in accordance with USP Chapter <71> in order to extend the BUD past the default dating in Chapter <797> and the appropriate documentation to support an extended BUD must be kept on file for presentation upon inspection.~~

~~10. Do batches less than 25 require sterility testing to be performed?~~

~~No, however, the batches may not be assigned a BUD which exceeds the default BUDs in USP Chapter <797>. The chapter requires sterility testing according to USP <71> before CSPs are dispensed or administered when:~~

- ~~high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or~~
- ~~in multiple-dose vials (MDVs) for administration to multiple patients or~~
- ~~CSPs that are exposed longer than 12 hours at 2 to 8 C and longer than 6 hours at warmer than 8 C before they are sterilized.~~

~~11. How often must the primary engineering control, e.g., laminar airflow workbench and secondary engineering control, e.g., ante and buffer rooms be certified?~~

~~Certification of the primary and secondary engineering controls shall be performed no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. The certification must be performed no later than *the last day of the sixth month*, following the previous certification.~~
~~***Note~~ - this guidance reflects a change to Major Deficiencies 22 and 23 in Guidance Document 110-9 which was amended at the March 2013 full board meeting.~~

~~12.~~3. ~~Must~~ Should compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test at each pharmacy where they will prepare CSPs?

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

~~***13. How often must media-fill testing be performed?***~~

~~Media-fill testing of all compounding personnel shall be performed initially prior to beginning sterile compounding and at least annually thereafter for low and medium-risk compounding, and semiannually for high-risk level compounding. ***Note – the terms "annually" and "semi-annually" are defined within this guidance document to mean every 12 months and every 6 months, respectively. Annual media-fill testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test was initiated. Semiannual media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated.~~

~~***14. If compounding personnel fail a media-fill test, may they continue preparing compounded sterile products?***~~

~~No, compounding personnel who failed a media-fill test may not be allowed to prepare compounded sterile products (low, medium, or high-risk) prior to retraining and receipt of a passing media-fill test. ***Note– this guidance reflects a change to Major Deficiency 26a in Guidance Document 110-9 which was amended at the March 2013 full board meeting.~~

~~***15. Because batches less than 25 do not require sterility testing to be performed, may the CSP which may have been autoclaved be assigned an extended BUD based on stability data?***~~

~~Per USP, sterility testing is not required for autoclaved CSP prepared in batches less than 25 and if the storage times for high-risk CSPs are not exceeded. If the storage times of high-risk CSPs are exceeded, sterility testing is required. Once sterility testing is successfully completed, a longer BUD may be assigned based on the criteria described in the chapter (e.g., based on stability studies).~~

~~***16. Does USP-NF address how long a CSP may hang for infusion?***~~

~~No, USP-NF does not address how long a CSP may hang for infusion. Refer to facility policy on this issue. USP-NF, however, does require the administration of CSPs to begin prior to the assigned BUD.~~

~~***17. May a pharmacist repackage Avastin for office administration not pursuant to a patient-specific prescription?***~~

~~No. While pharmacists may repackage a drug product when dispensing a drug pursuant to patient-specific prescription, a pharmacist may not repackage a drug for another entity. The~~

~~board has historically interpreted the repackaging of a drug for distribution purposes as an act restricted to a manufacturer, defined in Va Code §54.1-3401. This interpretation appears consistent with recent warning letters from the US Food and Drug Administration (FDA). The allowance in Va Code §54.1-3401 for a pharmacist to provide compounded drugs to a physician for office administration does not apply. Repackaging Avastin does not constitute compounding as it does not involve the mixing of two of more substances.~~

~~18. May a pharmacist repackage Avastin pursuant to a patient-specific prescription?~~

~~Yes, a pharmacist may repackage a drug as part of the dispensing process pursuant to a patient-specific prescription.~~

~~19. What concepts, at a minimum, should be taken into consideration when performing sterility testing of CSPs?~~

- ~~Maintain a written policy and procedure manual clearly identifying sterility testing procedures used by the pharmacy and processes for assigning BUDs.~~
- ~~Prior to using an outside testing company to perform sterility testing, evaluate the company to determine if it performs testing in full compliance with USP Chapter <71>. This may be done by reviewing 483 reports issued by the FDA to the testing company and which may be available on the FDA website. Alternatively, request copies of the 483 reports directly from the testing company. The observed deficiencies noted on the 483 reports will assist the pharmacist in evaluating the testing company's level of compliance. Also, request written documentation from the testing company which explains the sterility testing processes used and how it complies with USP Chapter <71> in its totality. This documentation should contain, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of testing method (membrane filtration is the preferred method of testing), two growth media, and number of days of incubation. Have this documentation readily available for inspector review.~~
- ~~When performing sterility testing in-house, document in the written policy and procedure manual, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of two growth media, and number of days of incubation.~~
- ~~Vendors providing products for in-house testing must describe all conditions and limitations to their testing products. Ensure the appropriate filtration volume and sample size is being tested.~~
- ~~When determining an appropriate sterility testing process, note that the preferred method per USP is membrane filtration. The Board strongly recommends that written documentation justifying the use of direct inoculation be available for inspection~~
- ~~Ensure the sterility testing incorporates two media for growth.~~
- ~~The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.~~

- ~~Maintain robust recordkeeping, e.g., chart the dates, temperatures, growth associated with the two media incubations, and employee signatures. Do not simply indicate "no growth" without indicating which growth media was used and the number of days incubated.~~

~~20. Must sterility testing be performed on all batches of CSPs?~~

~~Sterility testing is not required of low and medium-risk level batched CSPs if the BUDs do not exceed the default BUDs found in USP Chapter <797>. If the low or medium-risk level batched CSP is to be assigned an extended BUD, then sterility testing must be performed. Sterility testing must always be performed of high-risk level CSPs in batches greater than 25. See Response to Q#7~~

~~21. What is the definition of a "batch"?~~

~~USP does not currently define the term "batch". In 21CFR210.3, FDA defines "batch" to mean a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.~~

~~22. How should a dilution or stock bag for pediatrics be treated?~~

~~USP does not currently address this issue, however, the Board advises that the dilution or stock bag should be treated as a single dose container/vial with the remains being discarded within 6 hours of compounding.~~

~~23. What are some important considerations regarding membrane filtration and filter integrity testing, aka bubble point testing?~~

~~Membrane filtration may be accomplished using a 0.22 micron filter. It is important to note that sterility testing cannot be accomplished by simply performing membrane filtration. Filter integrity testing, also known as a bubble point test, must be performed to verify that the filter was successful in its application. Smaller disc filters may have filter volume limitations which must be taken into consideration. Because it is known that filtration has not always been successful in preventing the passing through of microorganisms, pharmacists must always build quality processes into their sterile compounding to minimize the risk and the introduction of contamination.~~

~~24. What are some best practices for performing required media fill testing and gloved fingertip sampling?~~

~~Persons performing high-risk level CSPs must successfully pass media fill testing prior to initially compounding sterile products and semi-annually (within 6 months of the last testing). Persons performing low or medium risk level CSPs must successfully pass media fill testing prior to initially compounding sterile products and annually (within 12 months of the last testing).~~

~~Persons who fail a media-fill test may not perform sterile compounding prior to retraining and receipt of a passing media-fill test.~~

~~Media fill testing should mimic the most challenging sterile compounding activity performed by those persons. Robust documentation regarding the media-fill testing process and individual testing must be maintained which documents, at a minimum, the media growth to include lot and expiration date, number of days in incubator, incubator temperature, name of person being tested, dates testing performed, results of growth. Blanks in the form used to document media fill testing should be evaluated and corrected to ensure an accurate testing process.~~

~~Glove finger tip testing verifies the person can properly don gloves without contaminating them and is routinely disinfecting them. To improve compliance with required testing, pharmacists should consider performing media fill testing and glove finger tip testing around the same time that environments are being certified. Employees who use isolators must also perform gloved fingertip sampling by donning sterile gloves within the ISO Class 5 main chamber and testing those gloves.~~

~~***25. How often must air and surface sampling be performed?***~~

~~USP requires air sampling to be performed at least every 6 months. Air sampling shall be conducted using volumetric air sampling equipment and the appropriate media (bacterial sampling for all risk levels and fungi sampling for high-risk level compounding operations). USP requires surface sampling to be performed "periodically". The Board advises that surface sampling should be performed at least quarterly. It may be performed by pharmacy personnel or outsourced.~~

~~***26. What minimally should be taken into consideration when having primary and secondary engineering controls certified?***~~

~~Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used. Pharmacists shall request written documentation from the certifying company explaining how the company's certifying processes fully comply with these standards. This shall include written acknowledgement that certification testing will be performed under dynamic conditions. Certifications issued shall specifically indicate the ISO standard for each primary and secondary engineering control and not simply indicate "passed".~~

~~***27. What minimally should be taken into consideration when compounding multidose vials?***~~

~~Currently USP Chapter <797> does not contain specific requirements for compounding multiple-dose containers, such as the need for a preservative, nor requirements for testing, labeling, and container closures for compounded multiple-dose containers. Chapter <797> references Chapter~~

~~<51> for informational purposes as the source of the 28-day BUD after initially entering or opening a multiple-dose container, unless otherwise specified by the manufacturer.~~

~~***28. What BUDs are recommended for non-sterile compounded products?***~~

~~USP Chapter <795> makes the following recommendations for assigned BUDs of non-sterile compounded products:~~

~~**Nonaqueous formulations** – The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.~~
~~**Water-Containing Oral Formulations** – The BUD is not later than 14 days when stored at controlled cold temperatures.~~
~~**Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations** – The BUD is not later than 30 days.~~

~~These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.~~

~~***29. May a non-sterile compounded product be assigned an extended BUD beyond the recommendations in USP Chapter <795>?***~~

~~The Board advises that non-sterile compounded products should not be assigned an extended BUD unless the pharmacist maintains full documentation to justify the appropriateness of the extended BUD.~~

~~***30. Under what conditions may a glove box be used to perform sterile compounding?***~~

~~The glove box, referred to as an isolator (CAI/CACI) in Chapter <797>, must be placed in an ISO 7 buffer area UNLESS it meets all of the following conditions listed in USP Chapter 797:~~

- ~~The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.~~
- ~~Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.~~
- ~~Not more than 3520 particles (0.5 µm and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.[8]~~

~~It is incumbent upon the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 for 0.5 µm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.~~

~~If the primary engineering control (PEC) is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.~~

~~The weighing of chemicals must occur in at least ISO Class 8 conditions. An isolator used to compound hazardous drugs (with exception of "low volume") must be located in a separate negative pressure room and exhausted outside.~~

~~31. May hazardous sterile products be compounded in the same hood as non-hazardous sterile drugs?~~

~~No. Hazardous sterile products may not be compounded in the same hood as non-hazardous CSPs.~~

~~32. Under what conditions may hazardous drugs be compounded in a cleanroom with positive air pressure?~~

~~USP allows a "low volume" of hazardous CSPs to be compounded in a cleanroom with positive air pressure, however, USP does not currently define the term "low volume". The "low volume" hazardous CSPs must be compounded under two tiers of containment, the isolator or biologic safety cabinet and closed system transfer device.~~

~~33~~4. Must a compounding pharmacy using Schedule II powders comply with the perpetual inventory requirements of Regulation 18VAC110-20-240?

Yes.

~~34. Must bladder irrigation fluids and irrigations for wounds be prepared in a sterile manner in compliance with USP-NF requirements?~~

~~Yes.~~

~~35. In addition to bladder irrigation and irrigations for wounds, what other types of drugs must be prepared in a sterile manner in compliance with USP-NF requirements?~~

~~USP Chapter <797> states that for the purposes of the chapter, a compounded sterile product includes any of the following: compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations for the lungs, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants. Note: Nasal sprays and irrigations for the nasal passages may be prepared as non-sterile compounds.~~

~~36~~5. May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?

No. Va 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.

VA Code §54.1-3410.2 does authorize pharmacists to provide compounded drug 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; and (v) quantity.

~~37~~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 ~~https://secure01.virginiainteractive.org/dhp/egi-bin/search_publicdb.egi~~ by searching the business name and choosing "nonresident pharmacy" as the occupation ~~of "non-resident pharmacy"~~.

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.

~~38. What risk level is associated with repackaging an undiluted multi-dose vial?~~

~~The repackaging of an undiluted multi-dose vial, e.g., insulin, into multiple syringes is a medium-risk level manipulation when puncturing the vial more than 3 times. Note: this guidance addresses repackaging, not administration.~~

~~39. May a microbiological method alternative to compendial methods be used?~~

~~Regarding sterility testing, USP Chapter <797> states, "The *Membrane Filtration* method is the method of choice where feasible (e.g., components are compatible with the membrane). A~~

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method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable as the *USP Membrane Filtration* method or the *USP Direct Inoculation of the Culture Medium* method where the *Membrane Filtration* method is not feasible." Additionally, USP General Chapter <1223> "provides guidance on the selection, evaluation, and use of microbiological methods as alternatives to compendial methods. To properly implement alternative methods, one must consider a number of important issues before selecting the analytical technology and qualifying that method with the actual product. These issues include, but are not limited to, identification of suitable alternative methodology, development of user specifications for equipment selection, demonstration of the applicability of the method as a replacement for a standard compendial method, and qualification of the method in the laboratory…..*General Notices and Requirements* in the *USP* states, "Alternative methods and/or procedures may be used if they provide advantages in terms of accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction, or in other special circumstances." General Chapter <1223> also makes reference to 21 CFR Part 211.194 stating, "This subsection of the regulations also recognizes the legal basis of *USP* and the *National Formulary (NF)* standards and makes it clear that it is the responsibility of the user to validate methods or procedures that differ from those standardized in the compendia." Refer to *USP* for additional guidance.

40. Does the December 1, 2019 official date of <800> impact my current or early adoption of the general chapter?

Per USP, no. USP encourages adoption and implementation of General Chapter <800> to help ensure a quality environment and protection of healthcare workers and patients when hazardous drugs are handled.

41. How do I adopt USP General Chapter <800> if sections are not harmonized with USP General Chapter <797>?

Per USP, two sections that are not harmonized between the two chapters are: Segregated Compounding Area and 'Low volume' hazardous drug compounding. Below please find guidance on how to adopt USP <800> until the revised USP <797> is published.

Segregated Compounding Area (SCA)

- USP <797> only allows low risk level nonhazardous and radiopharmaceutical Compounded Sterile Preparations (CSPs) with 12 hour or less beyond use date (BUD) to be prepared in an unclassified segregated compounding area (SCA).
- USP <800> allows low and medium risk level hazardous drug CSPs to be prepared in an unclassified containment segregated compounding area (C-SCA). The C-SCA is required to have fixed walls, be externally vented with 30 ACPH and have a negative pressure between 0.01 and 0.03 inches of water column relative to the adjacent areas.
- Note the differences in terminology and requirements in the SCA in USP <797> and C-SCA in <800>.
    - For early adoption of <800>, low- and medium- risk level HDs may be prepared in a C-SCA provided it meets the requirements in the chapter and the CSP is assigned a BUD of 12 hours or less.

- For facilities that have not yet adopted <800>, the standards in USP <797> would apply. Only low-risk level nonhazardous and radiopharmaceutical CSPs with 12 hour or less BUD may be prepared in a SCA.

"Low volume" hazardous drug compounding

- USP <797> allows facilities that prepare a "low volume" of HDs to compound these drugs in a non-negative pressure room if "two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room)" are used.
- USP <800> requires facilities that prepare HDs to have a containment secondary engineering control (C-SEC) that is externally vented, physically separated, have appropriate air exchange, and have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.
- For early adoption of <800>, HDs must be prepared in a C-SEC meeting the requirements in the chapter.
- For facilities that have not yet adopted <800>, the standards in <797> would apply. Facilities preparing a low volume of HDs may continue to compound these CSPs outside a negative pressure room if two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room)" are used.

42. What are the hazardous drugs (HD) that USP Chapter <800> oversees?

Refer to the most current National Institute for Occupational Safety and Health (NIOSH) list at www.cdc.gov. Note: Chapter <800> defines HDs are those on the NIOSH list, not the EPA hazardous materials list. Some drugs on the Environmental Protection Agency (EPA) list may not be on the NIOSH list, e.g., epinephrine.

43. In general, how are drugs grouped within the NIOSH list?

Hazardous drugs are categorized into three tables:

- Antineoplastic drugs, e.g., cisplatin, methotrexate
- Non-antineoplastic drugs, e.g., carbamazepine, estrogen/progesterone combinations
- Non-antineoplastic drugs that have adverse reproductive effects, e.g., temazepam, warfarin

44. What drugs MUST comply with all USP Chapter <800> containment requirements?

Drugs on the NIOSH list that will be involved in compounding must follow the requirements in this chapter include:

- Any HD active pharmaceutical ingredient (API) on any of the three tables, and
- Any antineoplastic requiring manipulation other than counting or repackaging.

45. How should a pharmacist determine how to comply with 800?

Pharmacists should ask themselves the following questions, at a minimum:

- Do I perform nonsterile or sterile compounding? If no compounding is performed, then the requirements of chapter <800> are recommended, but not required.

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- ~~What drugs do I receive, store, dispense that are deemed hazardous pursuant to the NIOSH list and are used in compounding products? If no hazardous drugs are used in compounding, then the requirements of chapter <800> are recommended, but not required.~~
- ~~If hazardous drugs are used in compounding, then:~~
- ~~Must those drugs comply with all containment requirements or do some qualify for performing an assessment of risk?~~
- ~~What changes will I need to make to my facility in order to comply with Chapter <800>?~~
- ~~What personnel training is needed to meet compliance?~~
- ~~What cleaning processes must be implemented or changed to meet compliance?~~
- ~~What activities do I perform with these hazardous drugs, e.g., compounding, administration, etc.?~~

~~***46. If the pharmacy does not compound with hazardous drugs, but does split tablets of hazardous drugs, must the pharmacy comply with the requirements of Chapter <800>?***~~

~~No. <795> states that splitting tablets is out of the scope of the chapter:~~

~~**Splitting tablets:** Breaking or cutting a tablet into smaller portions is not required to meet the standards in this chapter.~~

~~Thus, while <800> may speak about splitting tablet, it is not "compendially applicable" since it is not in scope of <795>.~~

~~***47. If it is determined that the pharmacy stocks HDs, what options exist for the pharmacy?***~~

~~The pharmacy may treat all dosage forms of all HDs that are used in compounding products the same and follow all containment requirements in Chapter <800> or it may perform an assessment of risk to identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or not API.~~

~~***48. What hazardous drugs may be considered during an assessment of risk?***~~

- ~~Antineoplastics that only need to be counted or packaged~~
- ~~Non-antineoplastics~~
- ~~Reproductive-only hazards~~

~~***49. What should be considered, at a minimum, during an assessment of risk?***~~

- ~~Type of HD, dosage form, risk of exposure, packaging, manipulation to be performed~~
- ~~Alternative containment strategies and/or work practices should be documented~~
- ~~The assessment of risk shall be reviewed every 12 months and documented.~~

~~***50. What minimal questions and/or information will an inspector for the Board of Pharmacy be asking during an inspection? Note: Refer to page 1 regarding enforcement of Chapter <800>.***~~

- ~~Does the pharmacy perform sterile or non-sterile compounding?~~

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- Does the pharmacy stock HDs that are used in compounding products? The list of HDs that are used in compounding products that the pharmacy stocks must be provided for inspector review.
- Are all HDs that are used in compounding products contained in a manner consistent with USP Chapter <800> or was an assessment of risk performed to identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or not API. The assessment of risk must be provided for inspector review.
- Who is the 'designated person' for the pharmacy who is responsible for the continuing to evaluate the fundamental practices and precautions for handling HDs?
- Documentation of required training.
- Appropriate personnel equipment.
- Appropriate engineering controls.
- Standard operating procedures for safe handling of HDs that are used in compounding products for all situations in which the HDs are used throughout the facility.

51. What does USP Chapter <800> list as the general engineering control requirements for performing non-sterile HD compounding?

Table 2. Engineering Controls for Nonsterile HD Compounding

Containment Primary Engineering Control (C-PEC)	Containment Secondary Engineering Control (C-SEC)
• Externally vented (preferred) or redundant-HEPA filtered in series • Examples: CVE, Class I or II BSC, CACI	• Externally vented • 12 air changes per hour (ACPH) • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas • Fixed walls

52. What does USP Chapter <800> list as the general engineering control requirements for performing sterile HD compounding?

Table 3. Engineering Controls for Sterile HD Compounding

Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 buffer room with an ISO Class 7 ante-room	• Externally vented • Examples: Class II BSC or CACI	• Externally vented • 30 air changes per hour ACPH • Negative pressure between 0.01 and 0.03 inches of water colum relative to adjacent areas	As described in (797
Unclassified C-SCA	• Externally vented • Examples: Class II BSC or CACI	• Externally vented • 12 ACPH • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas	As described in (797) for CSPs prepared in a segregated compounding area

53. Where may a list of recommended personal protective equipment by type of drug formulation and engineering controls for working with HDs in a healthcare setting be found?

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~~Table 5 of the NIOSH list.~~

~~***54. Regarding the Segregated Compounding Area (SCA) definition, Chapter <797> states an SCA may be a designated space, room or demarcated area. Chapter <800> states SCA requires fixed walls and removes the "space or demarcated area". Please clarify the Board's expectations on this issue.***~~

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~~Per USP, please note the differences in terminology in <797> and <800>. General Chapter <800> specifies that this is a containment segregated compounding area (C-SCA). For hazardous drug compounding, the C-SCA must have fixed walls. For nonhazardous drug sterile compounding, the SCA may be in an unclassified area (and not necessarily have fixed walls). For the C-SCA, fixed are also necessary to maintain negative pressure.~~

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~~***55. Regarding low-risk level compounding with 12 hour or less beyond use dating (hood within a non-ISO Class 7 area), Chapter <797> states that this configuration does not allow hazardous compounding. Chapter <800> states that it is allowed, but only low and medium risk HDs may be prepared and beyond use dating (BUD) that cannot exceed <797> for being prepared in a SCA. Please clarify the Board's understanding on this issue.***~~

~~Per USP, the intent of <800> is to apply a 12-hour or less BUD to low- and medium- risk level compounded sterile products prepared in a containment segregated compounding area (C-SCA). USP is aware of the confliet and is in the process of revising <797> to align with the requirements in <800>.~~

~~***56. Chapter <797> also allows for placement of an isolator outside of an ISO Class 7 buffer room with meeting of specification requirements and allowance of full BUD. Chapter <800> states if the containment primary engineering control (C-PEC) is placed in a containment segregated compounding area (C-SCA), then the BUD of all compounded sterile products must be limited as described in <797>. Again, Chapter <797> states that this configuration does not allow hazardous compounding. Please clarify the Board's understanding on this issue.***~~

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~~Per USP, the intent of <800> is to apply a 12-hour or less BUD to low- and medium- risk level compounded sterile products prepared in a C-SCA. USP is aware of the confliet and is in the process of revising <797> to align with the requirements in <800>.~~

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~~***57. With the implementation of Chapter <800>, will USP continue to allow compounding aseptic isolators (CAI) placed outside of a classified area to be used to compound sterile products and assigned a full BUD as authorized in <797>?***~~

~~Yes, Chapter <797> still allows for a compounding aseptic isolator (CAI) placed outside of a classified area to be used to compound sterile products and assigned the full storage period BUD provided the conditions specified in the chapter are met. Note, for compounding sterile hazardous drugs, the compounding aseptic containment isolator (CACI) must be placed in a negative pressure containment secondary engineering control (C-SEC) with adequate air changes per hour (ACPH).~~

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~~***58. Does Chapter <800> recommend wipe sampling and medical surveillance?***~~

~~Yes, Chapter <800> states that "environmental wipe sampling for HD surface residue should be performed routinely." Medical surveillance is also a recommendation of the chapter. The chapter states that "healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program." Note, both of these issues are recommendations of Chapter <800> and not a requirement.~~

~~***59. USP <797> and USP <800> recommend the use of closed system drug transfer devices (CSTD). Is there guidance on the proper evaluation of the available technologies?***~~

~~USP currently recommends the use of CSTDs for compounding HDs. Per USP, it is not a requirement as there is no published universal performance standard for evaluation of CSTD containment. NIOSH is currently working on developing such a protocol.~~

~~***60. Is a line of demarcation for doffing personal protective equipment (PPE) required for all hazardous containment secondary engineering controls?***~~

~~USP <800> *requires* a doffing area if the negative pressure hazardous drug (HD) buffer room is entered through the positive pressure non-hazardous drug buffer room. Additionally, it states a designated doffing area *should* be indicated within all containment secondary engineering controls (C-SEC). Other than the line of demarcation mentioned in section 5.3.2, General Chapter <800> does not specify where doffing should occur. However, this is entity dependent and should additionally follow garbing requirements in <797>.~~

~~***61. USP <800>, within Section 5.3, indicates that an eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available. Are there applicable laws and regulations in Virginia regarding eyewash stations and/or other emergency or safety precautions?***~~

~~The Board is not currently aware of laws and regulations in Virginia related to use of eyewash stations or other safety precautions related to this issue.~~

~~***62. May a laminar airflow workbench (LAFW) or a compounding aseptic isolator (CAI) be used for compounding with an antineoplastic hazardous drug (HD)?***~~

~~No.~~

~~***63. Is it required to compound all sterile hazardous drugs within an externally vented containment primary engineering control (biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI))?***~~

~~No, dosage forms of non-antineoplastic and reproductive risk hazardous drugs may be handled and compounded under an assessment of risk. If, however, bulk active pharmaceutical~~

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~~ingredients (API) of these drugs are used as starting ingredients, all of the containment requirements in <800> would apply. Refer to Box 1 within USP Chapter <800>.~~

~~***64. What are the specifications required of a pass through chamber? Is it required be interlocking and HEPA filtered purged? Between what areas may these chambers be utilized?***~~

~~General Chapter <800> defines a pass-through as "an enclosure with interlocking doors that is positioned between two spaces for the purpose of reducing particulate transfer while moving materials from one space to another. A pass through serving negative pressure rooms needs to be equipped with sealed doors. The chapter does not require the pass through to be HEPA filter purged and does not limit where these pass throughs may be placed. General Chapter <800> additionally states that refrigerator pass throughs must not be used.~~

~~***65. Chapter <800> states sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area. What is the intent of this statement?***~~

~~The intent of prohibiting the storage of nonsterile compounding materials in sterile compounding areas is to minimize traffic flow into the sterile classified areas.~~

~~***66. May bulk active pharmaceutical ingredients (API) used for sterile compounding be stored in the negative pressure C-SEC?***~~

~~Yes. Refer also to USP's frequently asked question #16 found at http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings~~

~~***67. Where must manipulation of non-sterile, non-antineoplastic and reproductive risk hazardous drugs (that are not bulk active pharmaceutical ingredients (API)) occur?***~~

~~The location where manipulation occurs should follow an assessment of risk for non-antineoplastic and reproductive risk hazardous drugs (that are not bulk APIs). Facilities should determine their own strategies based on its assessment of risk.~~

~~***68. Does Chapter <800> address whether scrubs that are worn within the hazardous compounding/storage area may be allowed to be taken home?***~~

~~No. General Chapter <800> does not specify best practices for clothing under the gown. However, section 7.2 does require gowns to be disposable and shown to resist permeability by HDs.~~

~~***69. What is the best practice for receiving hazardous drugs (HD)?***~~

~~USP <800>, within Section 5.1, states antineoplastic HDs and all HD active pharmaceutical ingredients (API) must be unpacked (i.e., removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas. HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive~~

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~~pressure areas. Best practice is to unpack the hazardous drugs from the delivery tote, and leave packaged in a zip-locked plastic bag. From there, the unopened plastic bags should be moved to HD storage room, where the HDs can be removed from the bags and received into inventory. HDs should never be withdrawn from the plastic transport bags in any room other than the HD storage room.~~

~~***70. If the C-PEC vents externally and the room is able to maintain appropriate negative pressure and air exchanges, does the C-SEC need to be vented?***~~

~~No.~~

~~For more information regarding USP Chapter <800>, an extensive list of frequently asked questions published by USP may be accessed at http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings.~~

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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 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 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. Va 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.

VA Code §54.1-3410.2 does authorize pharmacists to provide compounded drug 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; and (v) 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.

Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	2000
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	54.1-3434 and 18VAC110-20-110		1000
3. Unregistered persons performing duties restricted to pharmacy technician without first becoming registered as a pharmacy technician trainee	54.1-3321 and 18VAC110-20-111	per individual	First documented occurrence = no penalty Repeat = $ penalty 250
4. Pharmacists/pharmacy technicians/pharmacy interns[/pharmacy technician trainees] performing duties on an expired license/registration	18VAC110-21-60, 18VAC110-21-110, [18VAC110-21-141,] and 18VAC110-21-170.	per individual	First documented occurrence = no penalty Repeat = $ penalty 100

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
5. Pharmacy technicians, pharmacy interns, or pharmacy technician trainees performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320 18VAC110-20-112		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320 18VAC110-20-112	per each technician over the ratio	First documented occurrence = no penalty Repeat = $ penalty 100
7. Change of location or remodel of pharmacy without submitting application or Board approval	18VAC110-20-140	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	First documented occurrence = no penalty; drugs may be embargoed Repeat = $ penalty 100 Drugs may be embargoed
9. The alarm is not operational. The enclosure is not locked at all times when a pharmacist is not on duty. The alarm is not set at all times when the pharmacist is not on duty.	18VAC110-20-180 and 18VAC110-20-190		1000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. The alarm system does not include a feature by which any breach shall be communicated to the PIC or a pharmacist working at the pharmacy.	18VAC110-20-180		250
10. Unauthorized access to alarm or locking device to the prescription department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		First documented occurrence and no drug loss = no penalty Drug loss or repeat = $ penalty 500
12. Storage of prescription drugs not in the prescription department	18VAC110-20-190		500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe, or maintained in a manner that combines the two methods.	18VAC110-20-200		First documented occurrence and no drug loss of Schedule II = no penalty Drug loss or repeat = $ penalty 250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 and 18VAC110-20-240	Cite Deficiency 113 if only expired drugs not included in inventory.	Over 30 days late and first documented occurrence = no penalty Over 30 days late and repeat = $ penalty 500
14. No incoming change of Pharmacist-in-Charge inventory, inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3434 and 18VAC110-20-240	Per occurrence. Cite Deficiency 113 if only expired drugs not included in inventory.	500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
15. Perpetual inventory not being maintained as required as it does not: • Include all Schedule II drugs received or dispensed; • Accurately indicate the physical count of each Schedule II drug "on-hand" at the time of performing the inventory; • Include a reconciliation of each Schedule II drug at least monthly; or • Include a written explanation of any difference between the physical count and the theoretical count. Monthly perpetual inventory is performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required.	18VAC110-20-240	Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 drugs not compliant.	250
16. Theft/unusual loss of drugs not reported to the Board as required	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant.	250
20a. Pharmacist not documenting verification of accuracy of non-sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355	10% threshold	500
20b. Pharmacist not documenting verification of accuracy of sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355		5000
21. No clean room	54.1-3410.2		10000
21a. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
21b. Presterilization procedures for Category 2 or Category 3~~high-risk level~~ CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better.	54.1-3410.2		500
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months,~~ and~~ whenever there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow quality, and/or certification does not include airflow testing, HEPA filter integrity testing, total particle count testing, and dynamic airflow smoke pattern test. ~~the device or room is relocated, altered, or major service to the facility is performed.~~	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months, ~~and~~ whenever there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow quality, and/or certification does not include airflow testing, HEPA filter integrity testing, total particle count testing, and dynamic airflow smoke pattern test.~~the device or room is relocated, altered, or major service to the facility is performed.~~	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas	54.1-3410.2		2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for Category 2 CSPs and/or Category 3 CSPs~~high-risk level compounded sterile preparations or high risk compounded sterile preparations~~ assigned inappropriate beyond use date (BUD)	54.1-3410.2		5000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
25a. No documentation of initial and at least every ~~semi-annual (6~~ 3 months~~)~~ media-fill testing or gloved fingertip testing for persons performing compounding of Category 3 CSPs ~~high-risk level compounding of sterile preparations~~.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the ~~sixth~~ third month from the date the previous media-fill test and gloved fingertip testing was initiated.	5000
25b. ~~High-risk~~Category 3 compounded sterile preparations intended for use are improperly stored	54.1-3410.2		5000
25c. Documentation that a person who failed a media-fill test or gloved fingertip test has performed ~~high-risk level~~ compounding of Category 3 CSPs~~sterile preparations~~ after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test	54.1-3410.2		5000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
26. No documentation of initial and at least every ~~annual (12~~ 6 months~~)~~ media-fill testing or gloved fingertip testing for persons performing ~~low and medium risk level~~ compounding of Category 1 and Category 2 CSPs~~sterile preparations~~.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved finger-tip testing must be performed no later than the last day of the ~~twelfth~~ sixth month from the date the previous media-fill test and gloved fingertip testing was initiated.	500
26a. Documentation that a person who failed a media-fill test or gloved fingertip test has performed ~~low or medium risk level~~ compounding of Category 1 and Category 2 CSPs~~sterile preparations~~ after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test	54.1-3410.2		500
26b. No documentation of initial and at least every 12 months media-fill testing or gloved fingertip testing for persons who have direct oversight of compounding personnel, but do not compound.	54.1-3410.2		500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
27. Compounding using ingredients in violation of 54.1-3410.2.	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		First documented occurrence and no drug loss = no penalty Drug loss or repeat = $ penalty 500
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	18VAC110-20-555	Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C)	First documented occurrence and no known patient harm = no penalty Repeat = $ penalty 250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. ~~Low or medium risk compounded sterile preparations~~ Category 1 or Category 2 CSPs assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
34. Combined with Deficiency 142 – 12/2013.			
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	18VAC110-20-395		250

Other Deficiencies

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

Deficiency	Law/Regulation Cite	Conditions
101. Repealed 6/2011		
102. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
103. Repealed 12/2013		
104. Sink with hot and cold running water not available within the prescription department.	18VAC110-20-150	
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit. Temperature not being recorded daily or record of such not maintained properly.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer

Deficiency	Law/Regulation Cite	Conditions
106. Prescription department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
107. Current dispensing reference not maintained	18VAC110-20-170	
108. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold
110. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	

Deficiency	Law/Regulation Cite	Conditions
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	18VAC110-20-200	
112. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404, 54.1-3434 and 18VAC110-20-240	
114. Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
115. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285 18VAC110-20-270	10% threshold
117. Deficiency 117 combined with Deficiency 116 – 6/2011		
118. Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
119. Not properly documenting partial filling of prescriptions	54.1-3412, 18VAC110-20-255,18VAC110-20-310, and 18VAC110-20-320	
120. Offer to counsel not made as required	54.1-3319	

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

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

Deficiency	Law/Regulation Cite	Conditions
139. Emergency medical services procedures or records not in compliance	18VAC110-20-500	10% threshold
140. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
141. Maintaining floor stock in a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization	18VAC110-20-418	
143. Repealed 6/21/2018		
144. Repealed 6/21/2018		
145. Repealed 6/21/2018		
146. Repealed 6/21/2018		
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy	54.1-3404 and 18VAC110-20-240	

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

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

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

Agenda Topic: Discuss acceptance of outsourcing facility inspections performed by other states.

Included in Agenda Packet:

- Relevant law regarding qualifying inspection for outsourcing facilities and nonresident outsourcing facilities
- Excerpt from 2016 full board meeting minutes
- Florida and California inspection reports for outsourcing facilities

Staff Note:

- Regulation Committee recommended full board accept reports.

Action Needed:

- Vote to accept or deny recommendation of Regulation Committee to accept 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 U.S. Food and Drug Administration within the required period.

From *The Pharmacy Act and Drug Control Act with Related Statutes*, 7/1/2022

§ 54.1-3434.05. Permit to act as an outsourcing facility.

A. No person shall act as an outsourcing facility without first obtaining a permit from the Board.

B. Applications for a permit to act as an outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the outsourcing facility and who will be fully engaged in the compounding performed at the location designated on the application. Such application shall be accompanied by a fee determined by the Board in regulation. All permits shall expire annually on a date determined by the Board in regulation. No permit shall be issued or renewed for an outsourcing facility unless the facility can demonstrate compliance with all applicable federal and state laws and regulations governing outsourcing facilities.

C. As a prerequisite to obtaining or renewing a permit from the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for a permit to the Board or (b) no more than two years prior to the date of submission of an application for renewal of a permit to the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. Every outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations except § 54.1-3410.2, to include all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

E. An outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a permit to operate a pharmacy.

2015, c. 300.

§ 54.1-3434.5. Nonresident outsourcing facilities to register with the Board.

A. Any outsourcing facility located outside the Commonwealth that ships, mails, or delivers in any manner Schedule II through VI drugs or devices into the Commonwealth shall be considered a nonresident outsourcing facility and shall be registered with the Board.

B. Applications for registration to act as a non-resident outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who is licensed as a pharmacist in Virginia and who is in full and actual charge of the outsourcing facility, is fully engaged in the compounding performed at the location stated on the application, and is fully responsible for the outsourcing facility's compliance with state and federal law and regulations. Such application shall be accompanied by a fee determined by the Board in regulation. All registrations shall expire annually on a date determined by the Board in regulation.

C. As a prerequisite to registering or renewing a registration with the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for registration with the Board or (b) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. A nonresident outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a registration to operate a nonresident pharmacy. The nonresident pharmacy shall comply with all state and federal laws, regulations, and requirements except § 54.1-3410.2.

2015, c. 300.

Excerpt from 9/7/2016 Full Board Meeting Minutes:

OLD BUSINESS:

• Consideration for accepting inspection from Bestech GMP Contracting, Inc. in lieu of FDA inspection for outsourcing facility	Matthew Bestercy, Owner and Principal Consultant for Bestech GMP Contracting, Inc., provided a handout with additional information for board consideration in follow-up to the discussion during the June 2016 full board meeting. He is requesting the board to accept an inspection report of outsourcing facilities resulting from inspections performed by his company for satisfying the requirement for an outsourcing facility to submit a current inspection report when the FDA has not performed an inspection in the required timeframe as authorized in 54.1-3434.05 and 54.1-3434.5. Bestech would provide the board with the complete inspection report, collect a written corrective action plan from the outsourcing facility within 15 days of the inspection, and provide the board with a written opinion regarding the appropriateness of the written corrective action plan. Mr. Bestercy indicated his inspectors would be able to provide testimony during a disciplinary case, if necessary. It was stated that all inspection reports of outsourcing facilities resulting from an FDA inspection must be considered by the board and that an inspection from Bestech would not preclude this requirement. However, the board could consider accepting an inspection from Bestech for licensure purposes when the FDA had not performed an inspection in the required timeframe.
MOTION:	**The board voted 7 to 3 in support of accepting an inspection report from Bestech GMP Contracting, Inc. for licensure purposes of outsourcing facilities when the FDA has not performed an inspection within the required timeframe for a "current" inspection report pursuant to 54.1-3434.05 and 54.1-3434.5. (motion by Saenz, second by Shinaberry; M. Elliott, Boone, and S. Elliott opposed)**

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
503b Outsourcing Inspection

NAME	PERMIT NUMBER	DATE OF INSPECTION
DOING BUSINESS AS		
STREET ADDRESS	TELEPHONE #	EXT
CITY	COUNTY	STATE/ZIP

Pharmacy Affiliate	License #
Pharmacy Affiliate	License #

	License #

Quality - 21CFR part 211
subpart B

Firm has an independent Quality Control Unit.	
The QC unit has the authority and responsibility to approve or reject all components, drug product containers or closures, end process materials, packaging materials, labeling and drug products.	
QC unit reviews production records to assure that no errors have occurred, or if errors have occurred, that they have been fully investigated.	
Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products are available to the quality control unit.	
The quality unit approves or rejects all procedures or specifications impacting the identity, strength, quality, and purity of the drug product.	
The responsibilities and procedures applicable to the QC unit are in writing and such procedures are followed.	
QC unit personnel are qualified through training and experience.	

INVESTIGATIONS

The QC Unit conducts a written and thorough investigations of any unexplained discrepancy, deviation, equipment malfunctions, and OOS (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed.	
Investigations are conducted within time limits specified per SOP.	
When investigations are not conducted, the written records include the reason the investigation was not deemed to be necessary and the name of the person that made that determination.	
Investigations are extended to other batches that may have been impacted by a failure or discrepancy	
Investigations include findings, conclusions and follow up.	
Record of investigations are maintained at the establishment where the investigation occurred.	

Personnel Qualification –
21CFR Subpart B

All personnel involved in the processing, packing, or holding of a drug product have the education, training and experience to enable the person to perform the assigned functions.	
Facility has a written training program that describes the required training, frequency of training and process for evaluating the performance of individuals involved in compounding.	
Facility has documentation that compounding personnel have the required skills necessary to perform their assigned functions.	
Prior to beginning to prepare CSP's personnel have completed training and have demonstrated proficiency in the principles and hands on skills of aseptic manipulations.	
CGMP trainers are qualified through experience and training	
Personnel receive ongoing periodic CGMP training by qualified trainers for the specific tasks they are authorized to perform.	
Personnel are qualified for the number of units they can compound and the processes they perform.	
Prior to beginning to prepare CSP's personnel have completed training and have demonstrated proficiency in the principles and hands on skills of aseptic manipulations.	

Personnel have been periodically trained in core competencies, visual observation is conducted to confirm personnel have necessary skills (i.e. Hand hygiene and garbing, aseptic manipulations, cleaning and disinfecting).	
Personnel sampling including GFT is conducted after compounding and documented on each batch record.	
Personnel have completed media fill simulations for all aseptic compounding processes under the most difficult and challenging conditions which include the most manipulations/units, most complex flow of material, longest time to compound and all breaks and interventions.	
Personnel are retrained and requalified after failure of media fill, GFT or batch failures.	
Firm has adequate written procedures for visual inspection.	
Personnel conducting visual inspection of the final product have been qualified through training in applicable SOPs and have annual eye exams.	
Personnel conducting visual inspections have been qualified for the number of units and amount of time they can inspect before taking a break.	
Significant defect categories are identified in the SOP and personnel conducting visual inspection have demonstrated competency in identifying common defects.	
Persons supervising the manufacture, processing, packing or holding of a drug product have the education, training, and experience to perform assigned functions in a manner to provide assurance of the safety, identity, strength, quality and purity of the drug product.	
Employees are required to report to their supervisor any health issues that might impact the quality, safety and purity of the product.	
Temporary employees are given the same orientations as permanent employees.	
The firm has records stating the name, address, and qualification of all consultants and the type of service they provide.	
Documentation of training personnel on use of equipment.	

Facilities and Equipment –

21CFR part 211 subpart C and subpart D

The facility design is suitable for compounding sterile products.	
The facility is designed to allow adequate flow of components, drug product containers, closures, labeling, in-process materials and drug products through the building to prevent contamination.	
The facility has the space, construction, and location to facilitate cleaning, maintenance, and proper operation.	
There is adequate space for the orderly placement of equipment and materials to prevent mixups between different components, containers, closures, labeling, in-process materials, or drug products and to prevent contamination.	
Facility had adequate space to quarantine incoming components, drug product containers, closures, and labeling pending the sampling, testing or examination by the quality control unit prior to release.	
Facility has space to hold rejected components, container, closures and labeling prior to disposition.	
There is a separate, defined area for quarantine storage before release of drug products.	
Compounding of hazardous drugs is clearly separated from non-hazardous drugs to prevent cross contamination.	
Beta lactams are separated to prevent cross contamination with other drug products.	
Certifications of primary and secondary engineering controls are current and are conducted under dynamic, worst case conditions with the maximum number of personnel allowed per SOP present.	
All HEPA filters are leak tested.	
Visual smoke studies have been conducted under operational conditions to demonstrate laminar flow air in all primary engineering controls.	
Floors, walls and ceilings and other structures are smooth and easily cleanable	
Ceiling tiles are clean room grade and gasketed and sealed/clipped	
Air return vents are not blocked and are placed in a manner that allows adequate dilution of HEPA filtered air to prevent airborne contamination	

The control of air pressure, dust, humidity and temperature is adequate for the manufacturing, processing, storage or testing of drug products.	
Pressure gauges that monitor pressure differentials are calibrated.	
The facility is maintained in a clean and sanitary condition.	
The facility has written procedures that describe in sufficient detail the cleaning schedule, methods, equipment, and materials used in cleaning the facilities. Procedures are followed.	
The firm has an SOP for controlling rodents, birds, insects and other vermin. Pest control contracts specify which pesticides can be used. Procedures are followed and documented.	
The facility has a procedure for rotating cleaning solutions and documents in the cleaning record.	
Sporicidal agents are used. How often?	
The facility has validated the effectiveness of the cleaning solutions.	
All equipment has written procedures for use.	
Written procedures and schedules are established and followed for cleaning and maintenance of equipment and utensils used in the manufacture, processing, packing, or holding of a drug product.	
Surfaces that contact components, in-process materials, or drug products are not reactive, additive, or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product.	
Ovens and autoclaves have been temperature mapped, the cycles have been validated, and are monitored with calibrated thermometers.	
Autoclaved cycles are verified with BI's.	
Depyrogenation cycles have been validated with ECVs and demonstrates a 3 log reduction in endotoxin units	
All equipment is validated for its intended use.	
Refrigerators, freezers and incubators are monitored with calibrated thermometers.	
Written SOPs for changing the filters and prefilters of all engineering controls are established and followed.	
Appropriate controls over computer or related systems assure the changes in master production and control records are made by authorized personnel only.	

Environmental Monitoring - 21CFR 211.113

Facility has an environmental monitoring program.	
Air quality is monitored regularly under operating conditions using volumetric air sampling to ensure the environment remains suitable for sterile compounding.	
Settling plates are used during compounding to monitor the quality of air during compounding processes and documented in the batch records.	
Non-viable particle counts occur during operations in areas most at risk to exposed product, containers and closures.	
Surface sampling is conducted after each batch prior to cleaning and documented on batch records.	
Surface sampling is routinely conducted in all classified spaces in those locations identified to be at highest risk of contamination.	
Surface sampling is conducted in critical areas that are in contact with products, containers or other components used in compounding.	
Media used in environmental and personnel monitoring has been shown to promote the growth of microorganisms and contains agents to neutralize cleaning solutions and disinfectants.	
Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment.	
Environmental Monitoring Data is trended to support the adequacy of clean room quality.	

Adverse changes in the environment are investigated and promptly remediated.	
Alert and action levels for CFU counts have been established in SOP's for the facility.	
Air pressure differentials are continuously monitored and demonstrate that a cascading pressure differential is maintained throughout the compounding area during production of sterile compounds. Alarms and deviations are documented, investigated, and remediated.	

Control of Components, Containers and Closures

21CFR part211 Subpart E

Facility has a quality agreement with API suppliers to ensure all API's are manufactured in registered FDA facilities.	
Written procedures describe with sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures. Procedures are followed.	
Components and drug product containers and closures are handled and stored, at all times, in a manner to prevent contamination.	
Bagged or boxed components of drug product containers or closures are stored off the floor and suitably spaced to permit cleaning and inspection.	
Components, containers and closures are stored under quarantine until they have been sampled, tested or examined and released for use by the quality control unit. Each lot of components, containers and closures is appropriately identified as to its status (quarantined, approved, or rejected).	
Each component is tested for conformity to written specifications for identity, purity, strength and quality. Supplier analysis may be accepted provided that at least one specific identity test has been conducted by the firm and the firm has established the reliability of the supplier's analysis through validation of supplier's test results at appropriate intervals.	
Containers and closures are tested for conformity to written specifications. A certificate of testing from the supplier is acceptable if the reliability of the suppliers' test results is established and at least a visual identification is conducted by the firm.	
Each lot of component with potential for microbiological contamination are subjected to microbiological tests before use.	
Components, drug product containers and closures approved for use are rotated so that the oldest approved stock is used first. Deviations from this are temporary and appropriate.	
Drug product containers and closures are not reactive, additive, or adsorptive so as to alter the safety, identity, strength, quality or purity of the drug.	
Firm has written specifications, methods of testing if indicated, methods of cleaning, sterilizing and depyrogenating drug product containers and closures.	
Facility has a system in place to ensure final drug product containers, closures and stoppers are endotoxin free. Failures are investigated and documented.	
Written procedures include material transfer from less classified air to higher classified air and include procedures to sanitize materials prior to introduction into the clean room.	
Facility has appropriate sterile PPE.	
Materials for cleaning the PEC's are **sterile**.	
Filters used for sterilization have documentation that they are compatible with the product, are pharmaceutical grade, non-pyrogenic and capable of sterilizing the intended volume.	
Written procedures identify storage times beyond which materials must be reexamined before use.	
Release of retested material clearly identified for reuse.	

Production - 21CFR part 211 subpart F

There are written procedures for production and process controls to assure the drug products have the identity, strength, quality, and purity they purport to possess. Procedures are followed. Deviations are recorded and justified.	
Components removed from the original container to another are properly labeled.	
Weighing, measuring, or sub-dividing of components is supervised. Each container of component dispensed to manufacturing is examined by a second person.	
Each component added to the batch is verified by a second person unless added by automated equipment under 211.68.	
Actual and theoretical yields are determined at each production phase and are verified by a second person. If yields are calculated by automated equipment, verification is done by one person.	
Written procedures indicate how and who verifies that correct containers and packages are used for the finished product.	
In-process specifications have been established and followed for each production phase to ensure uniformity of drug product.	
Control procedures include disintegration time, adequacy of mixing, dissolution times and rates where appropriate.	
Quality control unit approves or rejects in- process materials that are tested during the production process after completion of significant phases of production.	
Time limits are established for the completion of each production phase; Deviations are justified and documented.	
Sterilization methods are validated.	
SOP's identify hold times for depyrogenated glassware, and the hold times have been validated.	
Integrity testing is conducted on all filters used to sterilize product and is documented on the batch record.	
Products prepared for lyophilization are maintained in ISO 5 laminar flow air throughout the production process from sterilization, filling, and transport to the lyophilizer.	
There are an adequate number of personnel to supervise the manufacture processing, packing, or holding of each drug product.	
All finished products are held in quarantine until QC has completed testing and releases the batch.	
A 100% inspection of finished sterile products for cracks, visible particles and significant defects is performed.	
Firm has written procedures that define the defects to be removed from the lot and actions to take if the number of critical defects exceeds the pre-determined level.	
Firm has a program for sampling and examination of inspected products that evaluates the effectiveness of inspection.	

Packaging and Labeling - 21 CFR part 211 subpart G

Written procedures describe the receipt, identification, storage, handling, examination and/or testing of labeling and packaging material. Procedures are followed.	
Written procedures describe control procedures employed for issuance of labeling. Procedures are followed.	
Written procedure specifies who is authorized to issue labels and strict control is exercised over labeling operations.	
Records are maintained for each shipment received of each different labeling material indicating receipt, examination/testing, and whether accepted or rejected.	
Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents are stored separately and properly identified.	
Access to label storage area is limited to authorized personnel	
Obsolete and outdated labels, labeling and packaging materials are destroyed.	

Unlabeled drug filled product containers intended for future labeling are identified with drug name, strength, quantity and lot number.	
Written procedure specify how labels are issued, used, reconciled with production, returned when unused, and the specific steps for evaluation of any discrepancies.	
Written procedures call for the destruction of excess labeling on which lot and control #'s have been stamped or imprinted.	
100% Visual inspection is conducted for correct labeling during or after completion of finishing operations for hand applied labeling. Such examination is performed by one person and independently verified by a second person. Or use of electronic equipment to conduct 100% examination.	
Procedures are established and followed to assure that correct labels, labeling, and packaging materials are used.	
Procedures are designed to prevent mix-ups and cross-contamination by physical or spatial separation from operations on other products.	
Written procedures detail examination of packaging and labeling materials for suitability and correctness and is documented on the batch record.	
Drug labels include the statement "this is a compounded drug, the name, address and phone # of the facility.	
The label of the drugs contains the lot or batch #, the established name of the drug, dosage form and strength, quantity or volume, the date the drug was compounded, the expiration date, storage and handling instructions, NDC # (if available), the statements "not for resale" and " For Office Use Only," and a list of active and inactive ingredients identified by established name and the quantity or proportion of each ingredient and route of administration.	
The label or container contains the following: www.fda.gov/medwatch and 1-800-FDA-1088.	
Written procedures detail how equipment is to be checked immediately prior to use for removal of any labels, labeling, and packaging materials from prior print operations, and is documented on the batch record. Procedures are followed.	

Holding and Distribution
21CFR Part 211 Subpart H

Written procedures describing warehousing of drugs include quarantine of drug product before release by QC unit, storage under appropriate temperature, relative humidity, and light.	
Procedures for the warehousing of drugs are followed.	
Written procedures include FIFO of product distributed and a system whereby product can be recalled.	
The firm has conducted shipping studies to confirm that drug products can be shipped without negatively impacting the safety, identity, strength, quality and purity of the drug product.	

Laboratory –

21 CFR part 211 subpart I

Contract labs are FDA registered.	
Facility has qualified their contract labs.	
Laboratory specifications, standards, sampling plans and test procedures are approved by Quality Unit; deviations from written specifications are recorded and justified.	
All laboratory procedures are followed and documented contemporaneously.	
Laboratory controls include procedures designed to assure that components, containers, closures, drug products, and in-process materials, conform to appropriate standards of identity, strength, quality and purity.	
Instruments, apparatus, gauges, and recording devices are calibrated at suitable intervals in accordance with an established written program.	
Stability tests are derived from reliable, meaningful and specific tests methods and justify the assigned BUD of each drug product.	
There is a written program to assess the stability characteristics of each product. The program includes sample size and test interval, storage conditions, and testing the drug product in the same container closure system in which the product is distributed.	

Lyophilized products have stability data for both before and after reconstitution.	
Facility has approved finished product specifications for all CSPs.	
All batches of drug products have undergone appropriate laboratory testing to determine conformance to specifications.	
Procedures describe sampling and testing plans and include method of sampling and the number of units per batch to be tested.	
Acceptance criteria for sampling and testing conducted by the quality control unit are adequate to assure that batches of drug products meet appropriate specifications.	
Drug products failing to meet established specifications or any other relevant quality control criteria are rejected.	
Stability studies, microbial effectiveness testing on the preservative, container closure studies and sterility testing have been conducted to ensure the CSP continues to meet all specifications over the intended shelf life of the product.	
Sterility testing for all batches is conducted using a USP 71 test or a validated alternate test that is proven equivalent or superior to the USP<71> test. .	
Sterility tests for products requiring reconstitution are conducted using preservative free diluent.	
Method suitability has been conducted for all products.	
Endotoxin testing is conducted on all batches.	
Potency is conducted on all batches.	
Appropriate # of articles/volume is tested for sterility.	
The accuracy, sensitivity, specificity, and reproducibility of test methods are established and documented; failures are rejected.	
A reserve sample, representative of each lot or batch of drug product, is retained and stored under conditions consistent with product labeling and in the same container-closure system for 1 year past the BUD of the drug product.	

Records and Reports
21CFR
Part 211 Subpart J

All records associated with a batch, including records of containers, closures and labeling are retained for at least 1 year after expiration of the batch. Records related to product distributed into the state of Florida are retained 4 years.	
Written records are maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product. Procedures include a review of complaints, recalls, and investigations for each drug product, and include a representative number of batches, whether approved or rejected.	
Records of maintenance, cleaning, sanitizing, inspection and use of major equipment are kept and show the date, time, product, and lot number of each batch produced.	
Logs are signed or initialed and dated by persons performing and double checking the cleaning and maintenance of equipment. Entries are in chronological order.	
All components, containers, closures, and labeling are identified on batch records and traceable to the finished product.	
Master production and control records for each drug product are prepared and include batch size, name and strength of product, dosage form, name and weight of each ingredient, complete list of all components, statement of theoretical yield, % deviation from theoretical yield that requires an investigation, description of containers, closures and packaging materials, specimen of labels, complete manufacturing and control instructions, sampling and testing procedures, product specification, special notations and precautions to follow.	
Master production and control records are prepared, dated and signed with a full signature by one person and independently checked, dated and signed by a second person.	
Batch Production and Control records are accurate and complete.	
Batch records include documentation that each significant step was accomplished and includes date and time.	
Major equipment is identified on the batch record.	
The identity of each person performing, supervising, or checking each step is documented on the batch record.	
The firm has an SOP for product release. The production batch and control records, including those for packaging and labeling, are reviewed and approved by the quality unit to determine compliance before a batch is released or distributed.	

Complete records of any modification of an established method used in testing are maintained.	
Records of calibration for laboratory equipment and gauges area maintained.	
Distribution records contain the name, strength, description, dosage form, lot number, quantity of the drug product and the date shipped as well as the name and address of the consignee.	
Firm has written procedures for handling all complaints which include provisions for review by the quality control unit. Procedures are followed.	
A written record of each complaint is maintained in a file designated for drug product complaints. Records are maintained at the establishment where the drug product was manufactured, or if kept at another facility, are readily retrievable.	
Records of complaints include the name, strength and lot number of the drug as well as the name of the complainant, nature of the complaint and response to complaint.	
The firm maintains separate, complete and readily retrievable records of distribution into the state of Florida.	
The firm has SOPs for adverse event reporting to the FDA.	
Firm has record of adverse event reports submitted to FDA.	
ADEs are adequately reported to FDA. Reasons for not reporting an ADE are documented.	

Remarks:

21CFR210.1(b) “The failure to comply with any regulation set forth in this part and in parts 211 through 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)2(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action”.

Virtual Inspection conducted by Senior Pharmacist,

I have read and have had this inspection report and the laws and regulations concerned herein explained and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Investigator/Sr. Pharmacist Signature: Representative:

Date: Date:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy __ _ Hospital Pharmacy ____ Clinic ____ Exempt Hospital ____ Wholesaler ____ Hypodermic ___

Date: 6/15/2022 Inspector: Margaret Panella-Spangler

Firm: MEDISOURCERX Phone: (714) 455-1300

Address: 10525 HUMBOLT ST City: LOS ALAMITOS Zip: 90720

Ownership: CORPORATION

Permit #: OSF124 Permit Exp: 11/1/2022 DEA#: [redacted] DEA Exp: 1/31/2023

Date of Self Assessment Form: _____ Other Permit #: N/A Date of DEA Inventory: 3/31/2022

Hours M-F: 0730-1600 Hours Saturday closed Hours Sunday: closed

PIC _____ _____ Administrator _____

RPH Consultant _____ _____

Staff RPH Name:	License #:	Staff Name:	License #:
PALLAVI D BADKAR	RPH75987	EMMA R SHEEHAN	TCH149972
VENUS FIROUZEHEE	RPH76758	RONNIE L PENROSE	TCH8714
		ROSEMARIE J TAUTUA	TCH77376
		TERRY PASKE	MANAGER

Inspector Remarks:

Medisource Outsourcing renewal inspection
Conducted on June 15, 2022
Completed by Inspectors Lyle Matthews and Peg Panella-Spangler
Assisted by Pallavi Badkar, Director of Operations, Terry Paske, Quality Manager, Venus Firouzehee, Production Manager
DEA registration, Narcotic inventory: DEA registration [redacted] -no controlled substances on hand, inventory provided during inspection

A partial Inspection was completed on 6/15/2022. Several documents were reviewed by Inspector Panella-Spangler prior to the in person inspection. Once the facility is back in production, Inspector Matthews will revisit to observe smoke studies, production, labeling and packaging and other documents as required to complete the inspection.

Since last renewal there have been no other state inspection(s) or executed recalls or ADEs/ADRs submitted (FDA SRP). The FDA provided an Establishment Inspection Report (EIR) pursuant to the FDA inspection in 2020 which produced a form 483 with seven inspectional observations on the firm's 503(B) outsourcing operations.

Annual outsourcing renewal inspection. Firm is licensed in California, Utah and Arizona. Firm produces two commercial products and one clinical trial drug in the following container closure types:

INSPECTION REPORT

- Glutathione 200 mg/mL in 30 mL amber vials, 120 days BUD assigned, 5 batches were released in 2021, 4 batches in 2022, since the last inspection
- Methylcobalamin 1 mg/mL in 30 mL amber vials, 270 days BUD assigned, 4 batches were released in 2022, since last inspection
- Methylcobalamin 5mg/ml in 30 ml amber vials, 60 day BUD with a stability currently in progress, no lots have been released for sale at the time of inspection
- Clinical trial drug in syringes, Aviptadil Acetate 0.1mg/ml in a 12 ml syringe. Drug stock is segregated and production occurs on different business days from 503B operations. Over 60 dispositions of the investigational drug were released since last inspection

Glutathione and methylcobalamin 1mg/ml have been shipped to California customers in the last 12 months. Several products are under R&D including but not limited to Thiamine 100 mg/Pyridoxine 100 mg injection, Ascorbic acid 500 mg/mL, Lidocaine 40 mg/mL, and Calcium gluconate 10%.

Follow-up to last year's inspection:
Per inspection remark, the visual inspection defect kit was updated. Promised date was September 2021. A deviation was created. This was provided with the pre-inspection documents.

Quality: Subpart B
Personnel and organization: New quality manager 2021, new production pharmacist 2022. Very small staff and some staff members have reporting to quality and production, blurring distinct units for each.
Policies and Procedures: Viewed during inspection
Personnel training and PPE: Facility dedicated scrubs. Single use disposable sterile coveralls with booties, hoods, sleeves, and goggles. Firm has re-usable sterile gowns, booties, hoods, and goggles as back-up.
Vendor qualifications: viewed vendor chart; quality agreements are in place. Critical vendors will be requalified annually. Other vendors to be requalified biannually. Chart provided at inspection was not updated or several vendor qualifications were out of date.
Validations and qualifications: New IOPQ provided for equipment
CAPAs, deviations, and customer complaints: Provided, several selected for review and reviewed during inspection.
ADRS: none reported since last inspection
Essential Copies / Drug Shortages:

Facilities: Subpart C
Layout: Small facility in a office business park. Floor plan was provided. Approximately 5000 square feet with a clean room suite of approximately 1000 square feet.
Inspectional walk-through:
Critical Utilities: Monthly routine maintenance by Air West; invoices viewed. Process gases included compressed air (crimping) and nitrogen (not in use). Both are delivered from purchased tanks. COA for compressed air viewed.
Certifications were conducted by TSS Inc. in November 2021
ISO 8 areas - Gown room, Prep room, SC ante room, SC room, Hallway: All areas had dynamic testing and met specifications for non-viable particles, air flow, pressurization and HEPA filter leak tests.
ISO 7 areas - Fill room 1 and Fill room 2. Each fill room has one ISO 5 laminar airflow workbench. All areas had

INSPECTION REPORT

dynamic testing and met specifications for non-viable particles, air flow, pressurization and HEPA filter leak tests.
ISO 5 workbenches; As above
Compounding space and aseptic area cleaning: cleaning logs provided. Cleaning/disinfecting agents include TX650 TexQ, Spor-Klenz, and 70% IP A; all sterile.

- Daily (TX650 and IP A) - only in areas where personnel have entered
- Weekly (Spor-Klenz and IP A) - in all ISO classified areas and sterilization room
- Monthly (TX650, Spor-Klenz, and IP A) - in all ISO classified areas and sterilization room

Equipment: Subpart D
Calibration and Equipment Maintenance: Master list provided during inspection and viewed
IQ, OQ, PQ: Provided for new equipment: Calibration document for new thermometer, IOPQ for new refrigerator, IOPQ for pH meter, all provided during inspection
Sterilizing Filter selection & compatibility: in batch record
Equipment cleaning log: Concerns it only takes 2 minutes to clean an incubator, January 2022 log

Control of Components and Drug Product Containers and Closures: Subpart E
Identification and inventory: There are dedicated areas for released and quarantined goods. Color coded hold (yellow), release (green), and quarantine (orange) stickers are used.
Storage conditions: Glutathione and Methylcobalamin finished goods are stored under refrigeration and protected from light.
Quarantine and release: Done by Quality
Component/ API testing: Annually for APL Every two years for components and excipients. Glutathione bulk API has had the COA from the vendor confirmed. Methylcobalamin bulk API has been tested for ID, assay, bioburden, and endotoxin. Firm is awaiting finalized results for the remaining COA tests for Methylcobalamin from ARL and Element labs.
Container Closure Suitability and Integrity: viewed for Methylcobalamin 1 mg/rnl (vacuum decay) at least at the beginning and at the end of the study period

Production and Process Controls: Subpart F
Master & Batch records: reviewed sample batches for the two products and investigational drug product: Batch records are not drug specific per CFR 211.188

- Components, bill of materials, equipment identification, personnel identification was not provided with pre inspection batch records
- Production processing steps with verification steps: Not in order and possible to switch out pages
- Specification sheet & laboratory COAs / raw materials: Not for all
- Production environmental monitoring and personnel monitoring sampling
    - Continuous non-viable particulate monitoring & volumetric viable air sampling during batch production in ISO-5
- Post-production evaluation – inspection, labeling, sampling: Deferred during inspection
- Processing start / end times noted
- In-Process controls – bubble point testing of filter, pH check, weight check, bioburden before filtration and

INSPECTION REPORT

end of hold time

- Limits of production time / hold time of intermediates – reviewed

Method Suitability and Container Closure Integrity: In the process of a very large investigation into their vials
Yields: Noted on the batch record
Remarks:

1. Per CFR 211.186, the Master Production records are not compliant making the batch records non-compliant. Please review the CFR and ensure new master production records and the batch records are compliant. Current draft is not adequate.

Packaging and Labeling Control: Subpart G
Acceptance of packaging and labeling materials:
Control of labels: Documented in the batch record
Line clearance: Deferred until production visualized
Visual inspection of product postproduction: Noted in the batch record, AQL done twice, before and after labeling. Per ICH and ANSI respectively.
Examination of finished labeled product: Noted in the batch record

Holding and Distribution: Subpart H
Warehousing procedures: No changes
Distribution procedures: Noted new SOP for packaging and distribution of product. SOP allows for hand delivery of product due to an "emergency" situation.

1. Pack-out procedures: Described in detail in new SOP #: PKC-003 MOCA #: M21-DOC-036 Revision #: 03 Effective: 12/20/2021

Laboratory Controls: Subpart I
Stability studies: All completed by independent laboratories (Eagle Analytical/ARL/Focus)
Release testing: Provided with batch record: specs include appearance, potency<1225>, sterility via Scan RDI, endotoxin <85>, pH<791>, sub-visible particles/particulates <788>/<789>, visual inspection<790/1790>, and preservative content
Testing Samples: Noted in batch record.
Reserve samples: 10 samples kept per batch; noted in batch record.
Equipment & facility: EM and PPM incubated in house and read in house: Samples sent out for ID when growth occurs
Environmental Sampling: new SOP effective 7/21/2021 SOP#: PPC-002 MOCA #: M21-DOC-004 Revision #: 05
ISO 5 Areas Daily and weekly except for personnel

- Personnel sampling include R/L fingertips, R/L sleeve, gown, hood at the end of each batch for aseptic operator for ISO 5 after production
- Non-viable particle counts - one-minute samples taken continuously in during production,
- Viable air sampling done passively during production Settling plate in ISO 5 - max of 4 hours; on left and right side of hood

ISO 7 Areas Daily and weekly except for personnel

INSPECTION REPORT

- Viable air sampling once during production in ISO 7
- At the beginning of each batch fill in ISO 7 (pumps, crimper, cart)
- Non-viable air sampling during production

ISO 8 Areas in the hallway and gowning area have Weekly monitoring
ISO 8 Areas in the building are monitored monthly
Media control: Commercial media used; growth promotion performed on each lot. Incubation at two temperatures (1) 30 to 35 deg C for NLT 72 hours followed by (2) 20 to 25 deg C for 5 to 7 days; first and second reading of plates.

Records and Reports: Subpart J
Batch records: Not drug product and batch size specific and could have data changed out
Usage and cleaning logs: See under facility and equipment
Annual product reviews: Provided for glutathione dated 6/25/2021.

Discussion:

1. [redacted]
2. [redacted]

The CA State Board of Pharmacy grants its inspectors the authority to inspect per CFR 210 and 211 for compliance with current Good Manufacturing Practices [BPC 4129.2(b)]

BPC 4129.1 (e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]

***Notification of recalls, ADRs, and complaints to the Board's email address: compounding.report@dca.ca.gov**

Please send all remark and observation responses to Peg Panella-Spangler: peg.panella-spangler@dca.ca.gov no later than June 30, 2022

The deviations and observed non-compliances referenced in this report are not intended to be an all-inclusive list of deviations and non-compliances that may exist at your firm. Your firm is responsible for investigating and determining the causes of any deviations and observed non-compliances and for

California State Board of Pharmacy
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Department of Consumer Affairs
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INSPECTION REPORT

preventing their recurrence or the occurrence of any other non-compliances and deviations.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) _____

Inspector (sign) _____

Inspector (print) _____

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

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

Included in your agenda package are:

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

Action needed:

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

COMMONWEALTH of VIRGINIA

DEPARTMENT OF FORENSIC SCIENCE

OFFICE OF THE DIRECTOR
A Nationally Accredited Laboratory

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: April 14, 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 five (5) compounds for recommended inclusion into the Code of Virginia.

The following compounds are classified as synthetic opioids. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.

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

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

3. **N-phenyl-N-(1-propionyl-4-piperidinyl)-propanamide (other name: N-propionyl Norfentanyl),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

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

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

5. **7-chloro-5-(2-chlorophenyl)-1-methyl-3H-1,4-benzodiazepin-2-one (other names: Diclazepam, 2-Chlorodiazepam)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

Robyn Weimer
Chemistry Program Manager

Project 7580 - Exempt Final

Board of Pharmacy

June 2023 scheduling of chemicals in Schedule I

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

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

1. Synthetic opioid. 1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

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

b. Alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agents.

a. Ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA), its salts, isomers, and salts of isomers whenever the existence of

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

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until August 16, 2023, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioid. 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole (other names: N-pyrrolidino etonitazene, etonitazepyne), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

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

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

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

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

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

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

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

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

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

4. Cannabimimetic agent. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indole-3-acetamide (other names: ADB-FUBIATA, AD-18, FUB-ACADB), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until March 14, 2024, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioid. N,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties. 1-(1,3-benzodioxol-5-yl)-2-(cyclohexylamino)butan-1-one (other names: Cybutylone, N-cyclohexyl Butylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

4. Cannabimimetic agents.

a. 5-bromo-N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-5Br-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-5-bromo-1-butylindazole-3-carboxamide (other name: ADB-5'Br-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until July 31, 2024, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioid. 2-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name: 2-methyl butyryl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 1-(7-methoxy-1,3-benzodioxol-5-yl)propan-2-amine (other names: 5-methoxy-3,4-methylenedioxyamphetamine, 3-methoxy MDA, MMDA), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 1-[1-(3-chlorophenyl)cyclohexyl]-piperidine (other names: 3-Chloro Phencyclidine, 3Cl-PCP, 3-chloro PCP), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

4. Compound classified as a cannabimimetic agent. Methyl N-[(5-bromo-1H-indazol-3-yl)carbonyl]-3-methyl-valinate (other name: MDMB-5Br-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until October 12, 2024, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioids:

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

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

c. N-phenyl-N-(1-propionyl-4-piperidinyl)-propanamide (other name: N-propionyl Norfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

2. Compounds expected to have depressive properties:

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

b. 7-chloro-5-(2-chlorophenyl)-1-methyl-3H-1,4-benzodiazepin-2-one (other names: Diclazepam, 2-Chlorodiazepam), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until [March 2, 2025], unless enacted into law in the Drug Control Act.

Agenda Item: Adoption of proposed regulations – implementation of 2022 legislation for pharmacists initiating treatment

Included in your agenda package are:

- Amendments to 18VAC110-21-46.
- Town Hall summary page for Emergency/NOIRA stage, showing no comments.
- Ch. 791 of the 2022 Acts of Assembly.

Action needed:

- Motion to adopt proposed regulatory changes as presented to implement Ch. 791 of the 2022 Acts of Assembly regarding pharmacists initiating treatment.

Project 7339 - Emergency/NOIRA

Board of Pharmacy

2022 Pharmacists initiating treatment

18VAC110-21-46. Initiation of treatment by a pharmacist.

A. Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older with whom the pharmacist has a bona fide pharmacist-patient relationship:

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

2. Epinephrine;

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

4. Prenatal vitamins for which a prescription is required;

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

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

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention [~~or that have a current emergency use authorization from the U.S. Food and Drug Administration~~ and vaccines for COVID-19];

8. Tuberculin purified protein derivative for tuberculosis testing; [~~and~~]

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; [and

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

B. Notwithstanding the provisions of § 54.1-3303 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older:

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

2. Tests for COVID-19 and other coronaviruses.

The provisions of this subsection will become effective upon expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors.

C. Pharmacists who initiate treatment with, dispense, or administer a drug ~~or~~, device, controlled paraphernalia, or other supplies or equipment pursuant to ~~subsection~~ subsections A and B of this section shall:

1. Follow the statewide protocol adopted by the board for each drug ~~or~~, device, controlled paraphernalia, or other supplies or equipment.

2. Notify the patient's primary health care provider that treatment has been initiated 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 USC § 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~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears. If the pharmacist is administering a vaccine pursuant to this section, the pharmacist shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01 of the Code of Virginia.

3. Maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:

a. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative; or

b. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.

4. Perform the activities in a manner that protects patient confidentiality and complies with the Health Insurance Portability and Accountability Act, 42 USC § 1320d et seq.

5. 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.

6. If administering a vaccination to a minor pursuant to subdivision B 1 of this section, provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

D. 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 of the Code of Virginia, in compliance with all requirements of § 54.1-3303 of the Code of Virginia and consistent with the applicable standard of care.

Virginia.gov Agencies | Governor

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians [18 VAC 110 - 21]**

Action: 2022 Pharmacists initiating treatment

Emergency/NOIRA Stage

Action 6070 / Stage 9778

Edit Stage | Go to RIS Project | Request Emergency Extension

Documents		
Emergency Text	3/7/2023 3:44 pm	Sync Text with RIS
Agency Background Document	8/25/2022 (modified 2/13/2023)	Upload / Replace
Attorney General Certification	2/3/2023	
Governor's Review Memo	2/21/2023	
Registrar Transmittal	2/21/2023	

Status	
Public Hearing	Will be held at the **proposed** stage
Emergency Authority	2.2-4011(B)
Attorney General Review	Submitted to OAG: 9/16/2022 Review Completed: 2/3/2023 Result: Certified
DPB Review	Submitted on 2/3/2023 Policy Analyst: Jeannine Rose Review Completed: 2/14/2023
Secretary Review	Secretary of Health and Human Resources Review Completed: 2/20/2023
Governor's Review	ORM Review: ORM Approved 2/21/2023 Governor Review Completed: 2/21/2023 Result: Approved
Virginia Registrar	Submitted on 2/21/2023 The Virginia Register of Regulations Publication Date: 3/13/2023 Volume: 39 Issue: 15
Comment Period	Ended 4/12/2023 0 comments
Effective Date	2/21/2023
Expiration Date	8/20/2024

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This person is the primary contact for this board.

This stage was created by Erin Barrett on 08/25/2022 at 1:25pm
This stage was last edited by Erin Barrett on 08/25/2022 at 1:26pm
RIS System last updated this stage on 02/22/2023 at 1:30pm

CHAPTER 791

An Act to amend and reenact §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia, relating to pharmacists; initiation of treatment with and dispensing and administration of vaccines.

[H 1323]

Approved May 27, 2022

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia are amended and reenacted as follows:

§ 32.1-325. Board to submit plan for medical assistance services to U.S. Secretary of Health and Human Services pursuant to federal law; administration of plan; contracts with health care providers.

A. The Board, subject to the approval of the Governor, is authorized to prepare, amend from time to time, and submit to the U.S. Secretary of Health and Human Services a state plan for medical assistance services pursuant to Title XIX of the United States Social Security Act and any amendments thereto. The Board shall include in such plan:

1. A provision for payment of medical assistance on behalf of individuals, up to the age of 21, placed in foster homes or private institutions by private, nonprofit agencies licensed as child-placing agencies by the Department of Social Services or placed through state and local subsidized adoptions to the extent permitted under federal statute;

2. A provision for determining eligibility for benefits for medically needy individuals which disregards from countable resources an amount not in excess of $3,500 for the individual and an amount not in excess of $3,500 for his spouse when such resources have been set aside to meet the burial expenses of the individual or his spouse. The amount disregarded shall be reduced by (i) the face value of life insurance on the life of an individual owned by the individual or his spouse if the cash surrender value of such policies has been excluded from countable resources and (ii) the amount of any other revocable or irrevocable trust, contract, or other arrangement specifically designated for the purpose of meeting the individual's or his spouse's burial expenses;

3. A requirement that, in determining eligibility, a home shall be disregarded. For those medically needy persons whose eligibility for medical assistance is required by federal law to be dependent on the budget methodology for Aid to Families with Dependent Children, a home means the house and lot used as the principal residence and all contiguous property. For all other persons, a home shall mean the house and lot used as the principal residence, as well as all contiguous property, as long as the value of the land, exclusive of the lot occupied by the house, does not exceed $5,000. In any case in which the definition of home as provided here is more restrictive than that provided in the state plan for medical assistance services in Virginia as it was in effect on January 1, 1972, then a home means the house and lot used as the principal residence and all contiguous property essential to the operation of the home regardless of value;

4. A provision for payment of medical assistance on behalf of individuals up to the age of 21, who are Medicaid eligible, for medically necessary stays in acute care facilities in excess of 21 days per admission;

5. A provision for deducting from an institutionalized recipient's income an amount for the maintenance of the individual's spouse at home;

6. A provision for payment of medical assistance on behalf of pregnant women which provides for payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Payment shall be made for any postpartum home visit or visits for the mothers and the children which are within the time periods recommended by the attending physicians in accordance with and as indicated by such Guidelines or Standards. For the purposes of this subdivision, such Guidelines or Standards shall include any changes thereto within six months of the publication of such Guidelines or Standards or any official amendment thereto;

7. A provision for the payment for family planning services on behalf of women who were Medicaid-eligible for prenatal care and delivery as provided in this section at the time of delivery. Such family planning services shall begin with delivery and continue for a period of 24 months, if the woman continues to meet the financial eligibility requirements for a pregnant woman under Medicaid. For the purposes of this section, family planning services shall not cover payment for abortion services and no funds shall be used to perform, assist, encourage or make direct referrals for abortions;

8. A provision for payment of medical assistance for high-dose chemotherapy and bone marrow transplants on behalf of individuals over the age of 21 who have been diagnosed with lymphoma, breast cancer, myeloma, or leukemia and have been determined by the treating health care provider to have a performance status sufficient to proceed with such high-dose chemotherapy and bone marrow transplant. Appeals of these cases shall be handled in accordance with the Department's expedited appeals process;

9. A provision identifying entities approved by the Board to receive applications and to determine eligibility for medical assistance, which shall include a requirement that such entities (i) obtain accurate contact information, including the best available address and telephone number, from each applicant for medical assistance, to the extent required by federal law and regulations, and (ii) provide each applicant for medical assistance with information about advance directives pursuant to Article 8 (§ 54.1-2981 et seq.) of Chapter 29 of Title 54.1, including information about the purpose and benefits of advance directives and how the applicant may make an advance directive;

10. A provision for breast reconstructive surgery following the medically necessary removal of a breast for any medical reason. Breast reductions shall be covered, if prior authorization has been obtained, for all medically necessary indications. Such procedures shall be considered noncosmetic;

11. A provision for payment of medical assistance for annual pap smears;

12. A provision for payment of medical assistance services for prostheses following the medically necessary complete or partial removal of a breast for any medical reason;

13. A provision for payment of medical assistance which provides for payment for 48 hours of inpatient treatment for a patient following a radical or modified radical mastectomy and 24 hours of inpatient care following a total mastectomy or a partial mastectomy with lymph node dissection for treatment of disease or trauma of the breast. Nothing in this subdivision shall be construed as requiring the provision of inpatient coverage where the attending physician in consultation with the patient determines that a shorter period of hospital stay is appropriate;

14. A requirement that certificates of medical necessity for durable medical equipment and any supporting verifiable documentation shall be signed, dated, and returned by the physician, physician assistant, or nurse practitioner and in the durable medical equipment provider's possession within 60 days from the time the ordered durable medical equipment and supplies are first furnished by the durable medical equipment provider;

15. A provision for payment of medical assistance to (i) persons age 50 and over and (ii) persons age 40 and over who are at high risk for prostate cancer, according to the most recent published guidelines of the American Cancer Society, for one PSA test in a 12-month period and digital rectal examinations, all in accordance with American Cancer Society guidelines. For the purpose of this subdivision, "PSA testing" means the analysis of a blood sample to determine the level of prostate specific antigen;

16. A provision for payment of medical assistance for low-dose screening mammograms for determining the presence of occult breast cancer. Such coverage shall make available one screening mammogram to persons age 35 through 39, one such mammogram biennially to persons age 40 through 49, and one such mammogram annually to persons age 50 and over. The term "mammogram" means an X-ray examination of the breast using equipment dedicated specifically for mammography, including but not limited to the X-ray tube, filter, compression device, screens, film and cassettes, with an average radiation exposure of less than one rad mid-breast, two views of each breast;

17. A provision, when in compliance with federal law and regulation and approved by the Centers for Medicare & Medicaid Services (CMS), for payment of medical assistance services delivered to Medicaid-eligible students when such services qualify for reimbursement by the Virginia Medicaid program and may be provided by school divisions, regardless of whether the student receiving care has an individualized education program or whether the health care service is included in a student's individualized education program. Such services shall include those covered under the state plan for medical assistance services or by the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit as specified in § 1905(r) of the federal Social Security Act, and shall include a provision for payment of medical assistance for health care services provided through telemedicine services, as defined in § 38.2-3418.16. No health care provider who provides health care services through telemedicine shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services;

18. A provision for payment of medical assistance services for liver, heart and lung transplantation procedures for individuals over the age of 21 years when (i) there is no effective alternative medical or surgical therapy available with outcomes that are at least comparable; (ii) the transplant procedure and application of the procedure in treatment of the specific condition have been clearly demonstrated to be medically effective and not experimental or investigational; (iii) prior authorization by the Department of Medical Assistance Services has been obtained; (iv) the patient selection criteria of the specific transplant center where the surgery is proposed to be performed have been used by the transplant team or program to determine the appropriateness of the patient for the procedure; (v) current medical therapy has failed and the patient has failed to respond to appropriate therapeutic management; (vi) the patient is not in an irreversible terminal state; and (vii) the transplant is likely to prolong the patient's life and

restore a range of physical and social functioning in the activities of daily living;

19. A provision for payment of medical assistance for colorectal cancer screening, specifically screening with an annual fecal occult blood test, flexible sigmoidoscopy or colonoscopy, or in appropriate circumstances radiologic imaging, in accordance with the most recently published recommendations established by the American College of Gastroenterology, in consultation with the American Cancer Society, for the ages, family histories, and frequencies referenced in such recommendations;

20. A provision for payment of medical assistance for custom ocular prostheses;

21. A provision for payment for medical assistance for infant hearing screenings and all necessary audiological examinations provided pursuant to § 32.1-64.1 using any technology approved by the United States Food and Drug Administration, and as recommended by the national Joint Committee on Infant Hearing in its most current position statement addressing early hearing detection and intervention programs. Such provision shall include payment for medical assistance for follow-up audiological examinations as recommended by a physician, physician assistant, nurse practitioner, or audiologist and performed by a licensed audiologist to confirm the existence or absence of hearing loss;

22. A provision for payment of medical assistance, pursuant to the Breast and Cervical Cancer Prevention and Treatment Act of 2000 (P.L. 106-354), for certain women with breast or cervical cancer when such women (i) have been screened for breast or cervical cancer under the Centers for Disease Control and Prevention (CDC) Breast and Cervical Cancer Early Detection Program established under Title XV of the Public Health Service Act; (ii) need treatment for breast or cervical cancer, including treatment for a precancerous condition of the breast or cervix; (iii) are not otherwise covered under creditable coverage, as defined in § 2701 (c) of the Public Health Service Act; (iv) are not otherwise eligible for medical assistance services under any mandatory categorically needy eligibility group; and (v) have not attained age 65. This provision shall include an expedited eligibility determination for such women;

23. A provision for the coordinated administration, including outreach, enrollment, re-enrollment and services delivery, of medical assistance services provided to medically indigent children pursuant to this chapter, which shall be called Family Access to Medical Insurance Security (FAMIS) Plus and the FAMIS Plan program in § 32.1-351. A single application form shall be used to determine eligibility for both programs;

24. A provision, when authorized by and in compliance with federal law, to establish a public-private long-term care partnership program between the Commonwealth of Virginia and private insurance companies that shall be established through the filing of an amendment to the state plan for medical assistance services by the Department of Medical Assistance Services. The purpose of the program shall be to reduce Medicaid costs for long-term care by delaying or eliminating dependence on Medicaid for such services through encouraging the purchase of private long-term care insurance policies that have been designated as qualified state long-term care insurance partnerships and may be used as the first source of benefits for the participant's long-term care. Components of the program, including the treatment of assets for Medicaid eligibility and estate recovery, shall be structured in accordance with federal law and applicable federal guidelines;

25. A provision for the payment of medical assistance for otherwise eligible pregnant women during the first five years of lawful residence in the United States, pursuant to § 214 of the Children's Health Insurance Program Reauthorization Act of 2009 (P.L. 111-3);

26. A provision for the payment of medical assistance for medically necessary health care services provided through telemedicine services, as defined in § 38.2-3418.16, regardless of the originating site or whether the patient is accompanied by a health care provider at the time such services are provided. No health care provider who provides health care services through telemedicine services shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services.

For the purposes of this subdivision, "originating site" means any location where the patient is located, including any medical care facility or office of a health care provider, the home of the patient, the patient's place of employment, or any public or private primary or secondary school or postsecondary institution of higher education at which the person to whom telemedicine services are provided is located;

27. A provision for the payment of medical assistance for the dispensing or furnishing of up to a 12-month supply of hormonal contraceptives at one time. Absent clinical contraindications, the Department shall not impose any utilization controls or other forms of medical management limiting the supply of hormonal contraceptives that may be dispensed or furnished to an amount less than a 12-month supply. Nothing in this subdivision shall be construed to (i) require a provider to prescribe, dispense, or furnish a 12-month supply of self-administered hormonal contraceptives at one time or (ii) exclude coverage for hormonal contraceptives as prescribed by a prescriber, acting within his scope of practice, for reasons other than contraceptive purposes. As used in this subdivision, "hormonal contraceptive" means a medication taken to prevent pregnancy by means of ingestion of hormones, including medications containing estrogen or progesterone, that is self-administered, requires a prescription, and is approved by the U.S. Food and Drug Administration for such purpose; and

28. A provision for payment of medical assistance for remote patient monitoring services provided via telemedicine, as defined in § 38.2-3418.16, for (i) high-risk pregnant persons; (ii) medically complex infants and children; (iii) transplant patients; (iv) patients who have undergone surgery, for up to three months following the date of such surgery; and (v) patients with a chronic health condition who have had two or more hospitalizations or emergency department visits related to such chronic health condition in the previous 12 months. For the purposes of this subdivision, "remote patient monitoring services" means the use of digital technologies to collect medical and other forms of health data from patients in one location and electronically transmit that information securely to health care providers in a different location for analysis, interpretation, and recommendations, and management of the patient. "Remote patient monitoring services" includes monitoring of clinical patient data such as weight, blood pressure, pulse, pulse oximetry, blood glucose, and other patient physiological data, treatment adherence monitoring, and interactive videoconferencing with or without digital image upload.

B. In preparing the plan, the Board shall:

1. Work cooperatively with the State Board of Health to ensure that quality patient care is provided and that the health, safety, security, rights and welfare of patients are ensured.

2. Initiate such cost containment or other measures as are set forth in the appropriation act.

3. Make, adopt, promulgate and enforce such regulations as may be necessary to carry out the provisions of this chapter.

4. Examine, before acting on a regulation to be published in the Virginia Register of Regulations pursuant to § 2.2-4007.05, the potential fiscal impact of such regulation on local boards of social services. For regulations with potential fiscal impact, the Board shall share copies of the fiscal impact analysis with local boards of social services prior to submission to the Registrar. The fiscal impact analysis shall include the projected costs/savings to the local boards of social services to implement or comply with such regulation and, where applicable, sources of potential funds to implement or comply with such regulation.

5. Incorporate sanctions and remedies for certified nursing facilities established by state law, in accordance with 42 C.F.R. § 488.400 et seq. "Enforcement of Compliance for Long-Term Care Facilities With Deficiencies."

6. On and after July 1, 2002, require that a prescription benefit card, health insurance benefit card, or other technology that complies with the requirements set forth in § 38.2-3407.4:2 be issued to each recipient of medical assistance services, and shall upon any changes in the required data elements set forth in subsection A of § 38.2-3407.4:2, either reissue the card or provide recipients such corrective information as may be required to electronically process a prescription claim.

C. In order to enable the Commonwealth to continue to receive federal grants or reimbursement for medical assistance or related services, the Board, subject to the approval of the Governor, may adopt, regardless of any other provision of this chapter, such amendments to the state plan for medical assistance services as may be necessary to conform such plan with amendments to the United States Social Security Act or other relevant federal law and their implementing regulations or constructions of these laws and regulations by courts of competent jurisdiction or the United States Secretary of Health and Human Services.

In the event conforming amendments to the state plan for medical assistance services are adopted, the Board shall not be required to comply with the requirements of Article 2 (§ 2.2-4006 et seq.) of Chapter 40 of Title 2.2. However, the Board shall, pursuant to the requirements of § 2.2-4002, (i) notify the Registrar of Regulations that such amendment is necessary to meet the requirements of federal law or regulations or because of the order of any state or federal court, or (ii) certify to the Governor that the regulations are necessitated by an emergency situation. Any such amendments that are in conflict with the Code of Virginia shall only remain in effect until July 1 following adjournment of the next regular session of the General Assembly unless enacted into law.

D. The Director of Medical Assistance Services is authorized to:

1. Administer such state plan and receive and expend federal funds therefor in accordance with applicable federal and state laws and regulations; and enter into all contracts necessary or incidental to the performance of the Department's duties and the execution of its powers as provided by law.

2. Enter into agreements and contracts with medical care facilities, physicians, dentists and other health care providers where necessary to carry out the provisions of such state plan. Any such agreement or contract shall terminate upon conviction of the provider of a felony. In the event such conviction is reversed upon appeal, the provider may apply to the Director of Medical Assistance Services for a new agreement or contract. Such provider may also apply to the Director for reconsideration of the agreement or contract termination if the conviction is not appealed, or if it is not reversed upon appeal.

3. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or pursuant to Subparts A, B, and C of 42 C.F.R. Part 1002, and upon notice of such action to the provider as required by 42 C.F.R. § 1002.212.

4. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with a provider who is or has been a principal in a professional or other corporation when

such corporation has been convicted of or otherwise pled guilty to any violation of § 32.1-314, 32.1-315, 32.1-316, or 32.1-317, or any other felony or has been excluded from participation in any federal program pursuant to 42 C.F.R. Part 1002.

5. Terminate or suspend a provider agreement with a home care organization pursuant to subsection E of § 32.1-162.13.

For the purposes of this subsection, "provider" may refer to an individual or an entity.

E. In any case in which a Medicaid agreement or contract is terminated or denied to a provider pursuant to subsection D, the provider shall be entitled to appeal the decision pursuant to 42 C.F.R. § 1002.213 and to a post-determination or post-denial hearing in accordance with the Administrative Process Act (§ 2.2-4000 et seq.). All such requests shall be in writing and be received within 15 days of the date of receipt of the notice.

The Director may consider aggravating and mitigating factors including the nature and extent of any adverse impact the agreement or contract denial or termination may have on the medical care provided to Virginia Medicaid recipients. In cases in which an agreement or contract is terminated pursuant to subsection D, the Director may determine the period of exclusion and may consider aggravating and mitigating factors to lengthen or shorten the period of exclusion, and may reinstate the provider pursuant to 42 C.F.R. § 1002.215.

F. When the services provided for by such plan are services which a marriage and family therapist, clinical psychologist, clinical social worker, professional counselor, or clinical nurse specialist is licensed to render in Virginia, the Director shall contract with any duly licensed marriage and family therapist, duly licensed clinical psychologist, licensed clinical social worker, licensed professional counselor or licensed clinical nurse specialist who makes application to be a provider of such services, and thereafter shall pay for covered services as provided in the state plan. The Board shall promulgate regulations which reimburse licensed marriage and family therapists, licensed clinical psychologists, licensed clinical social workers, licensed professional counselors and licensed clinical nurse specialists at rates based upon reasonable criteria, including the professional credentials required for licensure.

G. The Board shall prepare and submit to the Secretary of the United States Department of Health and Human Services such amendments to the state plan for medical assistance services as may be permitted by federal law to establish a program of family assistance whereby children over the age of 18 years shall make reasonable contributions, as determined by regulations of the Board, toward the cost of providing medical assistance under the plan to their parents.

H. The Department of Medical Assistance Services shall:

1. Include in its provider networks and all of its health maintenance organization contracts a provision for the payment of medical assistance on behalf of individuals up to the age of 21 who have special needs and who are Medicaid eligible, including individuals who have been victims of child abuse and neglect, for medically necessary assessment and treatment services, when such services are delivered by a provider which specializes solely in the diagnosis and treatment of child abuse and neglect, or a provider with comparable expertise, as determined by the Director.

2. Amend the Medallion II waiver and its implementing regulations to develop and implement an exception, with procedural requirements, to mandatory enrollment for certain children between birth and age three certified by the Department of Behavioral Health and Developmental Services as eligible for services pursuant to Part C of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.).

3. Utilize, to the extent practicable, electronic funds transfer technology for reimbursement to contractors and enrolled providers for the provision of health care services under Medicaid and the Family Access to Medical Insurance Security Plan established under § 32.1-351.

4. Require any managed care organization with which the Department enters into an agreement for the provision of medical assistance services to include in any contract between the managed care organization and a pharmacy benefits manager provisions prohibiting the pharmacy benefits manager or a representative of the pharmacy benefits manager from conducting spread pricing with regards to the managed care organization's managed care plans. For the purposes of this subdivision:

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a managed care organization for the benefit of covered individuals.

"Pharmacy benefits manager" means a person that performs pharmacy benefits management.

"Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager charges a managed care plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly pays the pharmacist or pharmacy for pharmacist services.

I. The Director is authorized to negotiate and enter into agreements for services rendered to eligible recipients with special needs. The Board shall promulgate regulations regarding these special needs patients, to include persons with AIDS, ventilator-dependent patients, and other recipients with special needs as defined by the Board.

J. Except as provided in subdivision A 1 of § 2.2-4345, the provisions of the Virginia Public Procurement Act (§ 2.2-4300 et seq.) shall not apply to the activities of the Director authorized by subsection I of this section. Agreements made pursuant to this subsection shall comply with federal law

and regulation.

K. When the services provided for by such plan are services related to initiation of treatment with or dispensing or administration of a vaccination by a pharmacist, pharmacy technician, or pharmacy intern in accordance with § 54.1-3303.1, the Department shall provide reimbursement for such service.

§ 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 ~~or that have a current emergency use authorization from the U.S. Food and Drug Administration~~ *and vaccines for COVID-19*;

8. Tuberculin purified protein derivative for tuberculosis testing; ~~and~~

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

2. 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~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

~~C.~~ *D.* A pharmacist who administers a vaccination pursuant to ~~subdivision~~ *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.

§ 54.1-3321. Registration of pharmacy technicians.

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

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

2. The preparation of prescription labels or patient information;

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

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

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

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

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

8. *Under the supervision of a pharmacist, meaning the supervising pharmacist is at the same physical location of the technician or pharmacy intern, and consistent with the requirements of § 54.1-3303.1, administration of the following drugs and devices to persons three years of age or older as set forth in regulations of the Board: vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and*

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

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

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

2. (Effective July 1, 2022) Evidence that he has successfully completed a training program that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military; and

3. Evidence that he has successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.

C. The Board shall promulgate regulations establishing requirements for:

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

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

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

D. The Board shall waive the initial registration fee for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

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

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

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

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

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

2. That the Board of Medicine, in collaboration with the Board of Pharmacy and the Department of Health, shall establish 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, 2022, and 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. § 1320d et seq., as amended.

3. That the provisions of subdivisions B 1 and 2 of § 54.1-3303.1 of the Code of Virginia, as amended by this act, shall become effective upon the expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors.

Agenda Item: Revision of Guidance Document 110-44, naloxone protocol, pursuant to legislative changes

Included in your agenda package are:

- Redline of changes to Guidance Document 110-44, reflecting changes contained in SB1415 and SB1424 of the 2023 General Assembly;
- Clean version of proposed amended Guidance Document 110-44;
- SB1415; and
- SB1424.

Action needed:

- Motion to amend Guidance Document 110-44.

Guidance Document: 110-44

Revised: ~~March 30~~, June 13, 2023
Effective: TBD

Virginia Board of Pharmacy

Naloxone Protocols

Virginia Code § 54.1-3408(X) and (Y) authorize certain persons to dispense naloxone 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 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.

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

a. Authorized Dispensers

The following individuals may dispense naloxone 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

~~And the following persons who have completed a training program:~~

- 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 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~~, and~~.
- ~~Employees or other persons acting on behalf of a "public place" which means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.~~
- Any person may "possess and administer naloxone or other opioid antagonist used for overdose reversal, other than in an injectable formulation with a hypodermic needle or syringe."

~~b. Required Training~~

~~i. Those persons listed above who must first complete a training program prior to dispensing naloxone shall complete training in accordance with policies and procedures of their employer or governing entity. Selection of or development of the training program is at the discretion of the employer or~~

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~~governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.~~

~~c.~~**b. Required Order**

i. Prior to dispensing naloxone, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive naloxone or a standing order issued by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense naloxone. 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 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 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, #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 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 minutes until emergency medical assistance arrives.

~~d.~~c. **Required Labeling and Recordkeeping**

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 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 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. Required~~ **Instruction**

i. While not required by law, the dispenser ~~The dispenser shall~~ 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 ~~If the recipient refuses instruction, the~~ 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.

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II. 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.

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. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for 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 emergency medical assistance arrives.	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 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.	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 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. ~~Required~~ Instruction

~~i.~~ While it is not required by law, the dispenser ~~The dispenser shall~~ 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 If the recipient refuses instruction, the~~ 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.

~~ii.~~i. 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 to Entities Authorized to Possess, Administer, and Dispense Naloxone

a. In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone 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;

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

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 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

Naloxone Protocols

Virginia Code § 54.1-3408(X) and (Y) authorize certain persons to dispense naloxone 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 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.

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

a. Authorized Dispensers

The following individuals may dispense naloxone 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 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.
- Any person may "possess and administer naloxone or other opioid antagonist used for overdose reversal, other than in an injectable formulation with a hypodermic needle or syringe."

b. Required Order

i. Prior to dispensing naloxone, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive naloxone or a standing order issued by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense naloxone. 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 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 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, #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 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 minutes until emergency medical assistance arrives.

c. Required Labeling and Recordkeeping

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 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 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, 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.

II. 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.

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. <u>Required Order</u>

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*	<u>Intranasal</u>
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. <u>Call 911.</u> 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. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg or 5mg, #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. <u>Call 911</u>. 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 emergency medical assistance arrives.	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 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.	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 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 to Entities Authorized to Possess, Administer, and Dispense Naloxone

a. In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone 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;

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

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 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

2023 SESSION

VIRGINIA ACTS OF ASSEMBLY -- CHAPTER

An Act to amend and reenact § 54.1-3408 of the Code of Virginia, relating to opioid impact reduction.

[S 1415]

Approved

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3408 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, 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 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:

1. A nurse, physician assistant, or intern under his direction and supervision;

2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;

3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol; or

4. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or standing protocol that shall be issued by the local health director within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by the local health director and trained in the administration of albuterol inhalers and valved holding chambers or nebulized albuterol may possess or administer an albuterol inhaler and a valved holding chamber or

nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § **22.1-319** and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § **22.1-19** as administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of (a) epinephrine may possess and administer epinephrine and (b) albuterol inhalers or nebulized albuterol may possess or administer an albuterol inhaler or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any nurse at an early childhood care and education entity, employee at the entity, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a public institution of higher education or a private institution of higher education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of an organization providing outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health, such prescriber may authorize any employee of a restaurant licensed pursuant to Chapter 3 (§ **35.1-18** et seq.) of Title 35.1 to possess and administer epinephrine on the premises of the restaurant at which the employee is employed, provided that such person is trained in the administration of epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any employee of a public place, as defined in § **15.2-2820**, who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen for use in emergency situations; epinephrine for use in emergency cases of anaphylactic shock; and naloxone or other opioid antagonist for overdose reversal.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § **32.1-50.2**, such prescriber may authorize registered nurses or licensed practical nurses under the supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for

preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § **22.1-1**, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § **22.1-319** licensed by the Board of Education, or (iii) a private school accredited pursuant to § **22.1-19** as administered by the Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a public institution of higher education or a private institution of higher education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administration of glucagon to a student diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § **54.1-2722**, or his remote supervision, as defined in subsection E or F of § **54.1-2722**, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, and any other Schedule VI topical drug approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day-care center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § **63.2-100** and licensed by the Department of Social Services, Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § **22.1-319** and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ **54.1-3041** et seq.) of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § **22.1-289.02** and regulated by the Board of Education or a local government pursuant to § **15.2-914**, or (ii) a student of a private school that is accredited pursuant to § **22.1-19** as administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, licensed practical nurse, nurse practitioner, physician assistant, doctor of medicine or osteopathic medicine, or pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established by the State Health Commissioner pursuant to § **32.1-42.1** when (i) the Governor has declared a disaster or a state of emergency, the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential

public health emergency, or the Board of Health has made an emergency order pursuant to § **32.1-13** for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious, and infectious diseases and other dangers to the public life and health and for the limited purpose of administering vaccines as an approved countermeasure for such communicable, contagious, and infectious diseases; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § **18.2-258.1**. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ **54.1-2729.1** et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, nurse practitioner, or physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ **54.1-2729.1** et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § **32.1-126.4**.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A physician assistant, nurse, dental hygienist, or authorized agent of a doctor of medicine, osteopathic medicine, or dentistry may possess and administer topical fluoride varnish pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry.

W. A prescriber, acting in accordance with guidelines developed pursuant to § **32.1-46.02**, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

X. Notwithstanding the provisions of § **54.1-3303**, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § **32.1-111.1**, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. 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 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, other school board employees or individuals contracted by a school board to provide school health services, and firefighters ~~who have completed a training program~~ may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding the provisions of § **54.1-3303**, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, ~~an employee or other person acting on behalf of a public place who has completed a training program~~ *any person* may ~~also~~ possess and administer naloxone or other opioid antagonist used for overdose reversal, other than naloxone in an injectable formulation with a hypodermic needle or syringe, in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

~~Notwithstanding any other law or regulation to the contrary, an employee or other person acting on behalf of a public place may possess and administer naloxone or other opioid antagonist, other than naloxone in an injectable formulation with a hypodermic needle or syringe, to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose if he has completed a training program on the administration of such naloxone and administers naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.~~

~~For the purposes of this subsection, "public place" means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.~~

Y. Notwithstanding any other law or regulation to the contrary, a person 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 dispense naloxone ~~to a person who has received instruction on the administration of naloxone for opioid overdose reversal~~, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he 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, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

Z. A person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

AA. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § **22.1-1**, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § **22.1-319** licensed by the Board of Education, or (iii) a private school accredited pursuant to § **22.1-19** as administered by the Virginia Council for Private Education who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medication to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be

experiencing or about to experience an adrenal crisis. Such authorization shall be effective only when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

2. That the Department of Health, the Department of Behavioral Health and Developmental Services, and the Department of Corrections shall review existing naloxone distribution programs and collaborate to develop a comprehensive statewide plan for the distribution of naloxone throughout the Commonwealth. The plan shall provide guidance to emergency medical services agencies on the distribution of naloxone in high-risk areas and shall ensure that every pharmacy that carries naloxone is provided with a supply of fentanyl test strips to include with every order of naloxone provided to consumers. The plan shall also provide guidance to localities for the implementation of local naloxone distribution plans. The respective departments are authorized to begin implementation of the plan, to the extent the agencies have existing resources to do so. The Department of Health shall provide a report on the statewide naloxone plan, including the resources needed to fully implement the plan, to the Chairs of the House Committee on Appropriations and the Senate Committee on Finance and Appropriations by September 1, 2023.

3. That the Department of Health shall begin development of a Commonwealth opioid impact reduction registry. The registry shall include a list of nonprofit organizations that work to reduce the impact of opioids in the Commonwealth and shall list the services provided by each such organization and contact information for each such organization to be published on the Department's website. The Department shall develop a process to determine what organizations that work to reduce the impact of opioids in the Commonwealth to include in such registry, and what criteria and metrics should be utilized to determine their inclusion in such registry. The Department shall examine administrative burdens on local governments in procuring the services of nonprofit organizations on the registry in a timely manner. The Department, within existing resources, may publish an initial list of known nonprofit organizations that work to reduce the impact of opioids on the Department's website that is searchable by zip code. The Department shall report on the process, criteria and metrics for the registry, including the verification process to ensure an organization meets the criteria to be listed on the registry, and recommendations on reducing administrative burdens on local governments to contract with organizations on the registry to the Chairs of the House Committee on Appropriations and the Senate Committee on Finance and Appropriations by September 1, 2023.

4. That the Department of Corrections shall amend its regulations to require that training in the administration of naloxone be provided to every inmate prior to release.

CHAPTER 116

An Act to amend and reenact § 54.1-3408 of the Code of Virginia, relating to Department of Corrections; possession and administration of naloxone.

[S 1424]

Approved March 21, 2023

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3408 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, 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 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:

1. A nurse, physician assistant, or intern under his direction and supervision;

2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;

3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol; or

4. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or standing protocol that shall be issued by the local health director within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by the local health director and trained in the administration of albuterol inhalers and valved holding chambers or nebulized albuterol may possess or administer an albuterol inhaler and a valved holding chamber or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of (a) epinephrine may possess and administer epinephrine and (b) albuterol inhalers or nebulized albuterol may possess or administer an albuterol inhaler or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any nurse at an early childhood care and education entity, employee at the entity,

or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a public institution of higher education or a private institution of higher education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of an organization providing outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health, such prescriber may authorize any employee of a restaurant licensed pursuant to Chapter 3 (§ 35.1-18 et seq.) of Title 35.1 to possess and administer epinephrine on the premises of the restaurant at which the employee is employed, provided that such person is trained in the administration of epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any employee of a public place, as defined in § 15.2-2820, who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen for use in emergency situations; epinephrine for use in emergency cases of anaphylactic shock; and naloxone or other opioid antagonist for overdose reversal.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses under the supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his

professional practice, such prescriber may authorize an employee of a public institution of higher education or a private institution of higher education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administration of glucagon to a student diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, or his remote supervision, as defined in subsection E or F of § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, and any other Schedule VI topical drug approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day-care center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services, Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.)

of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 22.1-289.02 and regulated by the Board of Education or a local government pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, licensed practical nurse, nurse practitioner, physician assistant, doctor of medicine or osteopathic medicine, or pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency, the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency, or the Board of Health has made an emergency order pursuant to § 32.1-13 for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious, and infectious diseases and other dangers to the public life and health and for the limited purpose of administering vaccines as an approved countermeasure for such communicable, contagious, and infectious diseases; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, nurse practitioner, or physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not

include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A physician assistant, nurse, dental hygienist, or authorized agent of a doctor of medicine, osteopathic medicine, or dentistry may possess and administer topical fluoride varnish pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. 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, other school board employees or individuals contracted by a school board to provide school health services, and firefighters who have completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, an employee or other person acting on behalf of a public place who has completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal other than naloxone in an injectable formulation with a hypodermic needle or syringe in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding any other law or regulation to the contrary, an employee or other person acting on behalf of a public place may possess and administer naloxone or other opioid antagonist, other than naloxone in an injectable formulation with a hypodermic needle or syringe, to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose if he has completed a training program on the administration of such naloxone and administers naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

For the purposes of this subsection, "public place" means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.

Y. Notwithstanding any other law or regulation to the contrary, a person 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 dispense naloxone to a person who has received instruction on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he 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, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

Z. A person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

AA. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medication to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis. Such authorization shall be effective only when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Agenda Item: Adoption of exempt regulatory changes pursuant to 2023 scheduling actions of the General Assembly

Included in your agenda package are:

- Amendments to 18VAC110-20-322.
- Chapter 188 (HB2364) of the 2023 Acts of Assembly.

Action needed:

- Motion to adopt exempt regulatory changes as presented to remove drugs and chemicals from 18VAC110-20-322 pursuant to Ch. 188 of the 2023 Acts of Assembly effective July 1, 2023.

Project 7581 - Exempt Final

Board of Pharmacy

Implementation of HB2364/SB894 of the 2023 General Assembly regarding Scheduled drugs

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

1. Synthetic opioid. N,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.~~ 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-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.

CHAPTER 188

An Act to amend and reenact § 54.1-3446 of the Code of Virginia, relating to Drug Control Act; Schedule I.

[H 2364]

Approved March 22, 2023

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3446 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3446. Schedule I.

The controlled substances listed in this section are included in Schedule I:

1. Any of the following opiates, including their 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:

1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine);

1-[2-methyl-4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone (other name: 2-methyl AP-237);

1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (other name: PEPAP);

1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238);

1-methyl-4-phenyl-4-propionoxypiperidine (other name: MPPP);

2-(4-ethoxybenzyl)-5-nitro-1-[2-(pyrrolidin-1-yl)ethyl]-1H-benzimidazole (other names: N-pyrrolidino etonitazene, etonitazepyne);

2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene);

2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Methoxyacetyl fentanyl);

3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700);

3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921);

Acetyl fentanyl (other name: desmethyl fentanyl);

Acetylmethadol;

Allylprodine;

Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM);

Alphameprodine;

Alphamethadol;

Benzethidine;

Betacetylmethadol;

Betameprodine;

Betamethadol;

Betaprodine;

Clonitazene;

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambutene;

Dioxaphetylbutyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Furethidine;

Hydroxypethidine;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Morpheridine;

MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine);

N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (other name: Cyclopropyl fentanyl);
N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (other name: Tetrahydrofuranyl fentanyl);
N-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]-N-phenylpropanamide (other name: alpha-methylthiofentanyl);
N-[1-(1-methyl-2-phenylethyl)-4-piperidyl]-N-phenylacetamide (other name: acetyl-alpha-methylfentanyl);
N-{1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl}-N-phenylpropanamide (other name: beta-hydroxythiofentanyl);
N-[1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxyfentanyl);
N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl]propionanilide (other names: 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine, alpha-methylfentanyl);
N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl);
N-(3-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl);
N-[3-methyl-1-(2-hydroxy-2-phenylethyl)4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxy-3-methylfentanyl);
N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide (other name: 3-methylfentanyl);
N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide (other name: 3-methylthiofentanyl);
N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: para-chlorofentanyl, 4-chlorofentanyl);
N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluoroisobutyryl fentanyl);
N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: para-fluorobutyrylfentanyl);
N-(4-fluorophenyl)-N-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluorofentanyl);
N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (other name: Isotonitazene);
N,N-diethyl-2-{[(4-ethoxyphenyl) methyl]-1H-benzimidazol-1-yl}-ethan-1-amine (other names: Etazene, Desnitroetonitazene);
N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene);
N-phenyl-N-[1-(2-phenylmethyl)-4-piperidinyl]-2-furancarboxamide (other name: N-benzyl Furanyl norfentanyl);
N-phenyl-N-(4-piperidinyl)-propanamide (other name: Norfentanyl);
Noracymethadol;
Norlevorphanol;
Normethadone;
Norpipanone;
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl);
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl fentanyl);
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl);
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl);
N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide (other name: thiofentanyl);
Phenadoxone;
Phenampromide;
Phenomorphan;
Phenoperidine;
Piritramide;
Proheptazine;
Properidine;
Propiram;
Racemoramide;
Tilidine;
Trimeperidine;
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-1,3-benzodioxole-5-carboxamide (other name: Benzodioxole fentanyl);
3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide (other name: U-49900);
2-(2,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methyl acetamide (other name: U-48800);
2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methyl acetamide (other name: U-51754);
N-(2-fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Ocfentanil);
N-(4-methoxyphenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name:

4-methoxybutyrylfentanyl);

N-phenyl-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: Isobutyryl fentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-cyclopentanecarboxamide (other name: Cyclopentyl fentanyl);

N-phenyl-N-(1-methyl-4-piperidinyl)-propanamide (other name: N-methyl norfentanyl);

N-[2-(dimethylamino)cyclohexyl]-N-methyl-1,3-benzodioxole-5-carboxamide (other names: 3,4-methylenedioxy U-47700 or 3,4-MDO-U-47700);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl fentanyl);

N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-benzamide (other names: Phenyl fentanyl, Benzoyl fentanyl);

N-[2-(dimethylamino)cyclohexyl]-N-phenylfuran-2-carboxamide (other name: Furanyl UF-17);

N-[2-(dimethylamino)cyclohexyl]-N-phenylpropionamide (other name: UF-17);

3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropyl-benzamide (other name: Isopropyl U-47700).

2. Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;
Acetyldihydrocodeine;
Benzylmorphine;
Codeine methylbromide;
Codeine-N-Oxide;
Cyprenorphine;
Desomorphine;
Dihydromorphine;
Drotebanol;
Etorphine;
Heroin;
Hydromorphinol;
Methyldesorphine;
Methyldihydromorphine;
Morphine methylbromide;
Morphine methylsulfonate;
Morphine-N-Oxide;
Myrophine;
Nicocodeine;
Nicomorphine;
Normorphine;
Pholcodine;
Thebacon.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of 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 (for purposes of this subdivision only, the term "isomer" includes the optical, position, and geometric isomers):

Alpha-ethyltryptamine (some trade or other names: Monase; a-ethyl-1H-indole-3-ethanamine; 3-2-aminobutyl] indole; a-ET; AET);

4-Bromo-2,5-dimethoxyphenethylamine (some trade or other names: 2-4-bromo-2,5-dimethoxyphenyl]-1-aminoethane;alpha-desmethyl DOB; 2C-B; Nexus);

3,4-methylenedioxy amphetamine;
5-methoxy-3,4-methylenedioxy amphetamine;
3,4,5-trimethoxy amphetamine;
Alpha-methyltryptamine (other name: AMT);
Bufotenine;
Diethyltryptamine;
Dimethyltryptamine;
4-methyl-2,5-dimethoxyamphetamine;
2,5-dimethoxy-4-ethylamphetamine (DOET);
4-fluoro-N-ethylamphetamine;
2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C-T-7);
Ibogaine;
5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeO-DIPT);
Lysergic acid diethylamide;

Mescaline;

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo [b,d] pyran; Synhexyl);

Peyote;

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocyn;

Salvinorin A;

Tetrahydrocannabinols, except as present in (i) industrial hemp, as defined in § 3.2-4112, that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent; (ii) a hemp product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law; (iii) marijuana; (iv) dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration; or (v) industrial hemp, as defined in § 3.2-4112, that is possessed by a person who holds a hemp producer license issued by the U.S. Department of Agriculture pursuant to 7 C.F.R. Part 990;

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA);

3,4-methylenedioxymethamphetamine (MDMA), its optical, positional and geometric isomers, salts and salts of isomers;

3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4 (methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA);

N-hydroxy-3,4-methylenedioxyamphetamine (some other names: N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA);

4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA);

4-methoxyamphetamine (some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA);

Ethylamine analog of phencyclidine (some other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE);

Pyrrolidine analog of phencyclidine (some other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP);

Thiophene analog of phencyclidine (some other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP);

1-1-(2-thienyl)cyclohexyl]pyrrolidine (other name: TCPy);

3,4-methylenedioxypyrovalerone (other name: MDPV);

4-methylmethcathinone (other names: mephedrone, 4-MMC);

3,4-methylenedioxymethcathinone (other name: methylone);

Naphthylpyrovalerone (other name: naphyrone);

4-fluoromethcathinone (other names: flephedrone, 4-FMC);

4-methoxymethcathinone (other names: methedrone; bk-PMMA);

Ethcathinone (other name: N-ethylcathinone);

3,4-methylenedioxyethcathinone (other name: ethylone);

Beta-keto-N-methyl-3,4-benzodioxolylbutanamine (other name: butylone);

N,N-dimethylcathinone (other name: metamfepramone);

Alpha-pyrrolidinopropiophenone (other name: alpha-PPP);

4-methoxy-alpha-pyrrolidinopropiophenone (other name: MOPPP);

3,4-methylenedioxy-alpha-pyrrolidinopropiophenone (other name: MDPPP);

Alpha-pyrrolidinovalerophenone (other name: alpha-PVP);

6,7-dihydro-5H-indeno-(5,6-d)-1,3-dioxol-6-amine (other name: MDAI);

3-fluoromethcathinone (other name: 3-FMC);

4-Ethyl-2,5-dimethoxyphenethylamine (other name: 2C-E);

4-Iodo-2,5-dimethoxyphenethylamine (other name: 2C-I);

4-Methylethcathinone (other name: 4-MEC);

4-Ethylmethcathinone (other name: 4-EMC);

N,N-diallyl-5-methoxytryptamine (other name: 5-MeO-DALT);

Beta-keto-methylbenzodioxolylpentanamine (other names: Pentylone, bk-MBDP);

Alpha-methylamino-butyrophenone (other name: Buphedrone);

Alpha-methylamino-valerophenone (other name: Pentedrone);

3,4-Dimethylmethcathinone (other name: 3,4-dmmc);

4-methyl-alpha-pyrrolidinopropiophenone (other name: MPPP);

4-Iodo-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 25-I, 25I-NBOMe, 2C-I-NBOMe);

Methoxetamine (other names: MXE, 3-MeO-2-Oxo-PCE);
4-Fluoromethamphetamine (other name: 4-FMA);
4-Fluoroamphetamine (other name: 4-FA);
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (other name: 2C-D);
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (other name: 2C-C);
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (other name: 2C-T-2);
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (other name: 2C-T-4);
2-(2,5-Dimethoxyphenyl)ethanamine (other name: 2C-H);
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (other name: 2C-N);
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (other name: 2C-P);
(2-aminopropyl)benzofuran (other name: APB);
(2-aminopropyl)-2,3-dihydrobenzofuran (other name: APDB);
4-chloro-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 2C-C-NBOMe, 25C-NBOMe, 25C);
4-bromo-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 2C-B-NBOMe, 25B-NBOMe, 25B);
Acetoxydimethyltryptamine (other names: AcO-Psilocin, AcO-DMT, Psilacetin);
Benocyclidine (other names: BCP, BTCP);
Alpha-pyrrolidinobutiophenone (other name: alpha-PBP);
3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA);
4-bromomethcathinone (other name: 4-BMC);
4-chloromethcathinone (other name: 4-CMC);
4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25I-NBOH);
Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP);
Alpha-Pyrrolidinoheptiophenone (other name: PV8);
5-methoxy-N,N-methylisopropyltryptamine (other name: 5-MeO-MIPT);
Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB);
Beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B);
1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone);
1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP);
1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP);
4-Chloroethcathinone (other name: 4-CEC);
3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone);
1-propionyl lysergic acid diethylamide (other name: 1P-LSD);
(2-Methylaminopropyl)benzofuran (other name: MAPB);
1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone);
1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9);
3,4-tetramethylene-alpha-pyrrolidinovalerophenone (other name: TH-PVP);
4-allyloxy-3,5-dimethoxyphenethylamine (other name: Allylescaline);
4-Bromo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25B-NBOH);
4-chloro-alpha-methylamino-valerophenone (other name: 4-chloropentedrone);
4-chloro-alpha-Pyrrolidinovalerophenone (other name: 4-chloro-alpha-PVP);
4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8);
4-hydroxy-N,N-diisopropyltryptamine (other name: 4-OH-DIPT);
4-methyl-alpha-ethylaminopentiophenone;
4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP);
5-methoxy-N,N-dimethyltryptamine (other name: 5-MeO-DMT);
5-methoxy-N-ethyl-N-isopropyltryptamine (other name: 5-MeO-EIPT);
6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD);
6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD);
(N-methyl aminopropyl)-2,3-dihydrobenzofuran (other name: MAPDB);
2-(methylamino)-2-phenyl-cyclohexanone (other name: Deschloroketamine);
2-(ethylamino)-2-phenyl-cyclohexanone (other name: deschloro-N-ethyl-ketamine);
2-methyl-1-(4-(methylthio)phenyl)-2-morpholinopropiophenone (other name: MMMP);
Alpha-ethylaminohexanophenone (other name: N-ethylhexedrone);
N-ethyl-1-(3-methoxyphenyl)cyclohexylamine (other name: 3-methoxy-PCE);
4-fluoro-alpha-pyrrolidinohexiophenone (other name: 4-fluoro-alpha-PHP);
N-ethyl-1,2-diphenylethylamine (other name: Ephenidine);
2,5-dimethoxy-4-chloroamphetamine (other name: DOC);
3,4-methylenedioxy-N-tert-butylcathinone;
Alpha-pyrrolidinoisohexiophenone (other name: alpha-PiHP);
1-[1-(3-hydroxyphenyl)cyclohexyl]piperidine (other name: 3-hydroxy PCP);
4-acetyloxy-N,N-diallyltryptamine (other name: 4-AcO-DALT);

4-hydroxy-N,N-methylisopropyltryptamine (other name: 4-hydroxy-MiPT);
3,4-Methylenedioxy-alpha-pyrrolidinohexanophenone (other name: MDPHP);
5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT);
1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other names: Eutylone, bk-EBDB);
1-(1,3-benzodioxol-5-yl)-2-(butylamino)-1-pentanone (other name: N-butylpentylone);
N-benzyl-3,4-dimethoxyamphetamine (other name: N-benzyl-3,4-DMA);
1-(benzo[d][1,3]dioxol-5-yl)-2-(sec-butylamino)pentan-1-one (other name: N-sec-butyl Pentylone);
1-cyclopropionyl lysergic acid diethylamide (other name: 1cP-LSD);
2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone);
(2-ethylaminopropyl)benzofuran (other name: EAPB);
4-ethyl-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25E-NBOH);
2-fluoro-Deschloroketamine (other name: 2-(2-fluorophenyl)-2-(methylamino)-cyclohexanone);
4-hydroxy-N-ethyl-N-propyltryptamine (other name: 4-hydroxy-EPT);
2-(isobutylamino)-1-phenylhexan-1-one (other names: N-Isobutyl Hexedrone, alpha-isobutylaminohexanphenone);
1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-Methoxymethamphetamine, PMMA);
N-ethyl-1-(3-hydroxyphenyl)cyclohexylamine (other name: 3-hydroxy-PCE);
N-heptyl-3,4-dimethoxyamphetamine (other name: N-heptyl-3,4-DMA);
N-hexyl-3,4-dimethoxyamphetamine (other name: N-hexyl-3,4-DMA);
4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alpha-PVP);
4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone);
N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4-DMA);
4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DiPT);
Alpha-pyrrolidinocyclohexanophenone (other name: alpha-PCYP);
3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8);
4-chloro-alpha-methylaminobutiophenone (other name: 4-chloro Buphedrone);
1-(1,3-benzodioxol-5-yl)-2-(propylamino)-1-butanone (other names: 3,4-Methylenedioxy-alpha-propylaminobutiophenone; N-propyl butylone);
2-(ethylamino)-1-phenylpentan-1-one (other names: N-ethylpentedrone, alpha-ethylaminopentiophenone);
3,4-methylenedioxy-alpha-cyclohexylaminopropiophenone (other name: Cyputylone);
3,4-methylenedioxy-alpha-cyclohexylmethylaminopropiophenone (other name: 3,4-Methylenedioxy-N,N-cyclohexylmethcathinone);
3,4-methylenedioxy-alpha-isopropylaminobutiophenone (other name: N-isopropyl butylone);
4-chloro-N-butylcathinone (other names: 4-chlorobutylcathinone, para-chloro-N-butylcathinone);
4-hydroxy-N-methyl-N-ethyltryptamine (other names: 4-hydroxy MET, Metocin);
4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline);
Alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV).

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including 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-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam);
7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam);
Bromazolam;
Clonazolam;
Deschloroetizolam;
Etizolam;
Flualprazolam;
Flubromazepam;
Flubromazolam;
Gamma hydroxybutyric acid (some other names include GHB; gamma hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate);
Mecloqualone;
Methaqualone.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:
2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine);
Aminorex (some trade or other names; aminoxaphen; 2-amino-5-phenyl-2-oxazoline; 4,5-dihydro-5-phenyl-2-oxazolamine);
Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone,

2-aminopropiophenone, norephedrone), and any plant material from which Cathinone may be derived;

Cis-4-methylaminorex (other name: cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Ethylamphetamine;

Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate);

Fenethylline;

Methcathinone (some other names: 2-(methylamino)-propiophenone; alpha-(methylamino)-propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR 1432);

N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine);

N,N-dimethylamphetamine (other names: N,N-alpha-trimethyl-benzeneethanamine, N,N-alpha-trimethylphenethylamine);

Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (other name: 4-fluoromethylphenidate);

Isopropyl-2-phenyl-2-(2-piperidinyl)acetate (other name: Isopropylphenidate);

4-chloro-N,N-dimethylcathinone;

3,4-methylenedioxy-N-benzylcathinone (other name: BMDP)*;*

4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA).

6. Any substance that contains one or more cannabimimetic agents or that contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of one or more cannabimimetic agents.

a. "Cannabimimetic agents" includes any substance that is within any of the following structural classes:

2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent;

3-(1-naphthoyl)indole or 1H-indol-3-yl-(1-naphthyl)methane with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent;

3-(1-naphthoyl)pyrrole with substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent;

1-(1-naphthylmethyl)indene with substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent;

3-phenylacetylindole or 3-benzoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent;

3-cyclopropoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the cyclopropyl ring to any extent;

3-adamantoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the adamantyl ring to any extent;

N-(adamantyl)-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the adamantyl ring to any extent; and

N-(adamantyl)-indazole-3-carboxamide with substitution at a nitrogen atom of the indazole ring, whether or not further substituted on the indazole ring to any extent, whether or not substituted on the adamantyl ring to any extent.

b. The term "cannabimimetic agents" includes:

5-(1,1-Dimethylheptyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497);

5-(1,1-Dimethylhexyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C6 homolog);

5-(1,1-Dimethyloctyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C8 homolog);

5-(1,1-Dimethylnonyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C9 homolog);

1-pentyl-3-(1-naphthoyl)indole (other names: JWH-018, AM-678);

1-butyl-3-(1-naphthoyl)indole (other name: JWH-073);

1-pentyl-3-(2-methoxyphenylacetyl)indole (other name: JWH-250);

1-hexyl-3-(naphthalen-1-oyl)indole (other name: JWH-019);

1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (other name: JWH-200);

(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (other name: HU-210);

1-pentyl-3-(4-methoxy-1-naphthoyl)indole (other name: JWH-081);

1-pentyl-3-(4-methyl-1-naphthoyl)indole (other name: JWH-122);

1-pentyl-3-(2-chlorophenylacetyl)indole (other name: JWH-203);

1-pentyl-3-(4-ethyl-1-naphthoyl)indole (other name: JWH-210);
1-pentyl-3-(4-chloro-1-naphthoyl)indole (other name: JWH-398);
1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (other name: AM-694);
1-((N-methylpiperidin-2-yl)methyl)-3-(1-naphthoyl)indole (other name: AM-1220);
1-(5-fluoropentyl)-3-(1-naphthoyl)indole (other name: AM-2201);
1-[(N-methylpiperidin-2-yl)methyl]-3-(2-iodobenzoyl)indole (other name: AM-2233);
Pravadoline (4-methoxyphenyl)-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-yl]methanone (other name: WIN 48,098);
1-pentyl-3-(4-methoxybenzoyl)indole (other names: RCS-4, SR-19);
1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole (other names: RCS-8, SR-18);
1-pentyl-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: UR-144);
1-(5-fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other names: XLR-11, 5-fluoro-UR-144);
N-adamantyl-1-fluoropentylindole-3-carboxamide (other name: STS-135);
N-adamantyl-1-pentylindazole-3-carboxamide (other names: AKB48, APINACA);
1-pentyl-3-(1-adamantoyl)indole (other name: AB-001);
(8-quinolinyl)(1-pentylindol-3-yl)carboxylate (other name: PB-22);
(8-quinolinyl)(1-(5-fluoropentyl)indol-3-yl)carboxylate (other name: 5-fluoro-PB-22);
(8-quinolinyl)(1-cyclohexylmethyl-indol-3-yl)carboxylate (other name: BB-22);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide (other name: AB-PINACA);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide (other name: AB-FUBINACA);
1-(5-fluoropentyl)-3-(1-naphthoyl)indazole (other name: THJ-2201);
N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide (other name: ADB-PINACA);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AB-PINACA);
N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA);
Methyl-2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (other name: 5-fluoro-AMB);
1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201);
1-(4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144);
1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl)indole (other name MAM-2201);
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA);
Methyl 2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA);
Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB, 5-Fluoro-MDMB-PINACA);
Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other names: AMB-FUBINACA, FUB-AMB);
N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other names: FUB-AKB48, 5F-APINACA);
N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48);
N-(adamantanyl)-1-(5-chloropentyl) indazole-3-carboxamide (other name: 5-chloro-AKB48);
Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide (other name: AB-CHMICA);
1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006);
Quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22);
Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (other name: MMB-CHMICA);
N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-ADB-PINACA);
1-(4-cyanobutyl)-N-(1-methyl-1-phenylethyl)-1H-indazole-3-carboxamide (other name: 4-cyano CUMYL-BUTINACA);
Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro MDMB-PICA, 5F-MDMB-PICA);
Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other name: EMB-FUBINACA);
Methyl 2-[1-4-fluorobutyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTINACA);

1-(5-fluoropentyl)-N-(1-methyl-1-phenylethyl)-1H-indole-3-carboxamide (other name: 5-fluoro CUMYL-PICA);

Methyl 2-[1-(pent-4-enyl)-1H-indazole-3-carboxamindo]-3,3-dimethylbutanoate (other name: MDMB-4en-PINACA);

Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indole-3-carbonyl}amino)-3-methylbutanoate (other names: MMB-FUBICA, AMB-FUBICA);

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

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

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

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butylindazole-3-carboxamide (other name: ADB-BUTINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)indazole-3-carboxamide (other name: 5-chloro-AB-PINACA);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (other names: 5F-CUMYL-PINACA, 5-fluoro CUMYL-PINACA, CUMYL-5F-PINACA);

Ethyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5F-EDMB-PINACA, 5-fluoro EDMB-PINACA);

Ethyl-2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3-methylbutanoate (other names: 5-fluoro-EMB-PINACA, 5F-AEB);

Ethyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5-fluoro-EMB-PICA);

Ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-PICA);

Methyl 2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTICA);

Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other names: MDMB-CHMICA, MMB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-enyl)indazole-3-carboxamide (other name: ADB-4en-PINACA)*;*

Ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA);

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).

2. That the provisions of this act may result in a net increase in periods of imprisonment or commitment. Pursuant to § 30-19.1:4 of the Code of Virginia, the estimated amount of the necessary appropriation is $0 for periods of imprisonment in state adult correctional facilities and cannot be determined for periods of commitment to the custody of the Department of Juvenile Justice.

Agenda Item: Adoption of fast-track regulatory action to amend 18VAC110-20-735

Included in your agenda package is:

- A draft amendment to 18VAC110-20-735, clarifying that the requirements in (A) apply only to individuals dispensing injectable formulations of naloxone under Virginia Code § 54.1-3408(Y).

Action needed:

- Motion to adopt proposed amendment to 18VAC110-20-735 as a fast-track regulatory action.

Project 7589 - Fast-Track

Board of Pharmacy

Amendment to clarify application of 18VAC110-20-735

18VAC110-20-735. Requirements for dispensing of naloxone by trained individuals.

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone in an injectable formulation with a hypodermic needle or syringe and dispense the naloxone for opioid overdose reversal pursuant to subsection Y of § 54.1-3408 of the Code of Virginia shall maintain the following records:

1. The prescriber's standing order issued in accordance with subsection Y of § 54.1-3408 of the Code of Virginia authorizing the trained individual to dispense naloxone.

2. Invoices or other records showing receipts of naloxone shall be maintained but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible image of the document or in secured storage either on site or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services.

4. Record of dispensing indicating the name of the person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

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

C. The naloxone shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect it from adulteration.

D. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate shall ensure compliance with recall procedures as issued by the manufacturer, U.S. Food and Drug Administration, or board to ensure an affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

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

Virginia Board of Pharmacy
June 13, 2023
Licenses Issued

	11/1/21 - 1/31/22	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	License Count 5/1/2023
Business CSR	28	35	30	32	25	26	1,453
CE Courses	0	1	0	0	0	0	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	7
Medical Equipment Supplier	0	0	4	3	3	6	224
Non-restricted Manufacturer	2	0	2	1	1	1	35
Outsourcing Facility	0	0	0	0	1	0	1
Permitted Physician	0	1	0	0	0	0	0
Pharmacist	157	187	265	252	164	144	16,191
Pharmacist Volunteer Registration	0	1	0	2	1	0	0
Pharmacy	16	9	11	10	11	11	1,760
Pharmacy Intern	87	88	56	96	179	91	1,209
Pharmacy Technician	360	360	531	430	311	339	12,622
Pharmacy Technician Trainee	1385	1042	777	1,226	1,185	789	8,225
Physician Selling Controlled Substances	14	17	33	27	43	16	560
Limited Use Practitioner Dispensing	0	0	1	1	0	0	3
Physician Selling Drugs Location	4	2	6	2	3	3	125
Pilot Programs	0	2	1	1	0	0	13
Registered Practitioner For Medical Cannabis	81	106	56	147	84	89	1,012
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	0	0	0	0	0	32
Third Party Logistics Provider	0	1	1	0	0	0	6
Warehouser	1	1	1	0	2	3	125
Limited Use Facility Dispensing	0	0	0	0	2	1	3
Wholesale Distributor	0	0	0	0	0	0	60
Total	**2,135**	**1,853**	**1,775**	**2,230**	**2,015**	**1,519**	**43,677**

Virginia Board of Pharmacy
June 13, 2023
Nonresident Licenses Issued

	11/1/21 - 1/31/22	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	License Count 5/22/2023
Nonresident Manufacturer	1	12	4	6	6	9	226
Nonresident Medical Equipment Supplier	5	5	7	11	4	11	354
Nonresident Outsourcing Facility	1	0	2	2	1	1	34
Nonresident Pharmacy	22	25	27	18	21	23	926
Nonresident Third Party Logistics Provider	7	1	8	11	10	15	216
Nonresident Warehouser	5	6	0	8	7	7	113
Nonresident Wholesale Distributor	14	6	7	9	2	11	618
Total	**55**	**55**	**55**	**65**	**51**	**77**	**2,487**

Pharmaceutical Processors Report-June 13, 2023

- Two additional cannabis dispensing facility haves been permitted during the last quarter, for a total of 15 cannabis dispensing facilities.
- The Virginia Court of Appeals ruled in favor of the Board of Pharmacy on the PharmaCann appeal.
- The RFA for a pharmaceutical processor permit in Health Service Area I that was posted from September 25, 2020 to December 4, 2020 resulted in 26 applications being received. Currently the BOP is reviewing next steps for addressing those applications.
- 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 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 June.
- 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 5/30/2023

Registered Practitioners	1,021
Registered Patients	20,393
Registered Parents/Guardians	89
Registered Agents	139
Registered Cannabis Oil Products (cumulative)	3,009

Discipline Program Report

Open Cases as of 5/17/23:

	PC	APD	Investigation	FH	IFC	Other	OAG	Pending Closure	Entry	TOTALS
Patient Care Cases	73	11	86	3	9	1	0	0	5	188
Non-Patient Care Cases	146	9	54	2	10	1	0	11	3	236
						TOTAL:				**424**

- The Board has two cases currently being appealed in circuit court (Category: Other).
- Total caseload remaining high.
- In the process of creating another discipline position to assist with the increasing caseload and electronic case management.

Upcoming Disciplinary Proceedings:

June 15, 2023	P. Richards-Spruill/Yuan	Informal Conferences
July 13, 2023	Ratliff/Lee	Informal Conferences
July 17, 2023	Garvin/Nash	Informal Conferences
July 26, 2023	Full Board	Formal Hearings
August 1, 2023	St.Clair/Garvin	Innovative Pilot
August 15, 2023	TBD	Informal Conferences
August 23, 2023	Full Board	Formal Hearings
September 5, 2023	Full Board	Full Board Meeting/Formal Hearing

Executive Director's Report – June 13, 2023

Meetings Recently Attended:

- VSHP Spring Seminar - presentation
- Right Help, Right Now Subgroup Meeting
- Forensic Science Board Meeting
- DOLI Pharmacy Technician Training/CTE Meeting
- DHP Executive Director Meeting
- NABP .Pharmacy Executive Board Meeting
- NABP EC Meeting and Annual Meeting
- Pulse by NABP meetings
- VCU School of Pharmacy Portrait Unveiling of Dean DiPiro
- SAMHSA Region 3 Meetings regarding Buprenorphine Access
- Virginia Cannabis Control Authority Meeting – co-presenter

Upcoming Meetings:

- 6/7/23 – Meeting to discuss role of community pharmacies to accelerate the country's progress toward ending the U.S. HIV epidemic. Hosted by White House Office of National AIDS Policy, U.S. Business Action to End HIV and the Elton John AIDS Foundation to be held at APhA.
- 6/20-6/21 - *Implementing Solutions: Building a Sustainable, Healthy Pharmacy Workforce and Workplace*, hosted by APhA, ASHP, and NABP.
- 7/25 - VTC School of Medicine – cannabis presentation
- 8/11 – Tentative Statewide Protocol Workgroup Meeting
- 9/5 – September Full Board Meeting
- 9/20-9/22 – NABP/AACP Districts 1 & 2 Meeting, New Jersey
- 9/26 – Tentative Work Group for Translated Directions for Use of Prescriptions