COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Tentative Agenda of Public Hearing and Full Board Meeting
December 10, 2020 Meeting
9AM

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

- Adoption of Exempt Regulation - Scheduling Change for Consistency with DEA **65-68**
- Consideration of Amendments to Incorporate Changes Currently in Approved Pilots – Medication Carousels and RFID Technology **69-74**
- Amendments to Guidance Documents **75-98**
- Adoption of a Notice of Periodic Review **99**

Reports:

- Chairman's Report – Kris Ratliff
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – Beth O'Halloran **100**
- Report on Inspection Program – Sammy Johnson **101-111**
- Report on Pharmaceutical Processors – Annette Kelley **112**
- Report on Disciplinary Program – Ellen B. Shinaberry **113**
- Executive Director's Report – Caroline D. Juran **114-133**

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

Instructions for Accessing December 10, 2020 Virtual Public Hearings/Full Board Meeting and Providing Public Comment

- **Access:** Perimeter Center building access remains restricted to the public due to the COVID-19 pandemic. To observe this virtual meeting, use one of the options below. Disregard any reference to the Board of Dentistry as a shared subscription to WebEx is being utilized. Participation capacity is limited and is on a first come, first serve basis due to the capacity of CISCO WebEx technology.
- **Public comment:** Comments will be received during the public hearings and during the full board meeting from those persons who have submitted an email to caroline.juran@dhp.virginia.gov **no later than 8am on December 10, 2020** indicating that they wish to offer comment. Be sure to specify if the comment is associated with a specific public hearing or the full board meeting. Comment may be offered by these individuals when their names are announced by the chairman.
- Public participation connections will be muted following the public comment periods.
- Should the Board enter into a closed session, public participants will be blocked from seeing and hearing the discussion. When the Board re-enters into open session, public participation connections to see and hear the discussions will be restored.
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- FOIA Council *Electronic Meetings Public Comment* form for submitting feedback on this electronic meeting may be accessed at http://foiacouncil.dls.virginia.gov/sample%20letters/welcome.htm

MEETING LINK

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AUDIO ONLY

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Meeting number (access code): 132 397 2833

Meeting password: 44357579

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, September 8, 2020
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:03 am.
PRESIDING:	Glenn Bolyard, Committee Chair
MEMBERS PRESENT:	Cheryl H. Nelson, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Jessica Kelley, DHP Adjudication Specialist Claire Foley, DHP Adjudication Specialist
HANNAH LEE MENDEZ Registration No. 0230-033133	Hannah Lee Mendez, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the July 23, 2020, Notice.
Closed Meeting:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, 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 Hannah Lee Mendez. 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 Ms. Nelson, and duly seconded by Mr. Bolyard, the Committee unanimously voted to refer the matter for a formal administrative hearing and offer Ms. Mendez a consent order for the revocation of the right to renew her registration.
MYCKIEALA C. COOPER License No. 0202-209657	Myckieala C. Cooper, pharmacist, appeared to discuss allegations that she may have violated certain terms and conditions of an Order of the Board of Pharmacy entered November 6, 2018 as stated in the July 23, 2020, Notice.
Closed Meeting:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, 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 Myckieala C. Cooper. 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 Ms. Nelson, and duly seconded by Mr. Bolyard, the Committee unanimously voted to extend the minimum duration of Ms. Cooper's probation by six months.
WALGREENS #18196 d/b/a/RITE AID #11239 Permit No. 0201-001911	No representatives appeared to discuss allegations that Rite Aid #11239 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the July 23, 2020 Notice.
Closed Meeting:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, 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 Rite

Aid #11239. 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 Ms. Nelson and duly seconded by Mr. Bolyard, the Committee voted unanimously to assess a monetary penalty against Rite Aid #11239.

WE CARE PHARMACY
Permit No. 0201-004566

Xuan K. Huynh, Pharmacist-in-Charge of We Care Pharmacy and Jennifer L. Bruckart, Director of Operations/Compliance for We Care Pharmacy, appeared to discuss allegations that We Care Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the July 23, 2020 Notice.

Closed Meeting:

Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, 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 We Care Pharmacy. 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 Ms. Nelson and duly seconded by Mr. Bolyard, the Committee voted unanimously

to place a condition on We Care Pharmacy's ability to resume sterile compounding and to assess a monetary penalty.

AVIANCE S. LEWIS
License No. 0202-207854

Aviance S. Lewis, pharmacist did not appear to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the July 23, 2020, Notice.

Closed Meeting:

Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, 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 Aviance S. Lewis. 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 Ms. Nelson, and duly seconded by Mr. Bolyard, the Committee unanimously voted to Reprimand Ms. Lewis, assess a monetary penalty and order her to take five additional hours of continuing education.

ADJOURNED:

3:04 pm

Glen Bolyard, Chair

Ellen B. Shinaberry
Deputy Executive Director

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

September 9, 2020
In-Person/Virtual Meeting

Department of Health Professions
Perimeter Center
9960 Mayland Drive
2nd Floor, Board Room 4
Henrico, Virginia 23233

CALL TO ORDER: An in-person meeting of the Board of Pharmacy was called to order at 9:27 AM. Public access to the meeting was offered on-site and via WebEx.

PRESIDING: Kristopher Ratliff, Chairman

MEMBERS PRESENT:
James L. Jenkins, Jr.
Glen Bolyard
Melvin L. Boone, Sr.
Ryan Logan
Cheryl H. Nelson
Patricia Richards-Spruill
Sarah Melton
Dale St.Clair
William Lee

STAFF PRESENT:
Caroline D. Juran, Executive Director
David E. Brown, D.C., Director, DHP (left at approx. 11am)
James Rutkowski, Assistant Attorney General
Elaine Yeatts, Senior Policy Analyst, DHP
Annette Kelley, Deputy Executive Director
Ellen Shinaberry, Deputy Executive Director (arrived at approx. noon)
Kiara Christian, Executive Assistant

PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:
Cynthia Warriner
Patricia Richards-Spruill
Natalie Nguyen
Michael Johnson
Monet Stanford

QUORUM: With ten members participating, a quorum was established.

APPROVAL OF AGENDA: Mr. Ratliff reported that staff recommended additions to the tentative agenda previously provided.

MOTION:

The agenda was unanimously approved as amended as described below:

- **Insert Adoption of emergency regulation for reporting pediatric immunizations to the Virginia Immunization Information System. (motion by Nelson, seconded by Jenkins)**

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

Ms. Juran offered that the August 17 Workgroup Meeting draft minutes should be amended to include Mr. William Lee's participation as a non-voting member under members present at the meeting.

MOTION:

The Board voted unanimously to adopt the minutes for the August 17, 2020 State Protocol workgroup meeting as amended by inserting that William Lee participated as a non-voting member, and adopted the minutes for the other meetings held between June 16, 2020 and August 18, 2020 as presented. (motion by Jenkins, seconded by Logan)

PUBLIC COMMENTS:

Mr. Ratliff stated as indicated in the meeting notice on Regulatory Townhall and in the agenda package that comments would be received during this public comment period via WebEx from those persons who submitted an email to Caroline Juran no later than 8am on September 9, 2020 indicating that they wish to offer comment. Mr. Ratliff also noted that the Board would receive comment from those persons who indicated they wished to provide comment in-person via the public sign in sheet. Mr. Ratliff noted that the board would not receive comment regarding the petition for rulemaking for pharmaceutical processors as the comment period closed on August 25, 2020.

Dylan Bishop, CannaBizVA, offer comment representing parties on industrial hemp and those that are looking to expand the pharmaceutical processor market with business opportunities in Richmond, VA. Mr. Bishop shared support of the adoption of emergency regulations governing pharmaceutical processors and expanding access by allowing additional dispensary locations and allowing treatment through temporary residence. He asked that there be some additional consideration of the regulation proposing that pharmaceutical processors only have 5% ownership in the requirement. Mr. Bishop offered comment on the adoption of fast-track regulations for use of industrial hemp extract and urged the board to offer some additional specification and consider allowing hemp that may exceed 0.3% to be transferred to the pharmaceutical processors, in lieu of destruction.

Christina Barrille, Executive Director of the Virginia Pharmacists Association (VPhA), welcomed Dr. Melton and Dr. St.Clair to the board. Ms. Barrille asked that the agenda packets be sent earlier to allow time for VPhA to

provide valuable feedback. She asked that the new board members refer to comment submitted by VPhA included in the agenda packet. Dr. Kelly Goode, also representing VPhA, asked the board to remember that pharmacist can use professional judgment and standards of care, encouraged the board to align the protocols with legislation. She also asked the Board to consider mirroring the Naloxone protocol with the Commissioner's protocol to avoid confusion and to include naltrexone as the "other antagonist" in the protocol, similar to Kentucky. For the Hormonal Contraceptive protocol, Dr. Goode recommended that the board consider the algorithm that could restrict access to care, and review the questionnaire for patient readability. Dr. Goode noted that VPhA hoped the board would consider making the notification of the patient's OB/GYN optional. She requested that the board ask the General Assembly to remove the age restrictions on the fluoride protocol. Lastly, Ms. Goode asked the board to consider including devices into the over-the-counter protocol, and asked the board to review the protocols for typos and consistent language.

Mike Ayotte, representing the National Association of Chain Drug Stores, thanked the board for their work on the development of state protocols. He thanked the board for their insertion of the Hormonal Contraceptive regulation that allows the pharmacy to use an electronic form in the pharmacy for patient intake. He asked that the board consider using "additional epinephrine formulations approved by the FDA for anaphylaxis". Mr. Ayotte also urged the board to ensure that all methods of training are approved and authorized in the emergency contraception protocol, and remove the one-hour ACPE-accredited training requirement.

Jodi Roth, Virginia Association of Chain Drug Stores, offered comment in alignment with VPhA and the National Association of Chain Drug Stores.

Jenn Michelle Pedini, Virginia NORML, thanked the board for their work to bring safe access to medical marijuana to Virginians. She offered comment related in support of the proposed pesticide use allowances from the state of Oregon, and for the board to adopt a reasonable resolution to the current pesticide testing issues so the products can be tested prior to being dispensed to patients.

Lisa Davis, Cardinal Testing Labs, offered that the board should narrow the current pesticide testing requirements as it may create issues in Virginia. She also asked that the board consider that laboratory personnel be included in the criminal liability exemptions. Dr. Davis asked that tamper-evident seals be required in the packaging.

Mark Hickman, representing the Virginia Society of Health-Systems Pharmacists (VSHP), welcomed Dr. Melton and Dr. St.Clair to the board. He asked that any submitted letters or changes to the pharmacy agenda be made

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available to the public participating via WebEx as well. He offered VSHP's support of the draft regulations for pharmacy technician educational standards. Mr. Hickman shared VSHP's concerns regarding the labeling of prescriptions and supported comments provided by VPhA on this topic. Mr. Hickman asked that the board consider moving forward with providing guidance on the state protocols after adoption. Lastly, Mr. Hickam offered VSHP's support of the drug disposal workgroup's recommendations.

Lisa Smith, parent of a child with intractable epilepsy, shared her positive experience with visiting one of the pharmaceutical processors. She stated families have been waiting for product for 5 years. She also asked that the board consider the comments provided by Lisa Davis regarding pesticide testing.

Michelle Peace, researcher at VCU, offered that it would be important to add tamper-evident packaging as a requirement for added patient safety. She also added that it would be beneficial to narrow the list of pesticide testing to limit the burden of unnecessary testing and to consider Oregon's list of pesticides. Dr. Peace asked that courier and laboratory employees be listed as exempt from criminal liability.

Katie Hellebush, Executive Director of the Virginia Medical Cannabis Coalition (VMCC), shared that the VMCC appreciated the board's help in providing a process for pharmaceutical processors to provide testing of their products. She asked that the board use the Oregon list as a guide in developing a list of approved pesticides. The VMCC supports an expiration date not more than 6 months, and recommends that the board adopt the Oregon list of pesticides and associated thresholds for product testing purposes. VMCC supports the proposed temperature and humidity changes. VMCC asked that the board consider adopting changes to visitor authorization as set forth in the VMCC petition for rulemaking. She asked that the board consider allowing non-pharmacist to witness green waste destruction.

Joy Strand, Executive Vice-President, GreenLeaf Medical, encouraged the board to consider the comments provided by Lisa Smith, and offered that the board and pharmaceutical processors work together in drafting regulations. She asked that the board consider removing the requirement to have a pharmacist witness the destruction of green waste. She stated green waste destruction can occur 2-3 times daily and will occur under camera surveillance. She is not aware of diversion. She requested amendments to the visitor approval process.

Ashley Allen, representing Dharma Pharmaceuticals, shared that they have products ready to go once testing has been completed. She offered that they are in support of recognizing the Oregon listing of pesticides for processor

use and also support the draft information given on the expiration date of cannabis products. Ms. Allen offered support of the comments provided by Joy Strand, and asked that changes made regarding visitors also be made for the dispensing facilities. She asked that the board consider keeping the language 'other areas" in regulation for non-pharmacists to access as identified in the code. She stated pharmacists are not needed in the extraction or production area as no special training is required.

Mark Gignac, Executive Director for the Institute of Advanced Learning and Research, recommended that the board adopt the Oregon list for pesticide testing. He stated the adoption of three broad categories for pesticide testing can create ambiguity as there is no definitive list.

Cynthia Warriner, representing Appalachian College of Pharmacy, thanked the protocol workgroup for its expertise with the development of the statewide protocols which will increase access to care. She then offered personal comments requesting the board to consider a liberal approach when developing the out-of-pocket cost protocol. She offered concern for the proposed regulations allowing pharmaceutical processors to purchase hemp extract from the hemp industry.

Hunter Jamerson, representing Dalitso, provided an overview of his written comment to the board regarding the proposed pharmaceutical processor regulations. He requested that stability testing not be required if expiration date does not exceed 6 months.

DHP DIRECTOR'S REPORT:

Dr. Brown extended his congratulations to the board's two new board members, Dr. Melton and Dr. St.Clair. He also thanked the board for their quick response to recent concerns with pesticide testing requirements.

LEGISLATIVE/
REGULATORY/ GUIDANCE

Report on Regulatory Action:

Ms. Yeatts reviewed the chart of regulatory action found on page 46. She pointed out the increase in fees action noting that it will become effective on October 14, 2020. She reviewed the action on page 47 related to the emergency action prohibiting products for vaping inhalation with Vitamin E acetate that became effective August 6, 2020. Lastly, she noted that the exempt pharmaceutical processor regulations conforming to legislation and adopted at the June meeting would become effective September 30, 2020.

Mr. Ratliff asked if there was any update to the prohibition against incentives to transfer action. Ms. Yeatts confirmed that there is no updated information at this time.

ADOPTION OF

EMERGENCY REGULATIONS REGARDING:

LIMITED USE LICENSE AND PERMIT FOR NON-PROFIT FACILITIES

Mr. Rutkowski advised that the term "non-profit" is defined in the Virginia tax Code and that those entities satisfying the definition would be recognized by the Board as a non-profit. There was discussion about whether a guidance document should be created to clarify to licensees that the term "non-profit" was being defined by the tax Code.

MOTION/ACTION ITEM:

The board voted unanimously to adopt the emergency regulations for limited-use license and permit for non-profit facilities as presented, to adopt a Notice of Intended Regulatory Action for replacement regulations, and to direct staff to work with counsel to develop a guidance document clarifying the term "non-profit" is as defined in the tax Code. (motion by Nelson, seconded by Richards-Spruill)

PHARMACEUTICAL PROCESSORS - *Cannabis dispensing facilities, temporary residency, controlled substance registrations for laboratories*

There was some discussion regarding the requirement of a criminal background check, and if clarification should be provided in a guidance document. Ms. Kelley confirmed that they 5% ownership requirement was in regulations for the pharmaceutical processors and dispensing facilities. The board had some discussion about 18VAC110-60-200, *Responsibilities of the PIC* regarding whether it would be beneficial to clarify that the dispensing sites must be in the same health service area. The board also discussed if it would be reasonable to allow non-pharmacists to access keys, codes, safes, approved vaults, or any other approved equipment pursuant to 18VAC110-60-240, *Security Requirements.*

MOTION:

The board voted unanimously to amend 18VAC110-60-200 by clarifying that the two dispensing facilities a pharmacist-in-charge may oversee must be located within the same health service area, to adopt the emergency regulations for pharmaceutical processor regulations regarding cannabis dispensing facilities, temporary residency, and controlled substance registration for laboratories as amended, and to adopt a Notice of Intended Regulatory Action for replacement regulations. (motion by Nelson, seconded by Boone)

STATEWIDE PROTOCOL FOR PHARMACIST TO INITIATE TREATMENT

Ms. Yeatts provided an overview of the proposed emergency regulations regarding statewide protocols for pharmacists to initiate certain treatment. The board determined it would be appropriate to require notification of a patient's OB/GYN in addition to the primary care provider as recommended by the protocol workgroup.

MOTION:

The board voted unanimously to adopt the emergency regulations for statewide protocols for pharmacists to initiate certain treatment as presented and to adopt a Notice of Intended Regulatory Action for

replacement regulations. (motion by Logan, seconded by Nelson)

PHARMACY TECHNICIAN EDUCATIONAL STANDARDS

Ms. Yeatts reviewed HB1304 and the proposed emergency regulations. There was discussion regarding duplicative language in 18VAC110-21-135.

MOTION:

The board voted unanimously to amend 18VAC110-21-135(B) by replacing "participating" with "progressing toward completion" and deleting subsection D, to adopt the emergency regulations as amended, and to adopt a Notice of Intended Regulatory Action for replacement regulations. (motion by Jenkins, seconded by Lee)

ADOPTION OF FINAL REGULATIONS PLACING CHEMICALS INTO SCHEDULE I

Ms. Yeatts reviewed the exempt action to recommend the 13 drugs be placed into Schedule I.

MOTION:

The board voted unanimously to adopt the final regulation amending 18VAC110-20-322 as presented which places the following chemicals into Schedule I:

- **N-phenyl-N-(4-piperidinyl)-propanamide (other name: Norfentanyl)**
- **2.N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (other name: Isotonitazene)**
- **(2-ethylaminopropyl)benzofuran (other name: EAPB)**
- **2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone)**
- **4-ethyl-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25ENBOH)**
- **4-hydroxy-N-ethyl-N-propyltryptamine (other name: 4-hydroxy-EPT)**
- **N-ethyl-1-(3-hydroxyphenyl)cyclohexylamine**
- **1-cyclopropionyl lysergic acid diethylamide (other name: 1cP-LSD)**
- **1-(4-methoxyphenyl)-N-methylpropan-2-amine**
- **methyl2-[1-(pent-4-enyl)-1H-indazole-3-carboxamindo]-3,3-dimethylbutanoate (other name: MDMB-4en-PINACA**
- **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butylindazole-3-carboxamide (other name: ADBBUTINACA)**
- **N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)indazole-3-carboxamide (other name: 5-chloro-AB-PINACA)**
- **(other names: MMB-FUBICA, AMB-FUBICA)**

(motion Jenkins, seconded by Richards-Spruill)

ADOPTION OF FINAL REGULATIONS FOR LABELING OF DISPENSED PRESCRIPTIONS

Ms. Yeatts reminded the board of the extension of the comment period due to the cancellation of the March public hearing. There was some discussion by the board on what identifiers should be placed on the label to identify pharmacies involved in the dispensing process.

MOTION:

The board voted 4:6 to adopt the final regulation as presented. (motion by Nelson, seconded by Bolyard; opposed by Logan, Lee, Melton, St.Clair, Jenkins, and Ratliff)

The board voted 6:3 to withdraw the regulatory action. (motion by Jenkins, seconded by Melton; opposed by Nelson, Richards-Spruill, Bolyard; Boone abstained)

ADOPTION OF EXEMPT REGULATION REGARDING COLLABORATIVE PRACTIVE AGREEMENTS

Ms. Yeatts provided a review of the draft amendments to 18VAC110-40-20.

MOTION:

The board voted unanimously to adopt the exempt regulatory amendments of 18VAC110-40-20 as presented. (motion by Nelson, seconded by Richards-Spruill)

ADOPTION OF FAST-TRACK REGULATION FOR USE OF INDUSTRIAL HEMP BY PHARMACEUTICAL PROCESSORS

Ms. Yeatts reviewed the draft language suggested for 18VAC110-60-280, Cultivation and production of cannabidiol oil or THC-A oil on page 166 of the agenda packet. Counsel confirmed that hemp exceeding 0.3% THC cannot legally be acquired by a pharmaceutical processor.

MOTION:

The board voted unanimously to adopt the fast-track regulation amending 18VAC110-60- 280 as presented. (motion by Nelson, seconded by Boone)

PETITION FOR RULE-MAKING REGARDING PHARMACEUTICAL PROCESSORS

Ms. Yeatts reminded the board that the petition came from the Virginia Medical Cannabis Coalition asking for amendments to 8 regulations, and offered the options for board action on this topic.

MOTION:

The board voted unanimously to publish a Notice of Intended Regulatory Action and refer the item to the Regulation Committee for further consideration. (motion by Logan, seconded by Jenkins)

REPORTING PEDIATRIC IMMUNIZATIONS TO THE VIRGINIA IMMUNIZATION INFORMATION SYSTEM

Ms. Juran offered that the HHS allowance preempts state law during the COVID-19 public health emergency and therefore, pharmacists may move forward and administer the pediatric immunizations in accordance with the HHS allowance. She added that VDH asked to have these immunizations reported to the Virginia Immunization Information System. A handout of draft emergency regulation 18VAC110-20-271 was provided to the board.

MOTION:

The board voted unanimously to adopt the emergency regulation for 18VAC110-20-271 as presented. (motion by Richards-Spruill, seconded by Boone)

ADOPTION OF FAQS REGARDING USE OF PESTICIDES BY PHARMACEUTICAL PROCESSORS, TESTING REQUIREMENTS FOR PESTICIDE CHEMICAL RESIDUE, AND ASSIGNMENT OF EXPIRATION DATE FOR CANNABIS OIL

Ms. Juran reviewed pages 184-185 in the agenda packet containing the draft FAQs regarding Pesticides and the Assigning of Expiration Dates for Cannabis Oil Products. Additionally, she provided a handout containing alternative language for the pesticide chemical residue testing based on recent feedback. The alternative language adopts the Oregon list for pesticide chemical residue testing requirements. The FAQs would be posted to the board's website.

MOTION:

The board voted unanimously to adopt the FAQs as presented pertaining to under what conditions a pharmaceutical processor may use pesticides, what pesticides the board authorizes to address an infestation that could result in a catastrophic loss, and what criteria the board will use to determine compliance with assigning an expiration date for cannabis oil products and to adopt the alternate language on the handout pertaining to what criteria will be used to determine compliance with pesticide chemical residue testing requirements which adopts the Oregon list. (motion by Logan, seconded by Boone)

ADOPTION OF STATEWIDE PROTOCOLS FOR PHARMACIST TO INITIATE TREATMENT

Ms. Juran reviewed HB1506 beginning on page 186 in the agenda packet and provided an overview of each draft protocol as recommended by the Protocol Workgroup. The board considered the public comment received in support of all forms of education and not limiting certain educational programs to ACPE-accredited programs. The board offered support of a legislative proposal to authorize fluoride supplements for persons under the age of eighteen. There was discussion on whether devices could be included within the protocol to lower out-of-pocket expenses. Board counsel advised against including "devices" in this protocol as he did not believe the law supported this inclusion. There was a robust discussion regarding whether adoption of a protocol that incudes devices may place pharmacists in a vulnerable position wherein third party payers may not cover the claim based on the legal concerns with adopting such a protocol based on the current law. Separate from the legal considerations based on the current law, the board strongly supported an ability for pharmacists to prescribe for ancillary devices to reduce patient cost.

MOTION:

The board voted 4:6 to amend the protocol to lower out-of-pocket expense to include devices. (motion by Lee, seconded by Jenkins; opposed by Boone, Nelson, Richards-Spruill, Logan, St.Clair, Bolyard)

MOTION:

The board voted unanimously to adopt all statewide protocols as presented and recommended by the Protocol Workgroup. (motion by Nelson, seconded by Richards-Spruill)

ADOPTION OF RECOMMENDATIONS OFFERED BY DRUG DISPOSAL WORKGROUP

The board reviewed the recommendations offered by the Drug Disposal Workgroup.

MOTION:

The board voted unanimously to adopt the drug disposal recommendations as presented and recommended by the Drug Disposal Workgroup. (motion by Boone, seconded by Melton)

ADOPTION OF AMENDMENTS TO BYLAWS-DELEGATION OF AUTHORITY REGARDING EXCEPTIONS TO REQUIREMENT FOR PIC TO HAVE 2 YEARS OF EXPERIENCE

Ms. Juran commented that the board considered this matter at a past meeting and voted to amend the Bylaws. However, it was realized after the meeting that the Bylaws cannot be amended unless the amendments are provided in writing to the board which was not the case at the previous meeting. Therefore, she requested that the board reconsider the amendment to the Bylaws based on the written material included in the agenda packet.

MOTION:

The board voted unanimously to amend the Bylaws, Guidance Document 110-12, as presented. (motion by Nelson, seconded by Boone)

OLD BUSINESS:

INFORMATION FOR LICENSURE RENEWAL NOTIFICATION REGARDING DISPENSING OF NALOXONE PER REQUEST FROM JOINT COMMISION ON HEALTH CARE

Ms. Juran reminded the board of the letter sent to the board by the Joint Commission on Healthcare which asked that information be included in renewal notices sent to pharmacists that references current laws related to dispensing of Naloxone. The board

MOTION:

The board voted unanimously to adopt the naloxone language as presented for inclusion in the pharmacist licensure renewal notification. (motion by Melton, seconded by Logan)

NEW BUSINESS:

REQUEST TO DELEGATE AUTHORITYTO CHAIRMAN IN CONSULTATION WITH EXECUTIVE DIRECTOR, FOR APPOINTING PERSONS TO EVALUATION

Ms. Juran offered that request for applications for Pharmaceutical Processors will begin in October. Ms. Juran clarified that an ad hoc committee would be assigned to review applications as they are received.

COMMITTEE FOR PHARMACEUTICAL PROCESSOR REQUEST FOR APPLICATION PROCESS

MOTION:

The board voted unanimously to delegate authority to the Chairman, in consultation with the Executive Director, appoint persons to the evaluation committee for the upcoming pharmaceutical processor request for application process. (motion by Lee, seconded by Richards-Spruill)

ADOPTION OF PHARMACIST AND PHARMACY TECHNICIAN WORKFORCE SURVEY REPORTS

The Pharmacist and Pharmacy Technician Workforce Survey were included with the agenda packet as Attachments.

MOTION:

The board voted unanimously to adopt the 2019 Pharmacist and Pharmacy Technician Workforce Survey Reports as presented. (motion by Melton, seconded by Bolyard)

TRIBUTE TO JOHN HASTY

Dr. Ellen Shinaberry offered verbal comments recognizing the recent passing of John W. Hasty and honoring his many contributions in the field of Pharmacy, including serving as a former Director of the Department of Health Professions.

REPORTS:

CHAIRMAN'S REPORT

Mr. Ratliff thanked everyone for their patience with the meeting. He also thanked Mr. Ryan Logan for chairing the State Protocol Work Group Meetings, and Ms. Nelson for her attendance in his place at the Drug Disposal Workgroup meeting. Mr. Ratliff also welcomed the new board members, and thanked Mr. Boone for his service to the board in light of his recent decision to resign from the board, effective September 30, 2020, due to personal reasons.

REPORT ON BOARD OF HEALTH PROFESSIONS

Mr. Logan offered that the Board of Health Professions met on August 20, 2020 and discussed the board study in the need to regulate neuropathic doctors.

REPORT ON LICENSURE REPORT

No presentation was provided. Board members were simply referred to the report on Licensure Program found on page 217 of the agenda packet. No questions were asked of staff.

REPORT ON INSPECTION PROGRAM

No presentation was provided. Board members were simply referred to the report on the Inspection Program found on pages 218-228 of the agenda packet. No questions were asked of staff.

REPORT ON PHARMACEUTICAL PROCESSORS	No presentation was provided. Board members were simply referred to the report found in the agenda packet. No questions were asked of staff.
REPORT ON DISCIPLINARY PROGRAM	No presentation was provided. Board members were simply referred to the report found in the agenda packet. No questions were asked of staff.
EXECUTIVE DIRECTORS REPORT	Ms. Juran commented that the NABP/AACP Districts 1 & 2 meeting was held virtually on 9/8/2020 and three resolutions were submitted to go forward to the NABP Annual meeting in May. No questions were asked of staff.
CLOSED SESSION:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, the panel voted 10-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding a consent order involving Meds Vs. Vets. Additionally, it was moved that Caroline Juran, Ellen Shinaberry, Kiara Christian and Jim Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (motion by Nelson, seconded Richards-Spruill)
DECISION: *Meds Vs. Vets*	Upon a motion by Dr. St.Clair, and duly seconded by Ms. Nelson, the panel voted 10-0 to accept the consent order proposed by Ms. Shinaberry regarding Meds Vs. Vets.
CLOSED SESSION:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Logan, the panel voted 10-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter involving consents orders for Wells Pharmacy LLC, Tennessee, and Wells Pharmacy LLC, Florida. Additionally, it was moved that Caroline Juran, Ellen Shinaberry, Kiara Christian and Jim Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (motion by Nelson, seconded Jenkins)
DECISION: *Wells Pharmacy, TN*	Upon a motion by Dr. Melton, and duly seconded by Dr. St.Clair, the panel voted 10-0 to accept the consent orders for Wells Pharmacy LLC, Tennessee

Wells Pharmacy, FL and Wells Pharmacy LLC, Florida as proposed by Ms. Shinaberry.

MEETING ADJOURNED: 4:35 PM

Kristopher Ratliff, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING TO SCHEDULE CERTAIN CHEMICALS IN SCHEDULE I

September 9, 2020
Commonwealth Conference Center
Second Floor
Board Room 4

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

CALL TO ORDER: An in-person public hearing with public access on-site and via WebEx was called to order at 9:17 a.m.

PRESIDING: Kristopher Ratliff, Chairman

MEMBERS PRESENT:
James L. Jenkins, Jr.
Glen Bolyard
Melvin L. Boone, Sr.
Ryan Logan
Cheryl H. Nelson
Patricia Richards-Spruill
William Lee
Sarah Melton
Dale St. Clair

STAFF PRESENT:
Caroline D. Juran, Executive Director
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Assistant
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP

STAFF PARTICIPATING VIRTUALLY:
Annette Kelley, Deputy Executive Director
Beth O' Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director

CALL FOR PUBLIC COMMENT: Mr. Ratliff called for comment to consider placement of the following chemicals into Schedule I:

Synthetic Opioid:

- N-phenyl-N-(4-piperidinyl)-propanamide (other name: Norfentanyl)
- N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (other name: Isotonitazene)

Research Chemicals:

- (2-ethylaminopropyl)benzofuran (other name: EAPB)
- 2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone)
- 4-ethyl-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25ENBOH)
- 4-hydroxy-N-ethyl-N-propyltryptamine (other name: 4-hydroxy-EPT)
- N-ethyl-1-(3-hydroxyphenyl)cyclohexylamine (other name: 3-hydroxy-PCE)
- 1-cyclopropionyl lysergic acid diethylamide (other name: 1cP-LSD)
- 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: paraMethoxymethamphetamine, PMMA)

Cannabimimetic Agent:

- methyl 2-[1-(pent-4-enyl)-1H-indazole-3-carboxamindo]-3,3-dimethylbutanoate (other name: MDMB-4en-PINACA)
- N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butylindazole-3-carboxamide (other name: ADBBUTINACA)
- N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)indazole-3-carboxamide (other name: 5-chloro-AB-PINACA)
- methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indole-3-carbonyl}amino)-3-methylbutanoate (other names: MMB-FUBICA, AMB-FUBICA)

If approved by the Board of Pharmacy, the placement of these substances in Schedule I shall go into effect 30 days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I.

PULIC COMMENT: Robyn Weimer, Virginia Department of Forensic Science, briefly reviewed the recommendation submitted to the board for consideration of placing into Schedule I.

ADJOURN: The public hearing adjourned at 9:25 am.

Kristopher Ratliff, Chairman

Caroline D. Juran, Executive Director

Date

Date

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

Wednesday, September 9, 2020
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 5:00 PM.

PRESIDING: Kris Ratliff, Chairman

MEMBERS PRESENT:
Glenn Bolyard
Sarah Melton
James Jenkins
Cheryl Nelson
Kris Ratliff
Dale St. Clair

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Administrative Assistant

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

ABIGAIL BARNES
License No. 0202-012470

A formal hearing was held in the matter of Abigail Barnes to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy in Virginia and to consider her application for reinstatement.

Jessica Kelley, DHP Adjudication Specialist, presented the case.

Ms. Barnes was present.

Alexandra Aloba, DHP Senior Investigator testified by telephone on behalf of the Commonwealth.

Ms. Barnes testified on her own behalf.

CLOSED MEETING:

Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, the panel voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Abigail Barnes. Additionally, he moved that Caroline Juran, Ellen Shinaberry, Jim Rutkowski and Kiara Christian 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.

DECISION:

Upon a motion by Mr. Jenkins, and duly seconded by Mr. Bolyard, the panel voted 7-0 to accept the Findings and Facts and Conclusion of Law proposed by Ms. Kelley and amended by the Board. Upon a motion by Ms. Melton, and duly seconded by Mr. Bolyard, the panel voted 7-0 to reinstate the pharmacist license of Ms. Barnes and with certain terms and conditions.

ADJOURN:

With all business concluded, the meeting adjourned at 7:05 pm.

Kris Ratliff, Chair

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF STATEWIDE PROTOCOL WORKGROUP MEETING

Monday, September 21, 2020
Virtual Meeting

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

CALL TO ORDER:

A virtual Webex meeting of a Statewide Protocol workgroup convened by the Board of Pharmacy was called to order at 9AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the workgroup convened a virtual meeting to consider such business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

PRESIDING VIRTUALLY:

Ryan Logan, RPh, *Workgroup Chairman*

WORKGROUP MEMBERS PARTICIPATING VIRTUALLY:

Kristopher Ratliff, DPh, *Chairman, Board of Pharmacy (non-voting member)*
Sarah Melton, PharmD, *Member, Board of Pharmacy (departed at 11:03am)*
Dale St.Clair, PharmD, *Member, Board of Pharmacy, (joined at 11:03AM)*
Jake Miller, D.O., *Member, Board of Medicine*
Brenda Stokes, M.D., *Member, Board of Medicine*
Stephanie Wheawill, PharmD, *VDH, Director of Division of Pharmacy Services*
Kristen Collins, MPH, *Policy Analyst, Office of Epidemiology, VDH*
Diana Jordan, *Director, Division of Disease Prevention, VDH*
Joe DiPiro, PharmD, *Dean, VCU School of Pharmacy*
Michael Justice, PharmD, *Assistant Professor, Appalachian College of Pharmacy (joined at 12:05pm)*
Al Arias, M.D., *VCU, School of Medicine*
John R. Lucas, D.O., *Edward Via College of Osteopathic Medicine (joined at 9:30am)*
Donna Francioni-Proffitt, RPh, *Pharmacy Program Manager, DMAS*
Doug Gray, *Executive Director, Virginia Association of Health Plans (joined at 10:05am)*
Kelly Goode, PharmD, *Virginia Pharmacist Association*
Terri Babineau, M.D., *Medical Society of Virginia*
Kerri Musselman, PharmD, *Virginia Society of Health-System Pharmacists*

Summer Williams Kerley, PharmD, *Virginia Association of Chain Drug Stores*
Lincy Abraham, PharmD, *National Association of Chain Drug Stores*

STAFF PARTICIPATING VIRTUALLY:

Caroline Juran, RPh, *Executive Director, Board of Pharmacy*
William Harp, M.D., *Executive Director, Board of Medicine*
Elaine Yeatts, *Senior Policy Analyst, DHP*
Jim Rutkowski, *Assistant Attorney General*
Sammy Johnson, *Pharmacist, Deputy Executive Director, Board of Pharmacy*
Ellen Shinaberry, PharmD, *Deputy Executive Director, Board of Pharmacy*
Kiara Christian, *Executive Assistant, Board of Pharmacy*

APPROVAL OF AGENDA: MOTION:

The workgroup voted unanimously to approve the agenda as presented. (motion by Miller, seconded Stokes)

PUBLIC COMMENT:

As noticed in the agenda, Mr. Logan invited those persons who had requested via email to Ms. Juran or Ms. Christian prior to 8am on September 21, 2020 to offer public comment to the workgroup.

Nathan Emerson, PharmD, Carillion Clinic, asked that the workgroup address the needs of pharmacists related to HIV PrEP management. He stated it is safe with very little risk. Current requirement for patient to see doctor first under collaborative practice agreement requirements is a barrier to care. He referenced allowances in Washington state and California, and requested that PrEP be handled separately from PEP.

Christina Barille, Executive Director, VPhA, thanked staff and the workgroup participants. She stated statewide protocols would not remove current patient access points, but would add to them. Adding point of care testing at community pharmacies will assist rural patients and connect them back to their primary care provider. Need to increase access to care as there are many barriers currently.

Jill McCormack, Director of State Government Affairs NACDS and also representing VACDS, offered support

for expanding access of care for patients. Pharmacists have a vital, safe track record; can provide continuity of care and as a gateway to connect patients with their primary care provider.

Mr. Logan asked if anyone else wished to offer comment even if didn't send email to staff. No other public comments were made.

REVIEW CHARGE OF THE WORKGROUP AS DESCRIBED IN THE 3RD ENACTMENT CLAUSE OF HB 1506

Mr. Logan reviewed the charge of the workgroup as outlined in the 3rd enactment clause of HB1506. Recommendations will be included in a legislative report submitted by staff by November 1, 2020 as required in the bill. If the workgroup concludes its work today, the second meeting tentatively scheduled for October 2, 2020 will be cancelled.

REVIEW REQUEST FROM JOINT COMMISSION ON HEALTH CARE, DATED 2/10/2020

Mr. Logan reviewed a letter received from the Joint Commission on Health Care (JCHC) in February 2020 prior to the passage of HB1506. Because the JCHC is requesting similar information, a copy of the legislative report from this workgroup will be sent to the JCHC as well by November 1, 2020.

OVERVIEW OF PHARMACIST EDUCATIONAL/TRAINING STANDARDS

Dean DiPiro provided a brief overview of the current educational and training standards for pharmacists.

REVIEW WORKFORCE STATISTICS OF PHARMACISTS

Ms. Juran highlighted key findings from the 2019 Pharmacist Workforce Survey Report which included: 66% hold a PharmD degree; 19% have completed a one-year residency; 7% have completed a two-year residency; and 10% have obtained a Board certification with 6% of those in Pharmacotherapy.

COPIES OF RECENTLY ADOPTED VIRGINIA PROTOCOLS

Mr. Logan briefly summarized the statewide protocols recently adopted by the Board in response to the 2nd enactment clause of HB 1506.

PROVIDE RECOMMENDATIONS REGARDING THE DEVELOPMENT OF PROTOCOLS FOR THE

INITIATING OF TREATMENT WITH AND DISPENSING AND ADMINISTERING BY PHARMACISTS TO PERSONS 18 YEARS OF AGE OR OLDER OF DRUGS AND DEVICES, INCLUDING:

VACCINES

Dr. Stokes supported reporting vaccines to the Virginia Immunization Information System and to the patient's primary care provider (PCP). If no PCP, then counsel on importance of a PCP. Dr. Babineau expressed concern for the financial impact on PCPs.

MOTION:

The workgroup voted 15: 1 with 1 abstention to include in the legislative report a recommendation that pharmacists should be authorized to order and administer vaccines included on the immunization schedule published by the CDC for persons 18 years of age and older, to require reporting to the Virginia Immunization Information System, and to inform the patient's primary care provider (PCP) of the administration or if none, to counsel the patient on the importance of having a relationship with a PCP. (motion by Melton, seconded by Miller; Babineau opposed; Arias abstained)

TOBACCO CESSATION

Dr. Stokes questioned how use of bupropion and Chantix would be monitored; stated that behavioral aspects are very important and should require follow-up. Dr. Kerley indicated questionnaires have been used successfully. It was stated that day supply could be limited or require check-ins. Dean DiPiro stated pharmacists are being used increasingly in ambulatory settings and that this subject may be better addressed in that setting. He indicated that pharmacy students are taught to recognize suicidal behavior, perform assessments, and must complete a mental health therapeutic module and a semester-long communication course.

MOTION:

A motion was made by Dr. Melton, seconded by Dr. Abraham to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer drugs approved by the FDA for tobacco cessation therapy, including nicotine replacement therapy.

AMENDED MOTION:

A motion to amend the main motion to exclude Wellbutrin and Chantix was made by Dr. Babineau, seconded by Dr. Miller. The workgroup voted 7:7 with 1 abstention, therefore, the motion to amend the main motion failed due to a tie.

VOTE ON MAIN MOTION:

The workgroup voted 10:5 on the main motion to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer drugs approved by the FDA for tobacco cessation therapy, including nicotine replacement therapy. (supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan; opposed by Miller, Stokes, Arias, Lucas, Babineau; Melton departed meeting prior to vote; Collins and Jordan not present for vote).

TUBERCULIN PURIFIED PROTEIN DERIVATIVE FOR TUBERCULOSIS TESTING

Dr. Stokes recommended referral if the TB test was positive. There was little discussion as there appeared to be general support for this particular subject.

MOTION:

The workgroup voted 17:0 to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer tuberculin purified protein derivative for tuberculosis testing. (motion by Lucas, seconded by DiPiro; supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan, Miller, Stokes, Arias, Lucas, Babineau, Collins, and Jordan)

CONTROLLED SUBSTANCES OR DEVICES FOR THE TREATMENT OF DISEASES OR CONDITIONS FOR WHICH CLINICAL DECISION MAKING CAN BE GUIDED BY A CLIA-WAIVED TEST, INCLUDING INFLUENZA VIRUS, H. PYLORI BACTERIA, UTI, AND GROUP A STREPTOCOCCUS BACTERIA

It was determined that each condition should be considered separately. Dr. Lucas stated clinical acumen was important to identify the infrequent, serious conditions. Dr. Kerley shared her experience with a very strict protocol which excludes patients that need to be seen by a physician and requires repeat or failed therapy to be referred for immediate care. She recommended a step-wise approach. Dr. Babineau expressed concern for overlooking pneumonia. Dr. Stokes supported influenza due to timeliness of starting medication. Dr. Abraham indicated 17 states allow for CLIA-waived tests and that Tamiflu is slated to move to an over-the-counter status.

INFLUENZA
MOTION:

The workgroup voted 15:3 to include in the legislative report a recommendation that pharmacists should be

authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of influenza, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by DiPiro; supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan, Stokes, Lucas, Collins, Justice, and Jordan; opposed by Babineau, Miller, Arias)

HELICOBACTER PYLORI BACTERIA

Dr. Stokes and Dr. Babineau expressed concern for the complexity in diagnosing H. Pylori. Dean DiPiro shared this concern, but stated pharmacists can be very supportive of patient care following diagnosis. Dr. Babineau agreed with DiPiro.

MOTION:

The workgroup voted 13:0 with 4 abstentions to exclude H. Pylori as a recommendation in the legislative report for pharmacists to initiate treatment with and dispense and administer controlled substances or devices. (motion by Miller, seconded by Stokes; supported by St.Clair, DiPiro, Proffitt, Gray, Goode, Musselman, Logan, Stokes, Lucas, Justice, Babineau, Miller, Arias; Wheawill, Collins, Jordan, and Abraham abstained; Kerley not present for vote)

UTI

Dr. Stokes expressed concern for UTI test. Dr. Babineau agreed and stated that a culture test is necessary. Dr. Goode reminded the workgroup that Sen. Dunnavant was supportive of the bill.

MOTION:

**The workgroup voted 7:8 with 3 abstentions to exclude urinary tract infections as a recommendation in the legislative report for pharmacists to initiate treatment with and dispense and administer controlled substances or devices, therefore, the motion failed. (motion by Miller, seconded by Stokes; supported by Miller, Stokes, Arias, Lucas, Proffitt, Gray, Babineau; opposed by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice;
Wheawill, Collins, Jordan abstained)**

MOTION:

The workgroup voted 10:5 with 3 abstentions to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of urinary tract infections, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by

Abraham; supported by Logan, St.Clair, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Justice; opposed by Miller, Stokes, Arias, Lucas, Babineau; Wheawill, Collins, Jordan abstained)

GROUP A STREPTOCOCCUS BACTERIA

Dr. Babineau expressed concern for CLIA-waived strep tests with false positives or false negatives, and that serious conditions could be missed. She stated diagnostic techniques are needed. Dr. Goode commented that US data suggests tests can be helpful. Dr. Abraham stated 17 states allow pharmacist-use of strep CLIA-waived tests. Dr. Goode stated if symptomatic with negative test pharmacist would refer patient and a confirmatory lab test could be performed. Dr. Babineau shared concern for testing during COVID-19 pandemic.

MOTION:

The workgroup voted 7:8 with 3 abstentions to exclude Group A Streptococcus bacteria as a recommendation in the legislative report for pharmacists to initiate treatment with and dispense and administer controlled substances or devices, therefore, the motion failed. (motion by Miller, seconded by Stokes; supported by Miller, Stokes, Arias, Lucas, Proffitt, Gray, Babineau; opposed by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice; Wheawill, Collins, Jordan abstained)

MOTION:

The workgroup voted 8:6 with 4 abstentions to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of Group A Streptococcus bacteria, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by Abraham; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice; opposed by Miller, Stokes, Arias, Lucas, Proffitt, Babineau; Wheawill, Collins, Jordan, Gray abstained)

CONTROLLED SUBSTANCES FOR THE PREVENTION OF HUMAN IMMUNODEFICIENCY VIRUS, INCLUDING CONTROLLED SUBSTANCES PRESCRIBED FOR PRE-EXPOSURE AND POST-EXPOSURE PROPHYLAXIS

Ms. Jordan stated VDH believes a well-constructed protocol with a thorough assessment could meet public need. VDH has experience working with pharmacists performing HIV testing and that PEP and PrEP could be built into a protocol. Dr. Abraham echoed Ms. Jordan's comments. Dr. Babineau expressed concern for assessing creatinine clearance. It was stated that retail/community

PURSUANT TO GUIDELINES AND RECOMMENDATIONS OF THE CDC

pharmacies have been very positive environments for HIV testing. Dr. Stokes commented that a protocol on this subject would provide a good service to a community and agreed that documentation of creatinine clearance would be important.

MOTION:

The workgroup voted unanimously 18:0 to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer 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. (motion by Abraham, seconded by DiPiro; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice, Miller, Stokes, Arias, Lucas, Proffitt, Babineau, Wheawill, Collins, Jordan, and Gray)

DRUGS OTHER THAN CONTROLLED SUBSTANCES, INCLUDING DRUGS SOLD OVER THE COUNTER, FOR WHICH THE PATIENT'S HEALTH INSURANCE PROVIDER REQUIRES A PRESCRIPTION

It was stated that this subject appears to have already been addressed by a statewide protocol recently adopted by the Board. It was acknowledged that the term "drugs" does not include "devices". There were comments supportive of a pharmacist's ability to prescribe devices such as glucometers, pen needles, syringes, and possibly other durable medical equipment. Dr. St.Clair recommended that a recommendation should not reference health insurance or limit the provision to times when the health plan is paying for it. Dr. Babineau expressed support and recommended that the provision be very specific. Dr. Stokes recommended looking at the Oregon protocol found on page 81 of the agenda packet. Mr. Gray and Dr. Babineau also supported Oregon's approach.

MOTION:

The workgroup voted 17:0 with 1 abstention to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer devices, controlled paraphernalia such as insulin pen needles and hypodermic syringes, and possibly other durable medical equipment to lower out-of-pocket expenses, not covered by a health plan. (motion by Goode, seconded by St.Clair; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice, Miller, Stokes, Arias, Lucas, Proffitt, Babineau, Wheawill, Collins, and Gray; Jordan abstained.)

ADJOURNED: With all business concluded, the workgroup adjourned the meeting at 2:14 pm.

Ryan Logan, Chairman

Caroline Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday September 23, 2020
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 9:07 am.

PRESIDING: Patricia Richards-Spruill, Committee Chair

MEMBERS PRESENT: William Lee, Committee Member
Dale St. Clair, Observing

STAFF PRESENT: Mykl Egan, Discipline Case Manager
Ileita Redd, Discipline Program Specialist
Claire Foley, DHP Adjudication Specialist

AKINA PHARMACY
Permit No. 0201-004538

Bassem Girgis, Pharmacist-in-Charge of Akina Pharmacy, and Tamer Girgis, a pharmacist for Akina Pharmacy appeared as representatives of Akina Pharmacy to discuss allegations that Akina Pharmacy may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the July 23, 2020 Notice. They were represented by Meredith Haynes, Esq.

Closed Meeting: Upon a motion by Mr. Lee, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Akina Pharmacy. Additionally, he moved that Mykl Egan, Ileita Redd and Dale St. Clair attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee

reconvened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Lee and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously to assess a monetary penalty against Akina Pharmacy.

TERRY YOUNG
Registration No. 0230-000229

Terry Young, pharmacy technician, did not appear to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacy technician as stated in the August 13, 2020, Notice.

Closed Meeting:

Upon a motion by Mr. Lee, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Terry Young. Additionally, he moved that Mykl Egan, Ileita Redd and Dale St. Clair attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Lee, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to refer the matter to a Formal Administrative Hearing, and to offer a Consent Order to Mr. Young.

FALLS CHURCH PHARMACY
Permit No. 0201-003833

Thu Ahn Bui, Pharmacist-in-Charge of Falls Church Pharmacy, appeared as a representative of Falls Church Pharmacy to request that the pharmacy be removed from the terms and conditions of its probation as set forth in a Consent Order entered June 18, 2019, and to discuss allegations that Falls Church Pharmacy may have violated certain laws

and regulations governing the conduct of pharmacy as stated in the May 14, 2020 Notice.

Closed Meeting:

Upon a motion by Mr. Lee, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Falls Church Pharmacy. Additionally, he moved that Mykl Egan, Ileita Redd and Dale St. Clair attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Lee and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously to assess a monetary penalty against Falls Church Pharmacy and to continue the pharmacy on probation under certain terms and conditions.

CARTHAN F. CURRAN, JR.
License No. 0202-003599

Carthan F. Curran, Jr., pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the August 19, 2020, Notice. He was represented by Nathan Kottkamp, Esq.

Closed Meeting:

Upon a motion by Mr. Lee, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Carthan F. Curran, Jr. Additionally, he moved that Mykl Egan, Ileita Redd and Dale St. Clair attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Lee, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to order Mr. Curran Be issued a REPRIMAND and that he must take additional hours of continuing education.
ADJOURNED:	3:45 pm

_____
Patricia Richards-Spruill, Chair

_____
Ellen B. Shinaberry
Deputy Executive Director

_____
Date

_____
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, September 24, 2020

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on September 24, 2020, at 3:00 p.m., to consider the summary suspension of the registration of Jalissa Taylor to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Kristopher Ratliff, Chair

MEMBERS PRESENT:
Melvin Boone
James Jenkins
William Lee
Kristopher Ratliff
Patricia Richards-Spruill
Dale St. Clair

STAFF PRESENT:
Mykl D. Egan, Discipline Case Manager
Ellen Shinaberry, Deputy Executive Director
Claire Foley, DHP Adjudication Specialist
James Rutkowski, Senior Assistant Attorney General
Sean J. Murphy, Assistant Attorney General

POLL OF MEMBERS: The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary suspension case. The Board members stated that they would not have been able to attend.

With six (6) members participating and four (4) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

JALISSA TAYLOR Sean J. Murphy, Assistant Attorney General, presented

Permit No. 0230-032023	a summary of the evidence in this case.
DECISION:	Upon a motion by Mr. Jenkins and duly seconded by Ms. Richards-Spruill, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Jalissa Taylor poses a substantial danger to the public; and therefore, the registration of Ms. Taylor shall be summarily suspended. Further, upon a motion by Mr. Boone and duly seconded by Mr. St. Claire, the Board unanimously voted that, with the Notice of Hearing, a Consent Order shall be offered to Ms. Taylor for the revocation of her registration.
ADJOURN:	With all business concluded, the meeting adjourned at 3:24 p.m.

Kristopher Ratliff, Chair

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

October 5, 2020
Second Floor
Board Room 4

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

CALL TO ORDER: A meeting of an informal conference committee of the Board of Pharmacy was called to order at 9:09 AM.

PRESIDING: Kris Ratliff, Committee Chairman

MEMBER PRESENT: William Lee, Committee Member

STAFF PRESENT: Caroline D. Juran, Executive Director
Ellen Shinaberry, Deputy Executive Director
Mykl Egan, Discipline Case Manager
Jess Kelley, DHP Adjudication Specialist

Free Clinic of Franklin County
Tech Pre-dispensing Preparation

Kimberly Florio, Pharmacist in charge of the Free Clinic of Franklin County was present to discuss the application for approval of an Innovative (Pilot) Program from the Free Clinic of Franklin.

The Free Clinic of Franklin is seeking permission to allow pharmacy technicians to perform prescription data entry and printing of prescription label and patient information leaflet outside of the pharmacy when a pharmacist is not on duty and is seeking a waiver of § 54.1-3320 dealing with Acts Restricted to Pharmacist and 18VAC110-20-112 Supervision of Pharmacy Technicians.

DISCUSSION: Ms. Florio presented information related to the process of preparing the prescription label and leaflet by the technician in a room adjacent to the pharmacy and answered questions regarding the functionality of the computer software.

DECISION: After consideration of the application and statements concerning the proposed Innovative (Pilot) program the committee denied the request.

Johnston Memorial Hospital
Tech-Check-Tech

Carmen Meadows, Clinical Coordinator and Christina Shelton, Pharmacist in Charge of Johnston Memorial Hospital were present to discuss the application for approval of an Innovative (Pilot) Program from Johnston Memorial Hospital.
Johnston Memorial Hospital is seeking permission to allow

technician to check technician for CII-CVI prescription drugs and over-the-counter (OTC) medications dispensed from the pharmacy and loaded into automated dispensing cabinets throughout the hospital and is seeking a waiver of 18 VAC 110-20-270(B) and 18 VAC 110-20-490(C) .

DISCUSSION: Ms. Meadows and Ms. Shelton described the hospitals dispensing process and pharmacy technology, including bar code restocking at the dispensing cabinets and nursing bedside medication verification via medication barcode scanning. They answered committee member questions regarding the process and procedures for monitoring drug theft and diversion.

DECISION: After consideration of the application and statements concerning the proposed Innovative (Pilot) program the committee approved the request but restricted the pilot to Schedule VI prescription medications and OTC drugs, and imposed other terms and conditions.

ADJOURN: With all business concluded, the meeting adjourned at 12:44 PM.

Kris Ratliff
Committee Chairman

Caroline D. Juran
Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday October 14, 2020
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 9:16 am.

PRESIDING: Patricia Richards-Spruill, Committee Chair

MEMBERS PRESENT: Dale St. Clair, Committee Member

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

PROMISE PHARMACY
Permit No. 0201-004538

Mipal Patel, Pharmacist-in-Charge of Promise Pharmacy, appeared as a representative of Promise Pharmacy to discuss its application for the renewal of its permit to conduct a non-resident pharmacy delivering in the Commonwealth of Virginia and to review allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the July 30, 2020 Notice.

Closed Meeting: Upon a motion by Mr. St. Claire, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Promise Pharmacy. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee

reconvened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. St. Claire and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously to grant Promise Pharmacy's request for the renewal of its permit.

JOANN ESPINAL
Registration No. 0230-007267

Joann Espinal, pharmacy technician, appeared to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the September 11, 2020, Notice.

Closed Meeting:

Upon a motion by Mr. St. Claire, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Joann Espinal. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. St. Claire, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to issue a REPRIMAND to Ms. Espinal and require her to take additional hours of continuing education.

ADJOURNED:

3:15 pm

Patricia Richards-Spruill, Chair

Ellen B. Shinaberry
Deputy Executive Director

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, October 20, 2020
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:07 am.
PRESIDING:	Glenn Bolyard, Committee Chair
MEMBERS PRESENT:	Cheryl H. Nelson, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Jessica Kelley, DHP Adjudication Specialist
WALGREENS #18429 Permit No. 0201-003569	Derek Parvizi, Health Care Supervisor appeared as a representative of Walgreens #18429 to discuss allegations that the pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the September 16, 2020 Notice. Walgreens was represented by Brian Bruns, Esq.
Closed Meeting:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, 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 Walgreens #18429. 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 Ms. Nelson and duly seconded by Mr. Bolyard, the Committee voted unanimously to assess a monetary penalty against Walgreens #18429 and to order an unannounced inspection of the pharmacy within six months.
WALGREENS #13682 Permit No. 0201-004479	Derek Parvizi, Health Care Supervisor appeared as a representative of Walgreens #13682 to discuss allegations that the pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the September 16, 2020 Notice. Walgreens was represented by Brian Bruns, Esq.
Closed Meeting:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, 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 Walgreens #13682. 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 Ms. Nelson and duly seconded by Mr. Bolyard, the Committee voted unanimously to assess a monetary penalty against Walgreens #13682 and to order an unannounced inspection of the pharmacy within six months.
JACOB JAMRON License No. 0202-218021	Jacob Jamron, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the September 16, 2020, Notice. He was represented by Marc Nocera, Esq. and Meredith Haynes, Esq.

Closed Meeting:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, 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 Jacob Jamron. 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 Ms. Nelson, and duly seconded by Mr. Bolyard, the Committee unanimously voted to Reprimand Mr. Jamron and to assess a monetary penalty.
SHERRI D. FRANCISCO License No. 0202-010041	Sherri D. Francisco, pharmacist appeared to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacist as stated in the September 17, 2020, Notice. She was represented by Molly Huffman, Esq.
Closed Meeting:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, 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 Sherri D. Francisco. 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 Ms. Nelson, and duly seconded by Mr. Bolyard, the Committee unanimously voted to Reprimand Ms. Francisco, and to assess a monetary penalty.

ADJOURNED: 3:46 pm

Glen Bolyard, Chair

Ellen B. Shinaberry
Deputy Executive Director

Date

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF VIRTUAL REGULATION COMMITTEE MEETING

November 12, 2020
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: A virtual Webex meeting of the Regulation Committee was called to order at 9:08AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the committee convened a virtual meeting to consider such business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

PRESIDING: Cheryl Nelson, Committee Chairman

MEMBERS PRESENT:
Glen Bolyard, Jr.
Dale St.Clair
William Lee
Patricia Richards-Spruill

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General
Matt Treacy, Media Production Specialist

QUORUM: With four members of the Committee present, a quorum was established.

APPROVAL OF AGENDA: Agenda was approved as provided.

PUBLIC COMMENT: Natalie Nguyen, PharmD, representing VSHP stated they support the intent of remote order processing by a pharmacy technician. She recommended the Board consider recent COVID experience. She recommended a hard upper limit for a pharmacist to pharmacy technician ratio. She reminded the board that space in a pharmacy is limited.

Cindy Warriner, RPh, representing Appalachian College of Pharmacy reacted to several items in the agenda packet. She recommended amending #2 in Guidance Document 110-13, expressed concern for removing personal supervision of a pharmacy technician, opposed a store

manager having the ability to determine the number of pharmacy technicians, and recommended keeping the square footage for a pharmacy.

Monet Stanford, PharmD representing Kaiser Permanente stated that pharmacy technicians can complete remote processing tasks under secure technology and can increase capacity of healthcare workforce.

Christina Barrille, Executive Director, VPhA encouraged the Board to strike B3 of 18VAC110-40-20. She recommended allowing a pharmacist to use professional discretion regarding the closing of the pharmacy during a required break. Regarding page 29 of the agenda packet, she recommended waiting until the pharmacy technician workgroup meets. She stated they oppose removing pharmacist supervision and ridding of pharmacist to pharmacy technician ratio. She commented that a pharmacy square footage can be waived, if necessary.

Update on Regulatory Actions

A more current version of the Chart of Regulatory Actions was shared on the screen via WebEx. Ms. Yeatts provided an overview of the chart.

Amendments to Guidance Documents

Ms. Yeatts indicated several guidance documents need to be amended based on recent statutory changes.

MOTION:

The committee voted unanimously to recommend to the full board that it amend Guidance Documents 110-1 (Categories of Facility Licensure), 110-29 (Guidance on Physician Dispensing Licenses), and 110-44 (Naloxone Protocol) as presented. (motion by Richards-Spruill, second by Bolyard)

The committee considered public comment received to amend #2 of Guidance Document 110-13, but concluded that such an amendment would require a regulatory change.

MOTION:

The committee voted unanimously to recommend to the full board that it amend Guidance Document 110-13 (Guidance Regarding Collaborative Practice Agreements) as presented. (motion by St.Clair, second by Richards-Spruill)

Staff indicated that Guidance Document 110-41 was recently incorporated into regulation during the last periodic regulatory review.

MOTION:

The committee voted unanimously to recommend to the full board that it repeal Guidance Document 110-41 (Changes a Pharmacist May Make to a Prescription Written for a Schedule II Controlled Substance) as presented. (motion by Bolyard, second by St.Clair)

There was much discussion regarding Guidance Document 110-39 (Guidance for Continuous Hours Worked by Pharmacists and Breaks).

There was general support for a pharmacist exercising discretion regarding whether he or she would close the pharmacy during a required pharmacist break, however, the Committee believed it was important to post in advance for the public the time period that the pharmacy may be closed.

MOTION:

The committee voted in favor 4:1 to recommend to the full board that it amend Guidance Document 110-39 to allow the pharmacist on-duty to determine if the pharmacy will close during a required pharmacist break, but to require the pharmacy to post in advance the time period that the pharmacy may be closed. (motion by Bolyard, second by Richards-Spruill; St.Clair opposed)

The Board discussed the draft guidance document regarding contract employees accessing the premises of a pharmaceutical processor.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the guidance document (Contracted Employee Access to Pharmaceutical Processor) as presented. (motion by St.Clair, second by Bolyard)

Consideration of Remote Order Processing by a Pharmacy Technician Outside of a Pharmacy

Staff reminded the Board that this issue resulted from a petition from rulemaking from Bioscript. In June 2020, the Board voted to not initiate rulemaking but to refer the issue to the Regulation Committee for further consideration. An excerpt of minutes from a 10/5/2020 special conference committee denying a request for a pilot was included in the agenda packet. There was discussion regarding the appropriate level of pharmacist supervision and use of technology to monitor pharmacy technician activities.

MOTION:

The committee voted in favor 3:2 to defer consideration of remote order processing by a pharmacy technician outside of a pharmacy to the workgroup to be convened in 2021 pursuant to HB 1304 to consider additional duties that a pharmacy technician may perform. (motion by Lee, second by Richards-Spruill; opposed by Bolyard and St.Clair)

Consideration of Amendments – Medication Carousels and RFID Technology

There was discussion regarding whether the preliminary text language requiring scanning of each drug unit, blister card, and unopened container was appropriate. Some commenters stated that it may not be efficient to scan each unit, particularly in a large hospital. Other commenters stated it was necessary for patient protection. The committee did not believe any changes were necessary to the preliminary text on RFID technology.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the proposed language as amended by: requiring the same safety processes for "spoke and wheel", i.e., allowing drugs to be pulled from the med carousel for wholesale distribution to an offsite entity; in 18VAC110-20-425(C), changing the second "3" to "4" and replacing "the robotic pharmacy system to guide" with

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"barcode scanning technology to verify the accuracy of"; and inserting a requirement for a pharmacist 5% verification as is currently required in the innovative pilots for using med carousels. (motion by Lee, second by St.Clair)

Adoption of NOIRA/Notice of Periodic Review

The committee did not review each item previously submitted following the last periodic review, but rather decided to recommend to the full board that it notice the public of a periodic review and request comments on changes it would like to have considered. If published, a 30-day public comment period would open.

MOTION:

The committee voted unanimously to recommend to the full board that it issue a Notice of Periodic Regulatory Review for Chapters 20, 21, 30, 40, and 50 and that it request comments on changes that the public would like to have considered. (motion by St.Clair, second by Richards-Spruill)

ADJOURN:

With all business concluded, the meeting adjourned at approximately 12:10 PM.

_____
Cheryl Nelson, Chairman

_____
DATE

_____
Caroline D. Juran, Executive Director

_____
DATE

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

Monday, November 16, 2020
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a quorum of the Board of Pharmacy ("Board") was called to order at 0932.

PRESIDING: Kris Ratliff, Chairman

MEMBERS PRESENT:
Sarah Melton
James Jenkins
William Lee
Cheryl Nelson
Patricia Richards-Spruill
Dale St. Clair

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

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

JALISSA LANAE TAYLOR
Registration No. 0230-032023

A formal hearing was held in the matter of JaLissa L. Taylor to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Claire Foley, DHP Adjudication Specialist, presented the case.

Ms. Taylor was present and was not represented by counsel.

Richie Waddel, Asset Protection Manager, Walgreens Pharmacies, testified in person on behalf of the Commonwealth.

Ms. Taylor testified on her own behalf.

CLOSED MEETING: Upon a motion by Ms. Nelson, and duly seconded by Mr. Jenkins, the panel voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of JaLissa L. Taylor. Additionally, she moved that Caroline Juran, Ellen Shinaberry, and Jim Rutkowski attend the closed meeting.

RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision.
DECISION:	Upon a motion by Ms. Nelson, and duly seconded by Mr. St. Clair, the panel voted 7-0 to accept the Findings and Facts and Conclusion of Law proposed by Ms. Foley and amended by the Board. Upon a motion by Ms. Richards-Spruill, and duly seconded by Ms. Nelson, the panel voted 7-0 to revoke the technician registration of Ms. Taylor.
HANNAH MENDEZ Registration #: 0230033133	Consideration of Consent Order.
DECISION:	Upon a motion by Mr. Jenkins, and duly seconded by Ms. Richards-Spruill, the panel voted 7-0 to accept the consent order proposed by Ms. Shinaberry regarding Hannah Mendez.
MIRIAM ELGAWLY License #: 0202216162	Consideration of Consent Order
DECISION:	Upon a motion by Dr. Melton, and duly seconded by Mr. Lee, the panel voted 6-1 to accept the consent order proposed by Ms. Shinaberry regarding Miriam Elgawly.
POSSIBLE SUMMARY SUSPENSION Case #204525 Registration #0230033187	Sean J. Murphy, Assistant Attorney General, presented a summary of the evidence in this case. He was assisted by Jess Kelley, Adjudication Specialist.
DECISION:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Jenkins, the Board voted 7-0 to summarily suspend the technician registration of Dena Robinette to notice her for a formal hearing, and to offer a consent order in lieu of the formal hearing.
ADJOURN:	With all business concluded, the meeting adjourned at 11:53 AM.

Kris Ratliff, Chair

Caroline D. Juran
Executive Director

Date

Date

Chart of current regulatory actions
As of November 23, 2020

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Reporting of immunizations to VIIS [Action 5598] Emergency - *Register Date: 10/12/20 Effective: 9/22/20*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Implementation of legislation for pharmacists initiating treatment [Action 5604] Emergency/NOIRA - *At Secretary's Office for 17 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Use of medication carousels and RFID technology [Action 5480] NOIRA - *Register Date: 9/14/20 Comment closed: 10/14/20 Board to adopt proposed: 12/10/20*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Handling fee [Action 5519] Fast-Track - *At Governor's Office for 27 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] Final - *At Governor's Office for 26 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling of chemicals in Schedule I [Action 5606] Final - *Register Date: 10/26/20 Effective: 11/25/20*
[18 VAC 110 - 21]	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians	Implementation of legislation for registration of pharmacy technicians [Action 5603] Emergency/NOIRA - *At Secretary's Office for 3 days*
[18 VAC 110 - 21]	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians	CE credit for volunteer hours [Action 5546] Fast-Track - *At Governor's Office for 27 days*
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	Limited license for prescribing Schedule VI drugs in non-profit clinics

		Emergency/NOIRA - *At Secretary's Office for 40 days*
[18 VAC 110 - 40]	Regulations Governing Collaborative Practice Agreements	(E) Implementation of 2020 legislation [Action 5607] Final - *Register Date: 10/26/20 Effective: 11/25/20*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Final - *At Governor's Office for 27 days*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Prohibition of products for vaping or inhalation with vitamin E acetate [Action 5452] Emergency/NOIRA - *Register Date: 8/31/20 Comment on NOIRA closed: 9/30/20 Board to adopt proposed: 12/20/20*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Amendments resulting from SB976 of the 2020 General Assembly [Action 5629] Emergency/NOIRA - *At Attorney General's Office*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Response to petition for rulemaking [Action 5611] NOIRA - *At Secretary's Office for 53 days*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Registered agents and wholesale distribution [Action 5398] Proposed - *At Governor's Office for 27 days Emergency expires: 6/29/21*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Acquisition of industrial hemp [Action 5602] Fast-Track - *At Secretary's Office for 5 days*

Agenda Item: Regulatory Action – Adoption of Proposed Regulations

Prohibition on oil products intended to be vaped that contains vitamin E acetate

Included in agenda package:

Copy of notice on Townhall – Notice of Intended Regulatory Action (NOIRA)

Copy of emergency regulation

Staff Note:

Emergency regulations are effective: 8/6/20 to 2/5/22

There were no comments on the NOIRA

Board action:

To amend Section 280 on cultivation and production of cannabis oil to prohibit the production of an oil intended to be vaporized or inhaled from containing vitamin E acetate. (Regulation identical to emergency in effect)

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VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

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

Action: Prohibition of products for vaping or inhalation with vitamin E acetate

Emergency/NOIRA Stage

Action 5452 / Stage 8856

Edit Stage | Go to RIS Project | Request Emergency Extension

Documents		
Emergency Text	12/17/2019 4:28 pm	Sync Text with RIS
Agency Background Document	12/17/2019 (modified 12/26/2019)	Upload / Replace
Attorney General Certification	12/31/2019	
Governor's Review Memo	8/6/2020	
Registrar Transmittal	8/6/2020	

Status	
Public Hearing	Will be held at the **proposed** stage
Emergency Authority	2.2-4001 A
Exempt from APA	No, this stage/action is subject to article 2 of the *Administrative Process Act* and the standard executive branch review process.
Attorney General Review	Submitted to OAG: 12/17/2019 Review Completed: 12/31/2019 Result: Certified
DPB Review	Submitted on 12/31/2019 Policy Analyst: Melanie West Review Completed: 1/10/2020 *DPB's policy memo is "Governor's Confidential Working Papers"*
Secretary Review	Secretary of Health and Human Resources Review Completed: 5/29/2020
Governor's Review	Review Completed: 8/6/2020 Result: Approved
Virginia Registrar	Submitted on 8/6/2020 The Virginia Register of Regulations Publication Date: 8/31/2020 Volume: 37 Issue: 1
Comment Period	Ended 9/30/2020 0 comments
Effective Date	8/6/2020

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Expiration Date	2/5/2022

Contact Information	
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This person is the primary contact for this board.
This stage was created by Elaine J. Yeatts on 12/17/2019
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Project 6250 - Emergency/NOIRA

Board Of Pharmacy

Prohibition of products for vaping or inhalation with vitamin E acetate

18VAC110-60-280. Cultivation and production of ~~cannabidiol oil or THC-A~~ cannabis oil.

Part VI

Cultivation, Production, and Dispensing of ~~Cannabidiol Oil or THC-A~~ Cannabis Oil

A. No ~~cannabidiol oil or THC-A~~ cannabis oil shall have had pesticide chemicals or petroleum-based solvents used during the cultivation, extraction, production, or manufacturing process, except that the board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of Cannabis crops.

B. Cultivation methods for Cannabis plants and extraction methods used to produce the ~~cannabidiol oil and THC-A~~ cannabis oil shall be performed in a manner deemed safe and effective based on current standards or scientific literature.

C. Any Cannabis plant, seed, parts of plant, extract, ~~cannabidiol oil,~~ or ~~THC-A~~ cannabis oil not in compliance with this section shall be deemed adulterated.

D. No cannabis oil intended to be vaporized or inhaled shall contain vitamin E acetate.

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

Scheduling Chemicals in Schedule I - Exempt action

Included in agenda package:

Copy of Notice of Public Hearing listing chemicals to be scheduled in Schedule I

Amendments to regulation: 18VAC110-20-322

Staff Note:

A public hearing was conducted before the meeting this morning.

Action is exempt from the provisions of the Administrative Process Act in accordance with § 2.2-4006.

Board action:

Adoption of final regulation in sections 322

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

Edit Notice

General Notice

Placement of chemicals in Schedule I

Date Posted: 10/16/2020

Expiration Date: 12/10/2020

Submitted to Registrar for publication: YES

55 Day Comment Forum is underway. Began on 10/16/2020 and will end on 12/10/2020

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified twelve (12) compounds for recommended inclusion into the Code of Virginia.

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

1. **N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene),** 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 hallucinogenic properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. **4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alpha-PVP)**, 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.

2. **4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone)**, its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

3. **N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4-DMA)**, its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

4. **4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DiPT)**, its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

5. **alpha-pyrrolidinocyclohexanophenone (other name: alpha-PCYP)**, its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

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6. **3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8)**, its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers 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.

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

2. **Deschloroetizolam, 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.**

1. **7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam)**, 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 following compounds are classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

1. **methyl 2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTICA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. **ethyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5-fluoro-EMB-PICA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

Contact Information

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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 opioids.

a. N-[2-(dimethylamino)cyclohexyl]-N-phenylfuran-2-carboxamide (other name: Furanyl UF-17), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

b. N-[2-(dimethylamino)cyclohexyl]-N-phenylpropionamide (other name: UF-17), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Research chemicals.

a. 5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other name: Eutylone, bk-EBDB), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 1-(1,3-benzodioxol-5-yl)-2-(butylamino)-1-pentanone (other name: N-butylpentylone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. N-benzyl-3,4-dimethoxyamphetamine (other name: N-benzyl-3,4-DMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

e. 3,4-methylenedioxy-N-benzylcathinone (other name: BMDP), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agents.

a. Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other name: EMB-FUBINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. Methyl 2-[1-4-fluorobutyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until June 10, 2021, unless enacted into law in the Drug Control Act.

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 opioids.

a. N-phenyl-N-[1-(2-phenylmethyl)-4-piperidinyl]-2-furancarboxamide (other name: N-benzyl Furanyl norfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

b. 1-[2-methyl-4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone (other name: 2-methyl AP-237), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Research chemicals.

a. N-hexyl-3,4-dimethoxyamphetamine (other names: N-hexyl-3.4-DMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-heptyl-3,4-dimethoxyamphetamine (other names: N-heptyl-3.4-DMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 2-(isobutylamino)-1-phenylhexan-1-one (other names: N-Isobutyl Hexedrone, α-isobutylaminohexanphenone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. 1-(benzo[d][1,3]dioxol-5-yl)-2-(sec-butylamino)pentan-1-one (other name: N-sec-butyl Pentylone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

e. 2-fluoro-Deschloroketamine (other name: 2-(2-fluorophenyl)-2-(methylamino)-cyclohexanone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agents.

a. Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: MMB 2201), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. Methyl 2-[1-(4-penten-1-yl)-1H-indole-3-carboxamido]-3-methylbutanoate (other names: MMB022, MMB-4en-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-phenylpropanoate (other name: 5-fluoro-MPP-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

The placement of drugs listed in this subsection shall remain in effect until February 4, 2022, 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. N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene), 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 hallucinogenic properties.

2. 4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alpha-PVP), 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. 4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone), its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

4. N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4-DMA), its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

5. 4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DiPT), its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

6. alpha-pyrrolidinocyclohexanophenone (other name: alpha-PCYP), its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

7. 3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8), its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

Based on their chemical structure, the following compounds are expected to have depressant properties.

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

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

10. 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam), 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 following compounds are classified as cannabimimetic agents.

11. methyl 2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTICA), 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.

12. ethyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5-fluoro-EMB-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

Scheduling change for consistency with DEA - Exempt action

Included in agenda package:

Copy of Notice of Public Hearing on rescheduling

Amendment to regulation 18VAC110-20-323 for de-scheduling of epidiolex

Staff Note:

A public hearing was conducted before the meeting this morning.

Action is exempt from the provisions of the Administrative Process Act in accordance with § 2.2-4006 A 13.

Board action:

Adoption of final regulation in section 323

Notice of Public Hearing
Scheduling to Conform to Federal Actions

Pursuant to subsection E of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider amendments regulations for consistency with recent scheduling actions by the Drug Enforcement Administration. The public hearing will be conducted at **9:10 a.m. on December 10, 2020** with electronic access.

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

Delete #4 from 18VAC110-20-323 which will remove cannabidiol from Schedule V and by default, place it into Schedule VI.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1308 and 1312

ACTION: Interim final rule with request for comments.

Executive Summary

This rulemaking makes four conforming changes to DEA's existing regulations:

- It removes from control in schedule V under **21 CFR 1308.15**(f) a "drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols."

Statutory authority

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

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of 30 days from publication in the Federal Register of a final or interim final order or rule designating a substance as a controlled substance or rescheduling or descheduling a substance by amending its regulations in accordance with the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. The Board shall include a list of all substances it intends to schedule by regulation in such notice.

Project 6584 - Final

Board Of Pharmacy

De-scheduling of epidiolex

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

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

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

2. Adds Dronabinol ((-)-delta-9-trans tetrahydrocannabinol) in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II;

3. Deletes naldemedine from Schedule II;

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

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

~~6.~~ 5. Adds solriamfetol (2-amino-3-phenylpropyl carbamate), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule IV;

~~7.~~ 6. Adds noroxymorphone, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule II;

~~8.~~ 7. Adds lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide], including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule V;

~~9.~~ 8. Adds brexanolone (3%u03B1-hydroxy-5%u03B1-pregnan-20-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in Schedule IV;

~~10.~~ 9. Deletes naloxegol and 6%u03B2-naltrexol from Schedule II;

~~11.~~ 10. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP);

~~12.~~ 11. Adds ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA), methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-MDMB-PICA), and 1-5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (other name: 5F-CUMYL-PINACA), and their optical, positional, and geometric isomers, salts, and salts of isomers to Schedule I; and

~~13.~~ 12. Adds other name 5F-APINACA to N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48) which is currently placed in Schedule I.

Agenda Item: Consideration of amendments to incorporate changes currently in approved as pilots – medication carousels and RFID technology

Included in your agenda package are:

DRAFT amendments to 18VAC110-20-425 and NEW section 18VAC110-20-505 as posted with the Notice of Intended Regulatory Action (NOIRA) with changes recommended by the Regulation Committee

Copy of notice of comment page posted on the Townhall

Copy of comments on the NOIRA

Staff note:

Amendments would incorporate allowances for medication carousels with robotic systems and for use of RFID technology in provision of floor stock.

Board action:

1) The Board can adopt the proposed amendments as recommended; OR

2) The Board can reject those amendments or propose other amendments.

PRELIMINARY TEXT

18VAC110-20-425. Robotic pharmacy systems.

A. Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in barcoded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply:

1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.

2. The packaging, repackaging, stocking, and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.

3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards.

4. A written policy and procedure must be maintained and complied with and shall include at a minimum procedures for ensuring:

a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter and assigned barcodes;

b. Accurate stocking and restocking of the robotic pharmacy system;

c. Removing expired drugs;

d. Proper handling of drugs that may be dropped by the robotic pharmacy system;

e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

f. Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;

g. Accurate recording of any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution;

h. Appropriately performing an analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

i. Maintaining quality assurance reports.

5. All manual picks shall be checked by pharmacists.

6. If it is identified that the robot selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot. An investigation of the cause of the event shall be completed, and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format.

7. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include a summary indicating the date and description of all discrepancies that include discrepancies involving the packaging, repackaging, and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

~~8. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or 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. Intravenous admixture robotics may be utilized to compound drugs in compliance with § 54.1-3410.2 of the Code of Virginia and 18VAC110-20-321; however, a pharmacist shall verify the accuracy of all compounded drugs pursuant to 18VAVC110-20-270 B.

C. Medication carousels functioning with or without ~~that are a component of~~ a robotic pharmacy system in a hospital may be utilized to store and guide the selection of drugs to be dispensed or removed from the pharmacy under the following conditions:

1. The entry of drug information into the barcode database for assignment of a barcode to an individual drug shall be performed by a pharmacist who shall verify the accuracy of the barcode assignment.

2. A pharmacist is not required to verify the accuracy of a patient-specific drug removed from a medication carousel if:

a. The entry of the order for a patient-specific drug into the pharmacy's dispensing software is verified by a pharmacist for accuracy and is electronically transmitted to the medication carousel; and

b. The patient-specific drug removed from the medication carousel by a pharmacy technician is verified for accuracy by the pharmacy technician who shall scan each drug unit~~, each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug~~ removed from the medication carousel prior to dispensing, and a nurse or other person authorized to administer drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient.

3. A pharmacist is not required to verify the accuracy of drug removed from the medication carousel by a pharmacy technician that is intended to be placed into an automated drug dispensing system as defined in § 54.1-3401 of the Code of Virginia or distributed to another entity legally authorized to possess the drugs if:

a. The list of drugs to be removed from the medication carousel for loading or replenishing an individual automated dispensing system is electronically transmitted to the medication carousel; and

b. The drug removed from the medication carousel is verified for accuracy by the pharmacy technician by scanning each drug unit~~, each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug~~ removed from the medication carousel prior to leaving the pharmacy and delivering the drug to the automated drug dispensing system or distributed to another entity, and a nurse or other person authorized to administer drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient. If the drug is placed into an automated drug dispensing system located within the hospital, or the entity receiving the distributed drug, wherein a nurse or other person authorized to administer drug will not be able to scan each drug unit using barcode technology to verify the accuracy of the drug prior to patient administration, then a second verification for accuracy shall be performed by a pharmacy technician by scanning each drug unit~~, each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug~~ at the time of placing the drugs into the automated dispensing system.

~~3~~4. A pharmacist shall verify the accuracy of all drugs prior to dispensing or leaving the pharmacy that are manually removed from the medication carousel by a pharmacy technician without the use of barcode scanning technology to verify the accuracy of ~~selection of drug product to the robotic pharmacy system to guide~~ the selection of the drug product.

5. A pharmacist shall perform a daily random check for verification of the accuracy of 5% of drugs prepared that day utilizing the medication carousel technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of pharmacist verifying the accuracy of the process.

D. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or 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.

18VAC110-20-500. Licensed emergency medical services (EMS) agencies program.

A. The pharmacy may prepare a kit for a licensed EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this kit. A Except as authorized in 18VAC110-20-505, a pharmacist shall check each kit after filling and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The kit is sealed, secured, and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection of theft or loss.

a. The hospital pharmacy shall have a method of sealing the kits such that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.

c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.

3. Drugs and devices may be administered by an EMS provider upon an oral or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The EMS provider shall make a record of all drugs and devices administered to a patient.

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

5. Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year:

a. The record of filling and verifying the kit to include the drug contents of the kit, the initials of the pharmacist verifying the contents, the date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit, which shall be no later than the expiration date associated with the first drug or device scheduled to expire.

b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.

6. Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation shall be maintained in the pharmacy for a period of two years from the date of destruction.

7. The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

8. Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.

9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.

B. A licensed EMS agency may obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.

1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.

2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.

3. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.

4. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge, which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

5. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs or devices, Schedule II, III, IV, or V drugs shall remain in a separate, sealed container and shall only be exchanged in accordance with provisions of subsection A of this section.

18VAC110-20-505. Use of radio-frequency identification.

A. A hospital pharmacy may use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for licensed emergency medical services pursuant to 18VAC110-20-500 or other kits used as floor stock throughout the hospital under the following conditions:

1. A pharmacist shall be responsible for performing and verifying the accuracy of the following tasks:

a. The addition, modification, or deletion of drug information into the RFID database for assignment of a RFID tag to an individual drug; and

b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags.

2. A pharmacy technician may place the RFID tag on the drugs and a pharmacist shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.

3. A pharmacy technician may remove RFID-tagged drugs from the pharmacy's inventory whose RFID tags have been previously verified for accuracy by a pharmacist, and place the drugs into the kit's container. A pharmacy technician may then place the container into the pharmacy's device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.

4. A pharmacist shall perform a daily random check for verification of the accuracy of 5% of all kits prepared that day utilizing the RFID technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of pharmacist verifying the accuracy of the process.

5. Pharmacies engaged in RFID tagging of drugs shall be exempt from the requirements in 18 VAC 110-20-490 (C), 18 VAC 110-20-460 (A) and 18 VAC 110-20-355 (A)

6. All records required by this subsection shall be maintained for a period of one year from the date of verification by the pharmacist.

Agenda Item: Amendments to Guidance documents

Staff Note:

1) Several guidance documents need to be amended for consistency with changes in the Code in 2020. They are:

110-1 – Categories of facility licensure
110-13 – Collaborative practice agreements
110-29 - Guidance on physician dispensing licenses
110-44 – Naloxone protocol

2) Provisions in guidance document 110-41 were incorporated into regulations during the last periodic review, so it can now be repealed.

3) The Board voted at its last meeting to refer 10-39 - Continuous Hours Worked by a Pharmacist and Breaks – to consider anonymous complaint that pharmacy was not closed during required break time

4) Consideration of adoption of new guidance document on access by contractors to pharmaceutical processor

Regulation Committee recommendations:

To adopt amendments to guidance documents listed in first grouping to conform to changes in the Code

To repeal 110-41

To amend 110-39 as presented in agenda package and recommended

To adopt 110-40 – Contract employee access to pharmaceutical processors

Board action:

The Board can consider the recommendations of the Regulation Committee in a block. As a recommendation of a Board committee, the motion does not require a second. If a member would like to take one of the actions out of the block, he/she can request to do so (does not require a separate motion)

VIRGINIA BOARD OF PHARMACY

CATEGORIES OF FACILITY LICENSURE

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

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

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

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

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

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

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

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

WHOLESALE DISTRIBUTOR: This license authorizes the license holder to distribute prescription drugs to other entities authorized to possess prescription drugs for their further or retail distribution. This license does not authorize distribution of prescription drugs or devices to the ultimate user.

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

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

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

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

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

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

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

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

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

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

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

* **§ 54.1-3455. Schedule VI.**

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

1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.
2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.
3. **Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription"** or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" **or any device which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____ ."** (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.)

Adopted: December 10, 2020
Effective: February 5, 2021

VIRGINIA BOARD OF PHARMACY

Guidance Regarding Collaborative Practice Agreements

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

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

References:

Code of Virginia:

§ 54.1-3300. Definitions.

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

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

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

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

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

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

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

Regulations of the Board:

Adopted: December 10, 2020
Effective: February 5, 2021

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

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

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

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

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

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

Revised: December 10, 2020
Effective: February 4, 2021

Virginia Board of Pharmacy

Physicians Dispensing Drugs

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

Permitted Physicians – Practice as a pharmacy

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

Physicians Selling Drugs

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

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

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

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

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

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

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

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

2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408, except that a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a 72-hour supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;

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

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

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

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

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

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

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

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

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

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

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

§ 54.1-3302. Restrictions on practitioners of the healing arts.

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

§ 54.1-3304. Licensing of physicians to dispense drugs; renewals.

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

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

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

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

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

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

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

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

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

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

Revised: December 10, 2020
Effective: February 4, 2021

Virginia Board of Pharmacy

Naloxone Protocols

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.

§54.1-3408

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 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

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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.

I. Protocol for the Prescribing and Dispensing of Naloxone by Persons Listed in 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 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,
- Other school board employees or individuals contracted by a school board to provide school health services, ~~and~~
- Firefighters
- 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.

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 governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.

c. 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
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.	Naloxone 2 mg #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.	Narcan 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.

Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.		

d. **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.

e. **Required Instruction**

i. The dispenser shall 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. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf 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 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*
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	Naloxone 2 mg #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.	Narcan Nasal Spray 4mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until	Naloxone 0.4mg/ml #2 single-use 1ml vials SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. #2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles SIG: Use as directed for naloxone administration.

SIG: Use as directed for naloxone administration. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration.		emergency medical assistance arrives.	Dispenser must dispense 2 single-use 1ml vials, 2 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.

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. The dispenser shall 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. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services

website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf 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. 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! Opioid Overdose Reversal for Virginia Training Curriculum "Understanding and Responding to Opioid Overdose Emergencies Using Naloxone", available at http://www.dhp.virginia.gov/pharmacy/docs/osas-revive-training-curriculum.pdf

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

Changes a Pharmacist May Make to a Prescription Written for a Schedule II Controlled Substance

On November 19, 2007, the DEA published in the Federal Register the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed)…may not be modified orally." This, however, is in opposition to DEA's previous policy which permitted the pharmacist to make limited changes to a prescription written for a Schedule II controlled substance after oral consultation with the prescriber. DEA plans to resolve this confusion through future rulemaking and instructs pharmacists to adhere to state regulations or policy regarding changes that a pharmacist may make to a schedule II prescription. Therefore, through policy, the Board will allow a pharmacist to make limited changes to a schedule II prescription as stated below.

When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist is never permitted to make changes to the controlled substance prescribed (except for generic substitution permitted by law) or the prescriber's signature.

Revised: December 10, 2020
Effective: February 4, 2021

Virginia Board of Pharmacy

Guidance for Continuous Hours Worked by Pharmacists and Breaks

Regulations Governing the Practice of Pharmacy

18VAC110-20-110. Pharmacy permits generally.

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

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

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

Adopted: December 10, 2020
Effective: February 4, 2020

Virginia Board of Pharmacy

Contracted Employee Access to a Pharmaceutical Processor

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

Excerpt from 18VAC110-60-20

18VAC110-60-220. Pharmaceutical processor prohibitions.

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

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

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

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

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

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

Agenda Item: Adoption of a Notice of Periodic Review

Staff note:

Regulations are required to be reviewed every four years. Therefore, the Regulation Committee has recommended initiation of a periodic review of the following chapters:

18 VAC 110-20 Regulations Governing the Practice of Pharmacy
18 VAC 110-21 Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
18 VAC 110-30 Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
18 VAC 110-40 Regulations Governing Collaborative Practice Agreements
18 VAC 110-50 Regulations Governing Wholesale Distributors, Manufacturers and Warehousers

Board Action:

To accept the recommendation of the Regulation Committee to initiate a periodic review for the Chapters listed above. The notice of periodic review would be published on January 4, 2021 with comment received until February 4, 2021.

Virginia Board of Pharmacy
Inspection Report
December 10, 2020
Licenses Issued

	5/1/19-7/31/19	8/1/19-10/31/19	11/1/19-1/31/20	2/1/20-4/30/30	5/1/20-7/30/20	8/1/20-10/31/20	License Count 11/16/2020
Business CSR	36	32	23	25	28	23	1,457
CE Courses	0	0	0	0	2	0	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	11
Medical Equipment Supplier	3	7	1	4	5	4	232
Nonresident Manufacturer	11	11	10	7	6	3	200
Nonresident Medical Equipment Supplier	30	12	14	9	5	11	364
Non-resident Outsourcing Facility	1	0	1	0	3	2	33
Non-resident Pharmacy	27	18	21	33	22	29	826
Non-resident Third Party Logistics Provider	58	42	17	14	5	12	150
Non-resident Warehouser	10	16	6	19	5	11	70
Non-resident Wholesale Distributor	22	13	8	8	11	5	624
Non-restricted Manufacturer	2	0	0	1	1	0	32
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmaceutical Processor			1	1	1	1	4
Pharmacist	316	328	187	120	309	301	16,044
Pharmacist Volunteer Registration	2	1	0	0	0	0	0
Pharmacy	13	10	11	10	12	7	1,762
Pharmacy Intern	65	225	43	160	76	177	1,639
Pharmacy Technician	426	433	485	345	333	447	13,897
Pharmacy Technician Training Program	3	3	1	0	2	7	126
Physician Selling Controlled Substances	25	18	23	28	22	24	669
Physician Selling Drugs Location	7	4	3	6	5	4	175
Pilot Programs	1	0	1	0	1	0	22
Registered Physician For CBD/THC-A Oil	52	59	39	58	68	106	567
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	1	0	0	1	1	0	43
Third Party Logistics Provider	1	0	0	1	0	0	6
Warehouser	0	1	3	2	1	4	115
Wholesale Distributor	1	3	0	0	2	1	67
Total	**1,113**	**1,236**	**898**	**852**	**926**	**1,179**	**39,146**

Virginia Board of Pharmacy
Inspection Report
December 10, 2020

Inspections Completed

	5/1/19-7/31/19		8/1/19-10/31/19		11/1/19-1/31/20		2/1/20-4/30/20		5/1/20-7/31/20		8/1/20-10/31/20	
License Type											Total	Virtual
Controlled Substances Registration	145		177		111		145		153		192	117
Medical Equipment Supplier	21		19		36		33		35		25	10
Non-restricted Manufacturer	3		0		0		1		2		0	
Permitted Physician	0		0		1		0		0		0	
Physician Selling Drugs Location	39		30		39		18		9		8	6
Restricted Manufacturer	1		0		0		2		1		0	
Third Party Logistics Provider	1		2		0		3		2		0	
Warehouse	10		7		11		16		27		16	7
Wholesale Distributor	11		7		5		5		15		12	6
Pharmacy	348		284		274		184		73		98	21
Pilot	0		0		0		6		8		0	
Pharmaceutical Processor					6		1		4		4	
Total	**579**		**526**		**483**		**414**		**329**		**355**	**167**
Pharmacy (0201) Inspections												
Change of Location	7		5		5		4		6		7	3
New	13		10		10		9		11		9	4
Reinspection	9		15		10		7		8		6	3
Remodel	53		49		39		42		30		31	10
Routine	253		193		207		121		15		45	1
Focus	2		3		2		1		2		0	
Federal Agency	11		9		0		0		0		0	
Compliance	0		0		1		0		1		0	
Pilot	0		0		0		0		0		0	
Total	**348**		**284**		**274**		**184**		**73**		**98**	**21**
Pharmacy Routine Inspections												
No Deficiency	98	39%	64	33%	73	35%	42	35%	7	47%	11	24%
Deficiency	76	34%	66	34%	70	34%	34	28%	3	20%	17	38%
Deficiency & IPHCO	79	31%	63	33%	64	31%	45	37%	5	33%	17	38%
Total	**253**		**193**		**207**		**121**		**15**		**45**	

Virginia Board of Pharmacy
December 10, 2020
Frequently Cited Deficiencies
May 2019 - October 2020

Deficiencies Numbered Less 1-100 (Formerly Major Deficiency)	Cumulative Total
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is requirec	94
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	47
14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	34
7. Change of location or remodel of pharmacy without submitting application or Board approval	25
20. Pharmacist not checking and documenting repackaging or bulk packaging	25
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (12/12/13 New Minor 44 if no drug loss)	21
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	20
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	20
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	20
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	20
Deficiencies Numbered Greater Than 100 (Formerly Minor Deficiency)	**Cumulative Total**
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	121
123. Engaging in remote processing not in compliance	85
127. Repackaging records and labeling not kept as required or in compliance	72
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.	65
108. Emergency access alarm code/key not maintained in compliance	50
130a. Compounded products not properly labeled	49
124. Labels do not include all required information	48
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	48
119. Not properly documenting partial filling of prescriptions	40
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	39

Virginia Board of Pharmacy
Inspection Report
December 10, 2020

Deficiencies 1 - 100
(Formerly Major Deficiency)

	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	8/20-10/20	Total	8/20-10/20	Cumulative
Routine Inspections Completed	**253**	**193**	**207**	**121**	**73**	**73**	**920**	**Repeat**	**Repeat**
Total Deficiencies	**123**	**119**	**111**	**74**	**8**	**34**	**469**	**1**	**267**
Average Deficiencies per Inspection	**0.5**	**0.6**	**0.5**	**0.6**	**0.1**	**0.5**	**0.5**		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	0	0	4	1	0	0	5		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	14	7	15	6	0	5	47		3
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	1	4	4	2	0	0	11		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	1	0	0	0	0	0	1		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	2	6	5	2	0	1	16		1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	1	0	1	0	0	0	2		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	11	4	2	5	2	1	25		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	0	0	3	0	0	0	3		1
9. Alarm not operational or not being set	0	0	1	1	0	0	2		
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (12/12/13 New Minor 44 if no drug loss)	2	11	5	1	1	1	21		1

Virginia Board of Pharmacy
Inspection Report
December 10, 2020

Deficiencies 1 - 100
(Formerly Major Deficiency)

	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	8/20-10/20	Total	8/20-10/20	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	2	7	3	0	0	0	12		1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	3	1	3	2	0	0	9		
12. Storage of prescription drugs not in the prescription department	5	5	3	1	1	0	15		11
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (12/12/13 New Minor 46 if no drug loss)	3	2	4	0	0	0	9		4
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	8	5	4	3	0	0	20		5
14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	6	7	8	6	1	6	34		8
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	31	19	17	18	2	7	94	1	120
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	4	5	3	6	0	2	20		4
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	0	3	0	2	0	1	6		
18. Records of dispensing not maintained as required	1	4	1	0	0	0	6		1
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	2	3	2	1	0	1	9		3

Virginia Board of Pharmacy
Inspection Report
December 10, 2020

Deficiencies 1 - 100
(Formerly Major Deficiency)

	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	8/20-10/20	Total	8/20-10/20	Cumulative
20. Pharmacist not checking and documenting repackaging or bulk packaging	10	5	5	3	0	2	25		18
20a. Pharmacist not documenting final verification of non-sterile compounding	5	1	2	2	0	0	10		4
20b. Pharmacist not documenting final verification of sterile compounding	1	3	4	0	0	1	9		16
21. No clean room	0	0	0	0	1	0	1		
21a. Performing sterile compounding outside of a clean room (Added 12/12/13)	0	0	0	0	0	0	0		
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed	0	1	0	1	0	0	2		
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	0	0	0	1	0	0	1		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	0	0	0	0	0	0	0		
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	0	0	0	0	0	0		2
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounding of sterile preparations.	0	1	0	0	0	0	1		1
25b. . High-risk compounded sterile preparations intended for use are improperly stored	0	0	0	0	0	0	0		

Virginia Board of Pharmacy
Inspection Report
December 10, 2020

Deficiencies 1 - 100
(Formerly Major Deficiency)

	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	8/20-10/20	Total	8/20-10/20	Cumulative
25c. Documentation that a person who failed a media-fill test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	0	0	0	0	0	0		
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	4	5	6	3	0	2	20		33
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	0	1	0	0	0	1		1
27. Compounding using ingredients in violation of 54.1-3410.2.	0	0	0	0	0	0	0		1
28. Compounding copies of commercially available products	1	2	0	0	0	1	4		1
29. Unlawful compounding for further distribution by other entities	1	1	0	1	0	1	4		
30. Security of after-hours stock not in compliance	0	0	0	1	0	0	1		
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	0	0	0	0	0	0	0		
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	4	6	4	4	0	2	20		22
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	1	0	1	0	0	2		1
34. Combined with Minor 42 – 12/2013.	0	0	0	0	0	0	0		
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	0	0	1	0	0	0	1		1

Virginia Board of Pharmacy
Inspection Report
December 10, 2020

Deficiencies Above 100
(Formerly Minor Deficiency)

	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	8/20-10/20	Total	8/20-10/20	Cumulative
Routine Inspections Completed	**253**	**193**	**207**	**121**	**73**	**73**	**920**	**Repeat**	**Repeat**
Total Deficiencies	**238**	**239**	**208**	**97**	**5**	**53**	**787**	**8**	**384**
Average Deficiencies per Inspection	**0.9**	**1.2**	**1.0**	**0.8**	**0.1**	**0.7**	**0.9**		
101. Repealed 6/2011	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
102. Special/limited-use scope being exceeded without approval	0	1	0	0	0	0	1		
103. Repealed 12/12/2013 - Decreased hours of operation without public/Board notice	0	0	0	0	0	0	0		
104. Sink with hot and cold running water not available within the prescription department.	3	1	3	2	0	0	9		7
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	1	0	4	1	0	0	6		7
106. Prescription department substantially not clean and sanitary and in good repair	2	0	0	0	0	0	2		2
107. Current dispensing reference not maintained	2	2	2	0	0	1	7		11
108. Emergency access alarm code/key not maintained in compliance	20	10	11	4	2	3	50	1	19
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)	31	38	37	11	0	4	121	3	56
110. Storage of paraphernalia/Rx devices not in compliance	0	0	0	0	0	0	0		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	0	0	0	0	0	1	1		2
112. Biennial taken late but within 30 days	2	0	1	0	0	1	4		
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.	21	16	15	6	0	7	65		63

Virginia Board of Pharmacy
Inspection Report
December 10, 2020

Deficiencies Above 100
(Formerly Minor Deficiency)

	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	8/20-10/20	Total	8/20-10/20	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	1	2	0	3	0	0	6		
115. Other records of distributions not maintained as required	0	0	1	1	0	0	2		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	12	11	7	5	1	3	39		2
117. Minor 17 combined with Minor 16 – 6/2011	0	0	0	0	0	0	0		
118. Schedule II emergency oral prescriptions not dispensed in compliance	1	1	0	0	0	0	2		
119. Not properly documenting partial filling of prescriptions	13	10	11	4	0	2	40		28
120. Offer to counsel not made as required	0	0	0	0	0	0	0		
121. Prospective drug review not performed as required	0	0	0	0	0	1	1	1	1
122. Engaging in alternate delivery not in compliance	3	13	6	4	0	5	31		11
123. Engaging in remote processing not in compliance	25	23	14	14	0	9	85	1	11
124. Labels do not include all required information	12	14	12	5	0	5	48	1	16
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	8	10	7	2	1	0	28		10
126. Special packaging not used or no documentation of request for non-special packaging	2	1	0	0	0	0	3		5
Repackaging, specialty dispensing, compounding:									
127. Repackaging records and labeling not kept as required or in compliance	20	20	19	10	1	2	72		38
128. Unit dose procedures or records not in compliance	0	0	0	0	0	0	0		
129. Robotic pharmacy systems not in compliance	0	0	0	0	0	0	0		
130. Required compounding/dispensing/distribution records not complete and properly maintained	9	8	9	2	0	2	30		16
130a. Compounded products not properly labeled	14	14	15	5	0	1	49		17

Virginia Board of Pharmacy
Inspection Report
December 10, 2020

Deficiencies Above 100
(Formerly Minor Deficiency)

	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	8/20-10/20	Total	8/20-10/20	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	1	7	7	2	0	2	19	1	1
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	7	8	6	0	0	1	22		8
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	0	1	0	0	0	0	1		
Hospital specific or long-term care specific:					0				
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	0	0	0	0	0	0	0		
135. Policies and procedures for drug therapy reviews not maintained or followed	0	0	0	0	0	0	0		
136. After hours access to a supply of drugs or records not in compliance	0	0	1	0	0	0	1		
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	0	1	0	1	0	0	2		2
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	2	3	0	1	0	1	7		1
139. Emergency medical services procedures or records not in compliance	1	2	2	0	0	0	5		5
140. Emergency kit or stat-drug box procedures or records not in compliance	0	3	2	1	0	0	6		7
141. Maintaining floor stock in a long-term care facility when not authorized	0	0	0	0	0	0	0		
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	14	14	12	6	0	2	48		20
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	0	0	0	0	0	0	0		

Virginia Board of Pharmacy
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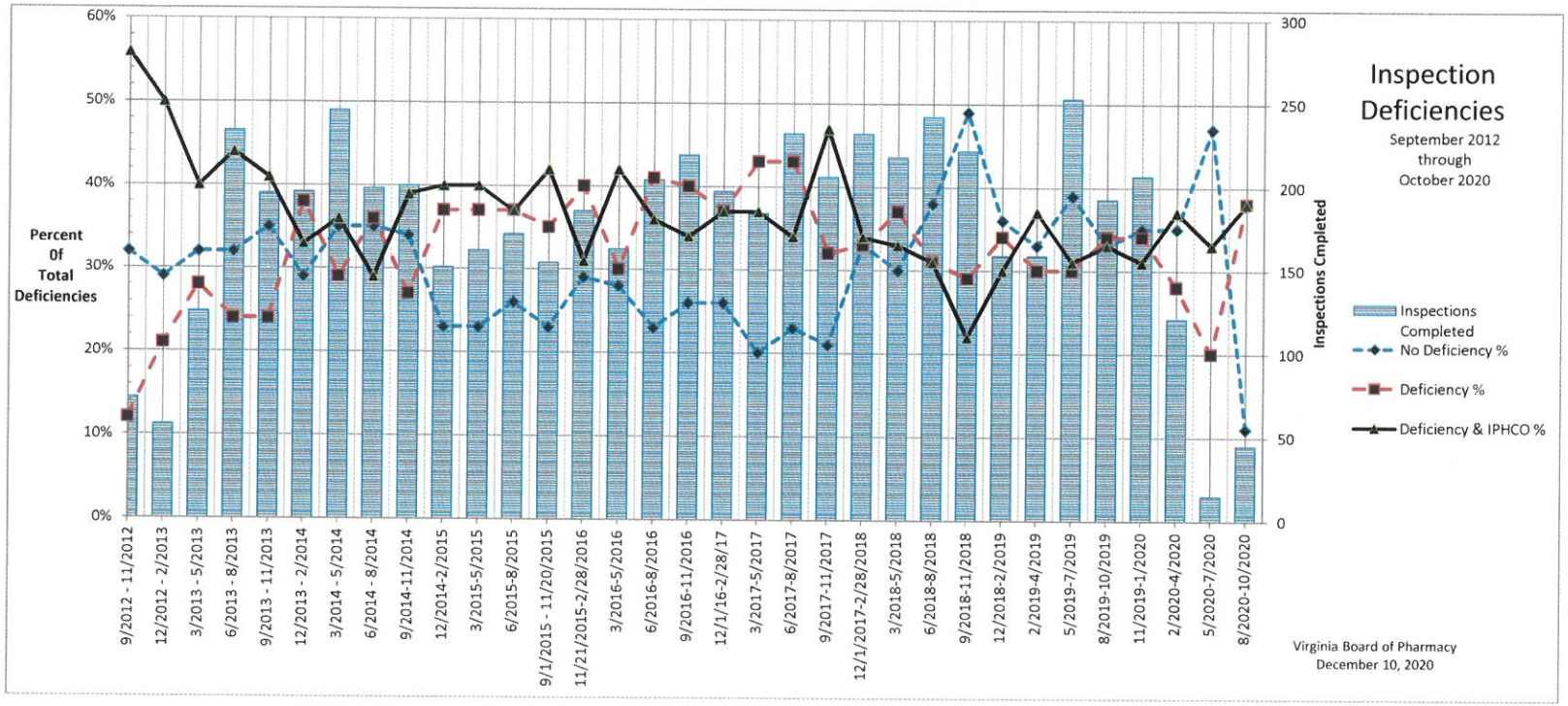
Deficiencies Above 100
(Formerly Minor Deficiency)

	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	8/20-10/20	Total	8/20-10/20	Cumulative
144. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (Added 12/12/13)	0	0	0	0	0	0	0		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	0	0	0	0	0	0	0		4
146. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (Added 12/12/13)	0	0	0	0	0	0	0		2
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	0	1	0	1	0	0	2		3
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18)	11	4	4	6	0	0	25		3


Inspection Deficiencies
September 2012 through October 2020
Percent Of Total Deficiencies
Inspections Cmpleted
60%
50%
40%
30%
20%
10%
0%
300
250
200
150
100
50
0
Inspections Completed
No Deficiency %
Deficiency %
Deficiency & IPHCO %
9/2012 - 11/2012
12/2012 - 2/2013
3/2013 - 5/2013
6/2013 - 8/2013
9/2013 - 11/2013
12/2013 - 2/2014
3/2014 - 5/2014
6/2014 - 8/2014
9/2014-11/2014
12/2014-2/2015
3/2015-5/2015
6/2015-8/2015
9/1/2015 - 11/20/2015
11/21/2015-2/28/2016
3/2016-5/2016
6/2016-8/2016
9/2016-11/2016
12/1/16-2/28/17
3/2017-5/2017
6/2017-8/2017
9/2017-11/2017
12/1/2017-2/28/2018
3/2018-5/2018
6/2018-8/2018
9/2018-11/2018
12/2018-2/2019
2/2019-4/2019
5/2019-7/2019
8/2019-10/2019
11/2019-1/2020
2/2020-4/2020
5/2020-7/2020
8/2020-10/2020
Virginia Board of Pharmacy
December 10, 2020

Pharmaceutical Processors Report-December 10, 2020

- Dharma Pharmaceuticals, LLC (Bristol) began dispensing cannabis oil products to registered patients in mid-October. Currently they have 15 approved products.
- Green Leaf Medical of Virginia, Inc. (Richmond) will begin dispensing cannabis oil products before the end of November. Currently they have eight approved products and have also purchased products from Dharma Pharmaceuticals to dispense from their location.
- Columbia Care of Eastern Virginia, LLC (Porsmouth) and Dalitso, LLC (Manassas) are both in the cultivation phase with plans to begin dispensing cannabis oil products in the first quarter of 2021.
- The RFA for a pharmaceutical processor permit in Health Service Area I was posted on September 25, 2020 with a deadline date of December 4, 2020 at 2:00 pm. There have been many inquiries from potential applicants.
- The Board is receiving, on average, 300 patient applications per week
- The Board is in the process of obtaining a temporary staff employee to assist with the processing of applications and will be recruiting for a full time administrative specialist to support the program.
- The Board is exploring a new patient registration platform/process to address the increase in patient registrations currently and expected next year due to anticipated legislative changes.

Pharmaceutical Processors Program-By the Numbers
As of 11/20/2020

Registered Practitioners	567
Registered Patients	7052
Registered Parents/Guardians	73
Registered Agents	13

Discipline Program Report

Open Cases as of 11-13-2020:

	PC	APD	Investigation	FH	IFC	Entry	Pending Closure	TOTALS
Patient Care Cases	65	2	63	7	13	1	0	151
Non-Patient Care Cases	97	3	28	2	5	1	7	143
						TOTAL:		**294**

- Patient care cases:
  - There are sixty-five (65) patient care cases at Probable Cause compared to sixty-seven reported for September 2020. Twenty-one (21) of these cases are pending an IFC or FH.
  - There are fourteen (14) fewer cases compared to September 2020.
- Non-patient care cases (inspection cases or compliance related cases):
  - The number of cases is five (5) fewer than reported in September 2020.
- There are twelve (12) cases > 365 days – these are all either at CAP, Formal Hearing, or Informal Conference status.

Upcoming Disciplinary Proceedings:

January 12, 2021	IFC-A	Patricia Richards-Spruill/Bill Lee
January 22, 2021	Formal Hearings Confirmed: Bill Lee, Glenn Bolyard, Dale St.Clair, Kris Ratliff, Jim Jenkins, Sarah Melton, Patricia Richards-Spruill, Bernie Henderson	
January 26, 2021	IFC-B	Glenn Bolyard/Ryan Logan
February 10, 2021	IFC-C	Cheryl Nelson/Dale St. Clair
February 16, 2021	IFC-A	Patricia Richards-Spruill/Bill Lee

Executive Director's Report – December 10, 2020

Newly Appointed Citizen Board Member:

- Bernard L. "Bernie" Henderson, Jr.

Recognition of Immediate Past Board Members

- Tentatively scheduled for June 2020

Board Reports Recently Submitted (included in agenda packet):

- Report on Drug Disposal
- Report on Development of Protocols for Pharmacist-Initiation of Treatment
- Report on Expansion of Statewide Standing Orders/Development of Protocols for Pharmacist-Initiation of Treatment

Recent Meetings Attended:

- COVID-19 Pharmacy Services Subcommittee of the Healthcare Coordination Committee
- NABP Monthly Executive Directors Meeting
- NABP Executive Committee
- NABP Solutions Board of Managers
- Marijuana Legalization Workgroup
- Medical Cannabis Workgroup
- Forensic Science Board
- New Board Member Orientation Meeting
- 2020 FDA Intergovernmental Working Meeting

Presentations:

- Academy of Medical Cannabis – Pharmaceutical Processor Update
- Rx Partnership – Law Update
- VSHP Fall Seminar - Law Update
- VACDS Annual Meeting - Law Update
- Marijuana Legalization Fiscal and Structural Subgroup – Processor Program Update

Staffing:

- Continuing to telework with limited hours on-site
- New facility licensing specialist hired – Sorayah Hayden
- Recruiting for temp employee for processor licensing position
- Staff members on approved extended leave; temporary shifting of responsibilities

Report on Drug Disposal

Virginia Department of Health Professions

Pursuant to Pursuant to Chapter 614 (HB 1531)

October, 2020

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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

www.dhp.virginia.gov
TEL (804) 367- 4400
FAX (804) 527- 4475

MEMORANDUM

TO: The Honorable Mark D. Sickles
Chair, House Health, Welfare, and Institutions
Pocahontas Building, Room W1312
900 East Main Street
Richmond, Virginia 23219

The Honorable L. Louise Lucas
Chair, Senate Education and Health
Pocahontas Building, Room E604
900 East Main Street
Richmond, Virginia 23219

FROM: Caroline D. Juran, RPh
Executive Director, Virginia Board of Pharmacy
Department of Health Professions

DATE: October 28, 2020

RE: **Report on Drug Disposal**

This report is provided to you pursuant to Chapter 614 of the 2020 Acts of the Assembly. Please feel free to contact me at (804) 367-4578 or caroline.juran@dhp.virginia.gov should you have any questions.

Drug Disposal

Virginia Board of Pharmacy

Pursuant to Chapter 614 (HB 1531)

Chapter 614 of the 2020 Acts of the Assembly specifies:

Be it enacted by the General Assembly of Virginia:

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

In accordance with the legislative provision, the Board of Pharmacy reports the following information:

ASSEMBLY OF STAKEHOLDERS:

Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the Board of Pharmacy convened a virtual meeting of stakeholders on July 21, 2020.

The meeting of stakeholders was comprised of the following individuals:

Cheryl Nelson, *Workgroup Chairman*
William Lee, *Board Member*
Glenn Bolyard, *Board Member*
Christina Barrille, *Executive Director, Virginia Pharmacists Association*
Nicole Lawter, *representing Virginia Association of Free and Charitable Clinics*
Natalie Nguyen, *representing Virginia Society of Health-System Pharmacists*
Jodi Roth, *representing Virginia Association of Chain Drug Stores*

Justin Wood, *Diversion Program Manager, Washington Field Division, Drug Enforcement Administration (DEA)*
Jennifer Wicker, *representing Virginia Hospital and Healthcare Association*

The following individuals staffed the meeting:
Caroline Juran, RPh, *Executive Director, Board of Pharmacy*
Elaine Yeatts, *Senior Policy Analyst, DHP*
Sammy Johnson, *Pharmacist, Deputy Executive Director, Board of Pharmacy*
Beth O'Halloran, *Deputy Executive Director, Board of Pharmacy*
Ellen Shinaberry, PharmD, *Deputy Executive Director, Board of Pharmacy*
Kiara Christian, *Executive Assistant, Board of Pharmacy*

FINDINGS AND RECOMMENDATIONS:

The stakeholders reviewed past actions taken to address proper drug disposal which includes: the adoption of Board of Pharmacy regulation 18VAC110-20-211 which authorizes any narcotic treatment program, hospital or clinic with an on-site pharmacy, or pharmacy to participate as an authorized collector of previously dispensed drugs for the purpose of destruction in compliance with federal requirements; adoption of Guidance Document 110-47, pursuant to HB 2046 passed in 2017, containing guidelines for the provision of counseling and information regarding proper drug disposal of unused dispensed drugs; the 2019 Report of the Joint Commission on Health Care, Report Document No. 272, *Pharmacy Drug Disposal Program*; the 2019 Board of Pharmacy *Report on Effort to Promote Drug Disposal Pursuant to the 2019 Appropriations Act,* and educational information posted on the websites of the Board of Pharmacy, other State and federal agencies, or national organizations.

The stakeholders offered the following recommendations which were subsequently adopted by the Board of Pharmacy on September 9, 2020:

- Post additional links on the Board of Pharmacy website to lists of authorized collectors as compiled by the Drug Enforcement Administration (DEA) and the National Association of Boards of Pharmacy which may include law enforcement agencies;
- Relocate drug disposal information on Board of Pharmacy website to a more prominent location;
- Emphasize to pharmacists and other providers the importance of informing patients, at the point of receiving new prescriptions, of proper drug disposal;
- Recommend to the DEA that it consider requesting the U.S. Congress expand allowances for prescribers to participate as an authorized drug collector to receive unused medications from patients for destruction purposes;
- Recommend standardization of drug disposal information published by State agencies to improve communication to consumers; and
- Recommend information on proper drug disposal be available to consumers in different languages.

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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Henrico, Virginia 23233-1463

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MEMORANDUM

TO: The Honorable Ralph S. Northam
Governor of Virginia
P.O. Box 1475
Richmond, VA 23218

The Honorable Mark D. Sickles
Chair, House Health, Welfare, and Institutions
Pocahontas Building, Room W1312
900 East Main Street
Richmond, Virginia 23219

The Honorable L. Louise Lucas
Chair, Senate Education and Health
Pocahontas Building, Room E604
900 East Main Street
Richmond, Virginia 23219

FROM: Caroline D. Juran, RPh
Executive Director, Virginia Board of Pharmacy
Department of Health Professions

DATE: October 28, 2020

RE: **Report on Development of Protocols for Pharmacist-Initiation of Treatment**

Pursuant to HB 1506, passed during the 2020 General Assembly Session, the Board of Pharmacy is providing the required report. Please feel free to contact me at (804) 367-4578 or caroline.juran@dhp.virginia.gov should you have any questions.

Report on Development of Protocols for Pharmacist-Initiation of Treatment

Virginia Department of Health Professions

Pursuant to HB 1506

October, 2020

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Report on Development of Protocols for Pharmacist-Initiation of Treatment

Virginia Board of Pharmacy

Pursuant to HB 1506

The third enactment clause of HB 1506 specifies:

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

In accordance with the legislative provision, the Board of Pharmacy reports the following information:

WORK GROUP:

Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the Board of Pharmacy convened a virtual work group meeting on September 21, 2020.

The work group was comprised of the following voting individuals:

Ryan Logan, RPh, *Work group Chairman, Member, Board of Pharmacy*

Sarah Melton, PharmD, *Member, Board of Pharmacy (departed early)*
Dale St.Clair, PharmD, *Member, Board of Pharmacy (replaced Dr. Melton)*
Jake Miller, D.O., *Member, Board of Medicine*
Brenda Stokes, M.D., *Member, Board of Medicine*
Stephanie Wheawill, PharmD, *VDH, Director of Division of Pharmacy Services*
Kristen Collins, MPH, *Policy Analyst, Office of Epidemiology, VDH*
Diana Jordan, *Director, Division of Disease Prevention, VDH*
Joe DiPiro, PharmD, *Dean, VCU School of Pharmacy*
Michael Justice, PharmD, *Assistant Professor, Appalachian College of Pharmacy*
Al Arias, M.D., *VCU, School of Medicine*
John R. Lucas, D.O., *Edward Via College of Osteopathic Medicine*
Donna Francioni-Proffitt, RPh, *Pharmacy Program Manager, DMAS*
Doug Gray, *Executive Director, Virginia Association of Health Plans*
Kelly Goode, PharmD, *Virginia Pharmacist Association*
Terri Babineau, M.D., *Medical Society of Virginia*
Kerri Musselman, PharmD, *Virginia Society of Health-System Pharmacists*
Summer Williams Kerley, PharmD, *Virginia Association of Chain Drug Stores*
Lincy Abraham, PharmD, *National Association of Chain Drug Stores*

The following individuals staffed the work group meeting:
Caroline Juran, RPh, *Executive Director, Board of Pharmacy*
William Harp, M.D., *Executive Director, Board of Medicine*
Elaine Yeatts, *Senior Policy Analyst, DHP*
Jim Rutkowski, *Assistant Attorney General*
Sammy Johnson, *Pharmacist, Deputy Executive Director, Board of Pharmacy*
Ellen Shinaberry, PharmD, *Deputy Executive Director, Board of Pharmacy*
Kiara Christian, *Executive Assistant, Board of Pharmacy*

RECOMMENDATIONS:

Vaccines

The work group was generally supportive and voted 15:1 with 1 abstention to include in the legislative report a recommendation that pharmacists should be authorized to order and administer vaccines included on the immunization schedule published by the Centers for Disease Control and Prevention for persons 18 years of age and older, to require reporting to the Virginia Immunization Information System, and to inform the patient's primary care provider (PCP) of the administration or if none, to counsel the patient on the importance of having a relationship with a PCP. (motion by Melton, seconded by Miller; Babineau opposed; Arias abstained)

Tobacco Cessation

There was some concern expressed by physician members for how a pharmacist would monitor certain prescription-only drug therapies requiring the monitoring of patient behavioral aspects. Pharmacist members generally believed that monitoring is currently being performed successfully

through questionnaires in other states, could be addressed through a limitation of day supply or required follow-up appointments, and stated that pharmacy students are taught to recognize suicidal behavior, how to perform patient assessments, and must complete a mental health therapeutic module, along with a semester-long communication course.

After a failed motion to exclude these prescription-only drugs from an allowance for pharmacists to initiate treatment, the work group voted 10:5 that pharmacists should be authorized to initiate treatment with and dispense and administer drugs approved by the United States Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. (motion by Melton, seconded by Abraham; supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan; opposed by Miller, Stokes, Arias, Lucas, Babineau; Melton departed meeting prior to vote; Collins and Jordan not present for vote).

Tuberculin Purified Protein Derivative for Tuberculosis Testing

The work group appeared to be in agreement on this subject and voted 17:0 to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer tuberculin purified protein derivative for tuberculosis testing. (motion by Lucas, seconded by DiPiro; supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan, Miller, Stokes, Arias, Lucas, Babineau, Collins, and Jordan)

Controlled Substances or Devices for the Treatment of Diseases or Conditions for which Clinical Decision Making can be guided by a CLIA-Waived Test:

Influenza

There was some disagreement regarding the use of a CLIA-waived test to guide clinical decisions regarding influenza. A physician member expressed concern for possibly overlooking pneumonia. Another physician member expressed support based on ability to increase timeliness in patients starting medication treatment. Pharmacist members generally supported the ability, indicated seventeen states allow use of CLIA-waived tests, and stated that the prescription-only drug, Tamiflu, is slated to move to an over-the-counter status.

The work group voted 15:3 to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of influenza, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by DiPiro; supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan, Stokes, Lucas, Collins, Justice, and Jordan; opposed by Babineau, Miller, Arias)

Helicobacter Pylori Bacteria

There appeared to be general agreement among physician and pharmacist members that diagnosing medical conditions involving Helicobacter Pylori bacteria was complex. The work group voted

13:0 with 4 abstentions to exclude Helicobacter Pylori as a condition for pharmacists to initiate treatment with and dispense and administer controlled substances or devices.

Urinary Tract Infection

Two physician members expressed concern for using a CLIA-waived test to guide clinical decisions regarding urinary tract infections and stated that a more complex culture test is necessary. Pharmacist members appeared to disagree. After a failed motion with a vote of 7:8 with 3 abstentions to exclude urinary tract infections as a recommendation in the legislative report, the work group voted 10:5 with 3 abstentions to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of urinary tract infections, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by Abraham; supported by Logan, St.Clair, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Justice; opposed by Miller, Stokes, Arias, Lucas, Babineau; Wheawill, Collins, Jordan abstained)

Group A Streptococcus Bacteria

There was some disagreement regarding the use of CLIA-waived tests for group A streptococcus bacteria. Some physician members expressed concern for the possibility of false negative or false positive tests, that a serious condition could be missed, and that diagnostic techniques are needed. Pharmacist members indicated U.S. data suggests these CLIA-waived tests can be helpful, reiterated that seventeen states allow pharmacist-use of CLIA-waived tests, and stated that the protocol should require a pharmacist to refer a symptomatic patient with a negative CLIA-waived test to a primary care provider for a confirmatory lab test.

After a failed motion with a vote of 7:8 with 3 abstentions to exclude Group A Streptococcus bacteria as a recommendation, the work group voted 8:6 with 4 abstentions to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of Group A Streptococcus bacteria, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by Abraham; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice; opposed by Miller, Stokes, Arias, Lucas, Proffitt, Babineau; Wheawill, Collins, Jordan, Gray abstained)

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

VDH members indicated a well-constructed statewide protocol with a thorough assessment could meet public need, VDH has experience working with pharmacists performing HIV testing, and that Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP) could be built into a protocol. The work group voted unanimously 18:0 to include in the legislative report a

recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer 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. (motion by Abraham, seconded by DiPiro; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice, Miller, Stokes, Arias, Lucas, Proffitt, Babineau, Wheawill, Collins, Jordan, and Gray)

Drugs other than Controlled Substances, including Drugs Sold Over-the-Counter, for which the Patient's Health Insurance Provider Requires a Prescription

The work group acknowledged that this subject appears to have already been addressed by a statewide protocol recently adopted by the Board. It was noted that the term "drugs" as defined in law does not include "devices". The workgroup supported a pharmacist's ability to prescribe devices such as glucometers, controlled paraphernalia such as insulin pen needles and syringes, and possibly other durable medical equipment.

The work group voted 17:0 with 1 abstention to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer devices, controlled paraphernalia such as insulin pen needles and hypodermic syringes, and possibly other durable medical equipment to lower out-of-pocket expenses, not covered by a health plan. (motion by Goode, seconded by St.Clair; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice, Miller, Stokes, Arias, Lucas, Proffitt, Babineau, Wheawill, Collins, and Gray; Jordan abstained.)

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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MEMORANDUM

TO: Jeff Lunardi
Executive Director
Joint Commission on Health Care
600 E. Main Street
3rd Floor, Ste 301
Richmond, VA 23219

FROM: Caroline D. Juran, RPh
Executive Director, Virginia Board of Pharmacy
Department of Health Professions

DATE: October 28, 2020

RE: **Report on Expansion of Statewide Standing Orders/Development of Protocols for Pharmacist-Initiation of Treatment**

This report is provided to you pursuant to a written request from the Joint Commission on Health Care dated February 10, 2020. Please feel free to contact me at (804) 367-4578 or caroline.juran@dhp.virginia.gov should you have any questions.

Report on Expansion of Statewide Standing Orders/Development of Protocols for Pharmacist-Initiation of Treatment

Virginia Department of Health Professions

Pursuant to Request from Joint Commission on Health Care and HB 1506

October, 2020

Expansion of Statewide Standing Orders/Development of Protocols for Pharmacist-Initiation of Treatment

Virginia Board of Pharmacy

Pursuant to Request from Joint Commission on Health Care and HB 1506

The request from Joint Commission on Health Care (JCHC), dated February 10, 2020 specifies:

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

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

The third enactment clause of HB 1506 specifies:

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

controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription. The work group shall report its findings and recommendations to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2020.

In accordance with the request from the JCHC and the legislative provision, the Board of Pharmacy reports the following information:

WORK GROUPS:

Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the Board of Pharmacy convened two virtual work group meetings on August 4, 2020 and August 17, 2020.

The work group was comprised of the following voting individuals:

Ryan Logan, RPh, *Work group Chairman, Member, Board of Pharmacy*
Kris Ratliff, DPh, *Chairman, Board of Pharmacy*
Jake Miller, D.O., *Member, Board of Medicine*
Brenda Stokes, M.D., *Member, Board of Medicine*
Emily Yeatts, *Reproductive Health Supervisor, VDH*
Stephanie Wheawill, PharmD, *VDH, Director of Division of Pharmacy Services*

A second work group convened a virtual meeting on September 21, 2020 to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older of drugs and devices for other conditions as specified in the third enactment clause of HB 1506.

The work group was comprised of the following voting individuals:

Ryan Logan, RPh, *Work group Chairman, Member, Board of Pharmacy*
Sarah Melton, PharmD, *Member, Board of Pharmacy (departed early)*
Dale St.Clair, PharmD, *Member, Board of Pharmacy (replaced Dr. Melton)*
Jake Miller, D.O., *Member, Board of Medicine*
Brenda Stokes, M.D., *Member, Board of Medicine*
Stephanie Wheawill, PharmD, *VDH, Director of Division of Pharmacy Services*
Kristen Collins, MPH, *Policy Analyst, Office of Epidemiology, VDH*
Diana Jordan, *Director, Division of Disease Prevention, VDH*
Joe DiPiro, PharmD, *Dean, VCU School of Pharmacy*
Michael Justice, PharmD, *Assistant Professor, Appalachian College of Pharmacy*
Al Arias, M.D., *VCU, School of Medicine*
John R. Lucas, D.O., *Edward Via College of Osteopathic Medicine*
Donna Francioni-Proffitt, RPh, *Pharmacy Program Manager, DMAS*
Doug Gray, *Executive Director, Virginia Association of Health Plans*
Kelly Goode, PharmD, *Virginia Pharmacist Association*

Terri Babineau, M.D., *Medical Society of Virginia*
Kerri Musselman, PharmD, *Virginia Society of Health-System Pharmacists*
Summer Williams Kerley, PharmD, *Virginia Association of Chain Drug Stores*
Lincy Abraham, PharmD, *National Association of Chain Drug Stores*

The following individuals staffed the work group meetings:
Caroline Juran, RPh, *Executive Director, Board of Pharmacy*
William Harp, M.D., *Executive Director, Board of Medicine*
Elaine Yeatts, *Senior Policy Analyst, DHP*
Jim Rutkowski, *Assistant Attorney General*
Sammy Johnson, *Pharmacist, Deputy Executive Director, Board of Pharmacy*
Ellen Shinaberry, PharmD, *Deputy Executive Director, Board of Pharmacy*
Kiara Christian, *Executive Assistant, Board of Pharmacy*

RECOMMENDATIONS:

The work group that met in August developed recommended statewide protocols for the following subjects as required by HB 1506 which were adopted by the Board of Pharmacy on September 9, 2020: naloxone, other opioid antagonist, including paraphernalia; epinephrine; prenatal vitamins; fluoride supplements; over-the-counter medications; and, hormonal contraceptives. Pharmacists may begin initiating drug treatment consistent with the protocols once the regulations become effective.

The following recommendations were offered by the work group that met September pursuant to the third enactment clause of HB 1506:

Vaccines

The work group was generally supportive and voted 15:1 with 1 abstention to include in the legislative report a recommendation that pharmacists should be authorized to order and administer vaccines included on the immunization schedule published by the Centers for Disease Control and Prevention for persons 18 years of age and older, to require reporting to the Virginia Immunization Information System, and to inform the patient's primary care provider (PCP) of the administration or if none, to counsel the patient on the importance of having a relationship with a PCP. (motion by Melton, seconded by Miller; Babineau opposed; Arias abstained)

Tobacco Cessation

There was some concern expressed by physician members for how a pharmacist would monitor certain prescription-only drug therapies requiring the monitoring of patient behavioral aspects. Pharmacist members generally believed that monitoring is currently being performed successfully through questionnaires in other states, could be addressed through a limitation of day supply or required follow-up appointments, and stated that pharmacy students are taught to recognize suicidal behavior, how to perform patient assessments, and must complete a mental health therapeutic module, along with a semester-long communication course.

After a failed motion to exclude these prescription-only drugs from an allowance for pharmacists to initiate treatment, the work group voted 10:5 that pharmacists should be authorized to initiate treatment with and dispense and administer drugs approved by the United States Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. (motion by Melton, seconded by Abraham; supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan; opposed by Miller, Stokes, Arias, Lucas, Babineau; Melton departed meeting prior to vote; Collins and Jordan not present for vote).

Tuberculin Purified Protein Derivative for Tuberculosis Testing

The work group appeared to be in agreement on this subject and voted 17:0 to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer tuberculin purified protein derivative for tuberculosis testing. (motion by Lucas, seconded by DiPiro; supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan, Miller, Stokes, Arias, Lucas, Babineau, Collins, and Jordan)

Controlled Substances or Devices for the Treatment of Diseases or Conditions for which Clinical Decision Making can be guided by a CLIA-Waived Test:

Influenza

There was some disagreement regarding the use of a CLIA-waived test to guide clinical decisions regarding influenza. A physician member expressed concern for possibly overlooking pneumonia. Another physician member expressed support based on ability to increase timeliness in patients starting medication treatment. Pharmacist members generally supported the ability, indicated seventeen states allow use of CLIA-waived tests, and stated that the prescription-only drug, Tamiflu, is slated to move to an over-the-counter status.

The work group voted 15:3 to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of influenza, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by DiPiro; supported by St.Clair, Wheawill, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Logan, Stokes, Lucas, Collins, Justice, and Jordan; opposed by Babineau, Miller, Arias)

Helicobacter Pylori Bacteria

There appeared to be general agreement among physician and pharmacist members that diagnosing medical conditions involving Helicobacter Pylori bacteria was complex. The work group voted 13:0 with 4 abstentions to exclude Helicobacter Pylori as a condition for pharmacists to initiate treatment with and dispense and administer controlled substances or devices.

Urinary Tract Infection

Two physician members expressed concern for using a CLIA-waived test to guide clinical decisions regarding urinary tract infections and stated that a more complex culture test is necessary. Pharmacist members appeared to disagree. After a failed motion with a vote of 7:8 with 3 abstentions to exclude urinary tract infections as a recommendation in the legislative report, the work group voted 10:5 with 3 abstentions to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of urinary tract infections, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by Abraham; supported by Logan, St.Clair, DiPiro, Proffitt, Gray, Goode, Musselman, Kerley, Abraham, Justice; opposed by Miller, Stokes, Arias, Lucas, Babineau; Wheawill, Collins, Jordan abstained)

Group A Streptococcus Bacteria

There was some disagreement regarding the use of CLIA-waived tests for group A streptococcus bacteria. Some physician members expressed concern for the possibility of false negative or false positive tests, that a serious condition could be missed, and that diagnostic techniques are needed. Pharmacist members indicated U.S. data suggests these CLIA-waived tests can be helpful, reiterated that seventeen states allow pharmacist-use of CLIA-waived tests, and stated that the protocol should require a pharmacist to refer a symptomatic patient with a negative CLIA-waived test to a primary care provider for a confirmatory lab test.

After a failed motion with a vote of 7:8 with 3 abstentions to exclude Group A Streptococcus bacteria as a recommendation, the work group voted 8:6 with 4 abstentions to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer controlled substances or devices for the treatment of Group A Streptococcus bacteria, following use of a CLIA-waived test to guide clinical decisions. (motion by Goode, seconded by Abraham; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice; opposed by Miller, Stokes, Arias, Lucas, Proffitt, Babineau; Wheawill, Collins, Jordan, Gray abstained)

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

VDH members indicated a well-constructed statewide protocol with a thorough assessment could meet public need, VDH has experience working with pharmacists performing HIV testing, and that Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP) could be built into a protocol. The work group voted unanimously 18:0 to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer 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. (motion by

Abraham, seconded by DiPiro; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice, Miller, Stokes, Arias, Lucas, Proffitt, Babineau, Wheawill, Collins, Jordan, and Gray)

Drugs other than Controlled Substances, including Drugs Sold Over-the-Counter, for which the Patient's Health Insurance Provider Requires a Prescription

The work group acknowledged that this subject appears to have already been addressed by a statewide protocol recently adopted by the Board. It was noted that the term "drugs" as defined in law does not include "devices". The workgroup supported a pharmacist's ability to prescribe devices such as glucometers, controlled paraphernalia such as insulin pen needles and syringes, and possibly other durable medical equipment.

The work group voted 17:0 with 1 abstention to include in the legislative report a recommendation that pharmacists should be authorized to initiate treatment with and dispense and administer devices, controlled paraphernalia such as insulin pen needles and hypodermic syringes, and possibly other durable medical equipment to lower out-of-pocket expenses, not covered by a health plan. (motion by Goode, seconded by St.Clair; supported by Logan, St.Clair, DiPiro, Goode, Musselman, Kerley, Abraham, Justice, Miller, Stokes, Arias, Lucas, Proffitt, Babineau, Wheawill, Collins, and Gray; Jordan abstained.)