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
June 4, 2021 Meeting
9AM
*******Refer to the Third Page of Agenda for Meeting Access Information*******

- Recommended Feedback for ACPE Standards 2025 (Standards may be found in May 2021 Regulation Committee agenda packet https://www.dhp.virginia.gov/Pharmacy/pharmacy_calendar.htm) **26**
- Legislative Proposals **26**

- Adoption of Exempt Regulations to Place Certain Chemicals into Schedule I **58-64**
- Interpretation Request from VHHA regarding Proposed White Bagging Regulations **65-66**
- Amend Guidance Document 110-9, Pharmacy Inspection Deficiency Monetary Penalty Guide **67-84**
- FAQs for Addressing the Pharmaceutical Processor RFA – *to be shared virtually during meeting*

Old Business: Caroline Juran/Jim Rutkowski

- FDA MOU on Compounding Inordinate Amounts **7**
  85-100

New Business:

- Election of Chairman and Vice Chairman
- Select 2022 Meeting Dates for Full Board and Regulation Committee Meetings

Reports:

- Chairman's Report – Kris Ratliff
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – Beth O'Halloran
- Report on Inspection Program – Katrina Trelease; *to be shared virtually during meeting* **101**
- Report on Pharmaceutical Processors – Annette Kelley
- Report on Disciplinary Program – Ellen B. Shinaberry **102**
- Executive Director's Report – Caroline D. Juran; *to be shared virtually during meeting* **103**

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

Adjourn

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

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

Virginia Board of Pharmacy

Instructions for Accessing June 4, 2021 Virtual Public Hearing/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. 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 June 4, 2021** indicating that they wish to offer comment. Be sure to specify if the comment is associated with the 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.
- Please call from a location without background noise.
- Dial (804) 367-4578 to report an interruption during the broadcast.
- 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

Join Interactive Meeting
https://covaconf.webex.com/covaconf/j.php?MTID=m3825a2da344f66f5dd419423adcb7cde
Meeting number: 185 627 0386
Password: Pharmacy1!

Join by video system
Dial 1856270386@covaconf.webex.com
You can also dial 173.243.2.68 and enter your meeting number.

Join by phone
+1-517-466-2023 US Toll
+1-866-692-4530 US Toll Free
Access code: 185 627 0386

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

March 30, 2021
Virtual Meeting

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

CALL TO ORDER: A virtual Webex meeting of the Board of Pharmacy was called to order at 9:12 AM. 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 convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

PRESIDING: Kristopher Ratliff, Chairman

MEMBERS PRESENT:
Cheryl H. Nelson, Vice Chairman
Glen Bolyard
Ryan Logan
Patricia Richards-Spruill
Sarah Melton
Dale St.Clair
William Lee
Bernard Henderson, Jr.

MEMBER ABSENT: James L. Jenkins, Jr.

STAFF PRESENT:
Caroline D. Juran, Executive Director
Annette Kelley, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP
Barbara Allison-Bryan, M.D., Chief Deputy, DHP
James Rutkowski, Assistant Attorney General
Melody Morton, Inspection Manager, DHP
Kiara Christian, Executive Assistant

PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE
William Lee
Patricia Richards-Spruill
Farzana Kennedy

CONTINUING EDUCATION FOR ATTENDING MEETING: Ademola Are

QUORUM: With nine 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 and described below:

- **Insert additional item, Adoption of new guidance document *Proximity for a School or Daycare to a Cannabis Dispensing or Pharmaceutical Processor* (motion by Nelson, seconded by Logan)**

APPROVAL OF PREVIOUS BOARD MEETING MINUTES: Mr. Ratliff stated that Mr. Henderson had informed staff that Ms. Yeatts name was misspelled on page 5 of the December 10, 2020 draft minutes. Additionally, Mr. Ratliff asked that staff include in the December draft minutes reference to the discussion regarding concerns for l

MOTION:

The board voted unanimously to adopt the minutes for December 9, 2020 through February 23, 2021 as presented and amended to correct Ms. Yeatts name and include reference to the discussion regarding concerns for legislation to authorize adult use marijuana in the December 10, 2020 full board meeting minutes. (motion by Nelson, seconded by Richards-Spruill)

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 March 30, 2021 indicating that they wish to offer comment.

Farzana Kennedy recommended that the Board perform more due diligence prior to signing the FDA MOU and stated that she is receiving increased requests to ship compounded drugs across states lines. Her pharmacy is located in northern Virginia and she frequently services patients in bordering states and Washington, DC.

Christina Barrille, Executive Director of the Virginia Pharmacists Association (VPhA) stated she was glad to see vaccine allocation to pharmacies increasing, but expressed concern that this may lead to more pharmacist burnout. She also offered thanks to the board and to the Medical Society of Virginia for their assistance throughout the pandemic. Ms. Barrille also asked

the board to delay any action related to the FDA MOU on compounding to the June board meeting. She indicated this would allow counsel more time to determine if signing the MOU would conflict with state law and allow time for national discussions play out.

Cynthia Warriner shared her concerns regarding adult-use of cannabis products. She stated three board members expressed similar concerns at the December 2020 board meeting. She referenced prescription drug interactions with cannabis that were referenced in a presentation during the April 2018 board retreat.

Hunter Jamerson, counsel for Dalitso, offered support of the draft Guidance Document for *Proximity for a School or Daycare to a Cannabis Dispensing or Pharmaceutical Processor Facility.*

DHP DIRECTOR'S REPORT:

Dr. Brown provided the board an update on recent news related to the agency. He discussed environmental protections within Executive Order 77 and that all state agencies are to develop a diversity and equity strategic plan. DHP recently hired a consultant to assist the agency in creating a Diversity, Equity, and Inclusion (DEI) Committee. The last all-staff training event was devoted to DEI issues. Dr. Brown also provided an update on cannabis legislation passed during the 2021 General Assembly session, including language for pharmaceutical processors and adult-use cannabis to be regulated by a new agency by 2024 and authorization for pharmaceutical processors to dispense botanical cannabis.

Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP, shared statistics regarding COVID-19 vaccine administrations in Virginia. Over one-half of the local health departments are in Phase 1C, over 3.6 million doses have been distributed in Virginia, and approximately one-third of Virginians have received one dose with about 15% fully vaccinated. She provided an overview of HB2333 which expanded who may administer a COVID-19 vaccine.

LEGISLATIVE/
REGULATORY/ GUIDANCE

REPORT ON 2021 GENERAL ASSEMBLY

Ms. Yeatts provided an overview of the 2021 General Assembly session on pages 42-50 of the agenda packet.

REPORT ON REGULATORY ACTION:

Ms. Yeatts provided an overview of regulatory actions on pages 51 and 52 of the agenda packet. Mr. Ratliff noted that the prohibition against incentives to transfer prescriptions status remains at the governor's office. Ms. Yeatts also

reviewed a chart, which was shared on the screen for all to see, of future actions that the board will need to take resulting from legislation passed. This includes promulgating emergency regulations, exempt regulations, and convening workgroups to discuss pharmacy technicians and additional protocols for pharmacists to initiate treatment.

ADOPTION OF EXEMPT REGULATIONS TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I

Ms. Yeatts provided an overview of the draft exempt regulations to temporarily place chemicals into Schedule I as recommended by the Department of Forensic Science and pursuant to 54.1-3443 (D) of the Code of Virginia.

MOTION:

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

- **1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine)**
- **N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: parachlorofentanyl, 4-chlorofentanyl)**
- **2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene)**
- **N,N diethyl 2 {[(4 ethoxyphenyl) methyl] 1H benzimidazol 1 yl} ethan 1 amine (other name: Etazene, Desnitroetonitazene)**
- **5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam)**
- **ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-PICA)**

(Motion by St Clair, seconded by Bolyard)

ADOPTION OF PROPOSED REGULATIONS FOR PHARMACISTS TO INITIATE TREATMENT

The board reviewed the copy of notice posted on Regulatory Townhall and copy of emergency regulations found on pages 67-72 of the agenda packet. It was noted that emergency regulations remain in place for 18 months, and must be replaced by permanent regulations. The proposed regulations are identical to the emergency regulations in place. No comments were received during the public comment period that ended March 3, 2021.

MOTION:

The board voted unanimously to adopt the proposed regulations as presented. (motion by Nelson, seconded by Lee)

ADOPTION OF PROPOSED REGULATIONS FOR PHARMACY TECHNICIAN TRAINEEE REGISTRATION AND TRAINING

The board reviewed the copy of notice posted on Regulatory Townhall and copy of emergency regulations found on pages 73-89 of the agenda packet. It was noted that emergency regulations remain in place for 18 months, and must be replaced by permanent regulations. Ms. Yeatts stated that the board receive one comment during the public comment period that ended March 3, 2021. The board discussed the two recommendations from the Virginia Association of Chain Drug Stores and the National Association of Chain Drug Stores. Because staff is able to issue a pharmacy technician trainee registration within 2-5 days of receiving a complete application and many accredited training programs require didactic training prior to performing duties of a pharmacy technician, the board did not believe an allowance for a person enrolled in a pharmacy technician training program to perform duties of a technician prior to being issued a trainee registration was necessary. The board did agree to the second recommendation to amend 18VAC110-21-140(C) to include reference to "NHA certification" as supported by the statute.

MOTION:

The board voted unanimously to adopt the proposed regulations as presented and amended by inserting "or NHA certification" after "PTCB certification" in 18VAC110-21-140 (C). (motion by Henderson, seconded by Richards-Spruill)

ADOPTION OF PROPOSED REGULATIONS FOR LIMITED LICENSE FOR DISPENSING SCHEDULE VI DRUGS FROM A NON-PROFIT FACILITY

The board reviewed the copy of notice posted on Regulatory Townhall and copy of emergency regulations found on pages 90-97 of the agenda packet. It was noted that emergency regulations remain in place for 18 months, and must be replaced by permanent regulations. The proposed regulations are identical to the emergency regulations. No comments were received during the recent public comment period that ended March 3, 2021.

MOTION:

The board voted unanimously to adopt the proposed regulations as presented (motion by Nelson, seconded by St Clair)

GUIDANCE DOCUMENTS 110-27, 110-31, 110- 33

REAFFIRMATION OF GUIDANCE DOCUMENT 110-38

REPEAL OF GUIDANCE DOCUMENT 110-20

The board reviewed the draft amendments to guidance documents found on pages 98-110 of the agenda packet. Changes in the pharmacy technician registration process and trainee registration necessitated amendments to Guidance Documents 110-27, 110-33, and repeal of 110-20; the link to the State Veterinarian's directive for Approved Capture Drugs and Drug Administering Equipment in 110-31 needed updating; and 110-38 needed to be readopted since it was last revised more than four years ago.

MOTION:

The board voted unanimously to adopt amendments to Guidance

Documents 110-27, 110-31, and 110-33 as presented, reaffirm Guidance Document 110-38, and repeal Guidance Document 110-20. (motion by Nelson, seconded by Logan)

NEW GUIDANCE DOCUMENT PROXIMITY OF A SCHOOL OR DAYCARE TO A CANNABIS DISPENSING FACILITY OR PHARMACEUTICAL PROCESSOR

A draft Guidance Document was shared on the screen for all to see. Because the laws and regulations do not allow for the board to issue conditional approval to cannabis dispensing facilities, Ms. Juran explained that counsel for Dalitso (located in northern Virginia) recently expressed concern about beginning construction and a school or daycare opening within 1,000 feet while construction of the dispensing facility is occurring. They also inquired what action the board would take if a pharmaceutical processor or cannabis dispensing facility is operational and a school or daycare opens within 1,000 feet of the processor or dispensing facility. There was much discussion regarding the attestation wording of the draft language. A motion was offered by Henderson, seconded by Bolyard to table the subject to the June board meeting. The motion was then withdrawn by Henderson and Bolyard.

MOTION:

The board voted unanimously to adopt the guidance document as amended which reads:

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

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

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

NEW BUSINESS:

DISCUSS SIGNING OF FDA MOU FOR COMPOUNDING

Ms. Juran provided an overview of the FDA MOU for compounding.

Related to Section 503A of the Federal Food, Drug, and Cosmetic Act, the FDA published a compounding MOU in October 2020 for the states to potentially enter into with FDA to strengthen state and federal oversight of compounding pharmacies shipping compounded drugs across state lines.

Compounding pharmacies and physicians located in a state that do not enter into the MOU may not distribute compounded drug products out of the State in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician;

Compounding pharmacies and physicians located in states that enter into the MOU may distribute "inordinate amounts" of compounded drug interstate and the State where the compounder is located must provide for appropriate investigation of complaints relating to compounded drug products distributed outside such State;

To assist the states and pharmacies with identifying if a pharmacy or compounding physician is shipping "inordinate amounts" outside of the state, FDA awarded the National Association of Boards of Pharmacy a grant to establish an electronic data sharing network which is now operational. Deadline for signing the MOU is October 2021.

The board discussed the need for counsel to review the document to determine if signing would conflict with any state laws and staff to identify any challenges with completing investigations based on complaints from individuals residing outside of Virginia. Members expressed general support for allowing compounding pharmacies to ship inordinate amounts of compounded drug interstate, but thought it may be premature to make a decision.

ACTION ITEM:

There was consensus to defer this subject to the June board meeting.

AMEND PHARMACIST WORKFORCE SURVEY TO INCLUDE QUESTION ABOUT STATEWIDE PROTOCOLS

Ms. Juran provided the board an overview of page 134 of the agenda packet. It was noted that a request was received from the VCU School of Pharmacy, Center for Pharmacy Practice Innovation to include a question on the annual pharmacy workforce survey to monitor use of statewide protocols.

MOTION:

The board voted unanimously to amend the Pharmacist Workforce Survey by inserting question #22c as presented which reads:

7

If you initiate patient treatment in accordance with statewide protocols, which of the statewide protocols below do you utilize? Check all that apply.
Hormonal contraception
Emergency contraception
Prenatal vitamins
Naloxone
Epinephrine
Lowering out-of-pocket expenses (motion by Nelson, seconded by StClair)

RECOGNITION OF FORMER BOARD MEMBERS

The board recognized and expressed appreciation for the leadership and service of former board members Cynthia Warriner, Melvin Boone, and Rebecca Thornbury. Ms. Warriner and Mr. Boone joined the meeting virtually. Ms. Thornbury was unable to participate due to a last-minute conflict.

REPORTS:

CHAIRMAN'S REPORT

Mr. Ratliff thanked all pharmacists and pharmacy technicians for their assistance with COVID-19 vaccine administrations. He also thanked Mr. Johnson for his time with the Board and noted his retirement effective April 1, 2021.

REPORT ON BOARD OF HEALTH PROFESSIONS

Mr. Logan provided an update for the Board of Health Professions meeting held on January 21, 2021. The next meeting is scheduled for May 13, 2021.

REPORT ON LICENSURE AND INSPECTION PROGRAM

Ms. O' Halloran reviewed pages 135-146 of the agenda packet. Melody Morton, Inspection Manager, DHP will provide the board with the Inspection Report going forward and Ms. O'Halloran will continue to provide the Licensure Report. Ms. Morton joined the meeting and requested suggested information that the board would like for her to capture on the Inspection Report in the future. The board agreed that it was not necessary to capture repeat deficiencies in the chart since this required a manual count and was time-consuming for staff to prepare.

REPORT ON PHARMACEUTICAL PROCESSORS

Ms. Kelley reviewed the report provided on page 147 of the agenda packet.

REPORT ON DISCIPLINARY PROGRAM

Ms. Shinaberry reviewed the disciplinary report provided on page 148 of the agenda packet.

EXECUTIVE DIRECTORS REPORT	Ms. Juran reviewed the report provided on page 149 of the agenda packet. She expressed sincere gratitude for former Deputy Executive Director Sammy Johnson who retired on April 1, 2021. Mr. Johnson retired with 25 years of state service, 21 years at DHP. She stated that interviews for this position will be held soon.
PRESENTATION OF POSSIBLE SUMMARY SUSPENSION: **Case #205818**	Assistant Attorney General James Schliessmann, presented information a summary of the evidence in this case. Adjudication Specialist Jess Kelley assisted Mr. Schliessmann.
CLOSED SESSION:	Upon a motion by Ms. Nelson, and duly seconded by Mr. St Clair, the panel voted 9-0, 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 Ellen Katherine Daniels. 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 reconvened an open meeting and announced the decision. (motion by Nelson, seconded by St Clair)
DECISION:	Upon a motion by Melton, and duly seconded by Ms. Richards-Spruill, the panel voted 8-1 (Henderson opposed) to summarily suspend the technician registration of Ellen Katherine Daniels, to notice her for a formal hearing, and to offer a consent order for indefinite suspension for no less than two years, with the suspension stayed upon proof of entry into the Health Practitioners Monitoring Program.
MEETING ADJOURNED:	2:38 PM

Kristopher Ratliff, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

9

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARING TO SCHEDULE CERTAIN CHEMICALS INTO SCHEDULE I

March 30, 2021
Virtual Meeting

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	The public hearing was called to order at 9:10 a.m.
PRESIDING:	Kristopher Ratliff, Chairman
MEMBERS PRESENT:	Cheryl Nelson, Vice Chairman Glen Bolyard Ryan Logan Patricia Richards-Spruill William Lee Sarah Melton Dale St. Clair Bernard Henderson
MEMBER ABSENT:	James L. Jenkins, Jr.
STAFF PRESENT:	Caroline D. Juran, Executive Director Annette Kelley, Deputy Executive Director Beth O' Halloran, Deputy Executive Director Ellen B. Shinaberry, Deputy Executive Director Elaine Yeatts, Senior Policy Analyst, DHP David E. Brown, D.C., Director, DHP Barbara Allison-Bryan, M.D., Chief Deputy, DHP James Rutkowski, Assistant Attorney General Kiara Christian, Executive Assistant

CALL FOR PUBLIC COMMENT:

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

Synthetic Opioid:

- **1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine)**
- **N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: parachlorofentanyl, 4-chlorofentanyl)**
- **2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene)**
- **N,N-diethyl-2-{[(4-ethoxyphenyl) methyl]-1H-benzimidazol-1-yl}-ethan-1-amine (other name: Etazene, Desnitroetonitazene)**

Compounds expected to have depressant properties:

- **5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam)**

Cannabimimetic agents:

- **ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-PICA)**

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 to place these chemicals into Schedule I.

No other comments were received.

ADJOURN:

The public hearing adjourned at 9:12 am.

Kristopher Ratliff, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARING FOR REGISTERED AGENTS AND WHOLESALE DISTRIBUTORS OF CANNABIS OIL

March 30, 2021
Virtual Meeting

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	The public hearing was called to order at 9:05 a.m.
PRESIDING:	Kristopher Ratliff, Chairman
MEMBERS PRESENT:	Cheryl Nelson, Vice Chairman Glen Bolyard Ryan Logan Patricia Richards-Spruill William Lee Sarah Melton Dale St. Clair Bernard Henderson
MEMBER ABSENT:	James L. Jenkins, Jr.
STAFF PRESENT:	Caroline D. Juran, Executive Director Annette Kelley, Deputy Executive Director Beth O' Halloran, Deputy Executive Director Ellen B. Shinaberry, Deputy Executive Director Elaine Yeatts, Senior Policy Analyst, DHP David E. Brown, D.C., Director, DHP Barbara Allison-Bryan, M.D., Chief Deputy, DHP James Rutkowski, Assistant Attorney General Kiara Christian, Executive Assistant
CALL FOR PUBLIC COMMENT	**Mr. Ratliff called for comment to consider proposed text for 18VA110-60-10.**
PULIC COMMENT:	There was no public comment offered.
ADJOURN:	The public hearing adjourned at 9:10 am.

Kristopher Ratliff, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, April 14, 2021
Virtually via WebEx

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 9:02 am.
PRESIDING:	Glenn Bolyard, Committee Chair
MEMBERS PRESENT:	Ryan Logan, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Kiara Christian, Executive Assistant Jessica Kelley, DHP Adjudication Specialist
EDGE PHARMA LLC, Applicant Permit No. (Applicant)	Tyler Wingood, Chief Operating Officer, Kurt Radke, Director of Quality Assurance, Jordan Webinger, Senior Quality Control Manager, and Dylan Waters, Document Control Specialist appeared as representatives of Edge Pharma, LLC to discuss Edge Pharma, LLC's application for registration as a non-resident pharmacy and that allegations exist to deny that application as stated in the January 13, 2021 Notice. The pharmacy was not represented by counsel.
Closed Meeting:	Upon a motion by Mr. Logan, 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 Edge Pharma, LLC. Additionally, he moved that Mykl Egan, Ileita Redd, and Kiara Christian 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. Logan and duly seconded by Mr. Bolyard, the Committee voted unanimously to deny Edge Pharma's application for registration as a non-resident pharmacy.

LAUREN DANFORTH
Registration No. 0230-034434

Lauren Danforth, 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 December 15, 2020, Notice and continued to April 14, 2021 in the March 23, 2021 Notice. She was not represented by counsel.

Closed Meeting:

Upon a motion by Mr. Logan, 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 Lauren Danforth. Additionally, he moved that Mykl Egan, Ileita Redd, and Kiara Christian 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. Logan, and duly seconded by Mr. Bolyard, the Committee unanimously voted to issue Ms. Danforth a Reprimand.

DAVINDER PAL SING KAHLON
License No. 0202-214712

Davinder Khalon, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist and to review his probation as stated in the December 3, 2020, Notice and continued to April

14, 2021 in the March 23, 2021 Notice. He was not represented by counsel

Closed Meeting:

Upon a motion by Mr. Logan, 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 Davinder Khalon. Additionally, he moved that Mykl Egan, Ileita Redd, and Kiara Christian 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. Logan, and duly seconded by Mr. Bolyard, the Committee unanimously voted to end Mr. Kahlon's probation.

PULASKI COMMUNITY HOSPITAL d/b/a/ LEWIS GALE HOSPITAL-PULASKI
Permit No. 0201-001187

Jeffery Edwards, Pharmacist-in-Charge appeared as a representative of Pulaski Community Hospital d/b/a/ Lewis Gale Hospital-Pulaski to discuss allegations that the pharmacy may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the December 17, 2020 Notice and continued to April 14, 2021 in the March 23, 2021 Notice. The pharmacy was not represented by counsel.

Closed Meeting:

Upon a motion by Mr. Logan, 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 Pulaski Community Hospital d/b/a/ Lewis Gale Hospital-Pulaski. Additionally, he moved that Mykl Egan, Ileita Redd, and Kiara Christian 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. Logan and duly seconded by Mr. Bolyard, the Committee voted unanimously to issue a monetary penalty against Pulaski Community Hospital d/b/a/ Lewis Gale Hospital-Pulaski and to order that the hospital be assessed a monetary penalty.

ADJOURNED:

1:48 p.m.

_____
Glen Bolyard, Chair

_____
Mykl Egan
Discipline Case Manager

_____
Date

_____
Date

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

Tuesday, April 27, 2021
Commonwealth Conference Center
Via WebEX Virtual Platform

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 09:02 AM.

PRESIDING: Kris Ratliff, Chairman

MEMBERS PRESENT:
Dr. Dale St. Clair
Dr. Bill Lee
Mr. Ryan Logan
Dr. Cheryl Nelson
Mr. Bernie Henderson
Mr. Jim Jenkins
Ms. Patricia Richards-Spruill
Dr. Sarah Melton
Mr. Glenn Bolyard

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

QUORUM: With ten (10) members of the Board present, a panel of the board was established.

JERRY RAY HARPER, JR.
License No. 0202-006615

A formal hearing was held in the matter of Jerry Ray Harper, Jr. to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia and to act on his application for reinstatement of his pharmacist license.

Jess Kelly, DHP Adjudication Specialist, presented the case via WebEx.

Jerry Harper, Jr. was present via WebEX and was not represented by counsel.

Lisa Elgen, DHP Senior Investigator, and Sarah Rogers, DHP Senior Investigator, testified via WebEx on behalf of the Commonwealth.

Mr. Harper testified in person on his behalf.

CLOSED MEETING:	Upon a motion by Dr. Nelson, and duly seconded by Mr. Jenkins, 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 of Jerry Ray Harper, Jr. Additionally, she 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.
DECISION:	Upon a motion by Mr. Jenkins, and duly seconded by Ms. Richards-Spruill, the panel voted 10-0 to accept the Findings and Facts and Conclusion of Law as proposed by the Commonwealth and revised by the Board. Upon a motion by Mr. Henderson, and duly seconded by Mr. Logan, the panel voted 10-0 to deny Mr. Harper's application for reinstatement.
POSSIBLE SUMMARY SUSPENSION Registration No. 0230-032676	Sean J. Murphy, Assistant Attorney General, assisted by Jess Kelley, Adjudication Specialist, presented a summary of the evidence in this case.
CLOSED MEETING	Upon a motion by Dr. Nelson, and duly seconded by Ms. Patricia Richards-Spruill, 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 of Juanita Thomas. Additionally, she 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.
DECISION:	Upon a motion by Mr. Bolyard and duly seconded by Dr. Melton, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Juanita Thomas poses a substantial danger to the public; and therefore, the registration of Ms. Thomas shall be summarily suspended. Further, upon a motion by Mr. Logan and duly seconded by Dr. Nelson, the Board unanimously voted that, with the Notice of Hearing, a Consent Order shall be offered to Ms. Thomas for the indefinite suspension of her pharmacy technician registration for not less than two years.

ADJOURN:	With all business concluded, the meeting adjourned at 12:35 PM.
Kris Ratliff, Chair	Caroline D. Juran Executive Director
Date	Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF VIRTUAL REGULATION COMMITTEE MEETING

May 3, 2021
Virtual Meeting

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 9:07AM. 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 (Joined at 12:40 PM)
STAFF PRESENT:	Caroline D. Juran, Executive Director Ellen B. Shinaberry, Deputy Executive Director Beth O'Halloran, Deputy Executive Director Elaine J. Yeatts, Senior Policy Analyst, DHP James Rutkowski, Assistant Attorney General Kiara Christian, Executive Assistant
QUORUM:	With four members of the Committee present, a quorum was established.
APPROVAL OF AGENDA:	Agenda was approved as provided.
PUBLIC COMMENT:	No public comment was received.
UPDATE ON REGULATORY ACTIONS	Ms. Yeatts reviewed the chart of regulatory action found on pages 1-2 of the agenda packet.
CHART OF REGULATORY /WORKGROUPS FROM 2021 GENERAL ASSEMBLY ACTIONS	Ms. Yeatts reviewed the chart found on page 3 of the agenda packet. She informed the board that staff will publish a draft of proposed pharmaceutical processor regulations resulting from legislative changes by May 6th which will open a 60-day public comment period until July 5th as required by the legislation. The board will convene a special virtual

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meeting on July 6th to consider the draft language and any comment received, and adopt the regulations which must be effective by September 1, 2021. Early submission of comment is strongly encouraged. Ms. Juran shared that staff is working with the chairman to identify dates for the statewide protocols and pharmacy technician workgroups and will contact invited stakeholders in the near future. The virtual pharmacy technician workgroup meeting resulting from HB1304/SB830 will be tentatively held on a date between September 13-17 or 20-23. One to two virtual meetings to establish statewide protocols resulting from H2079 will be tentatively held on August 2, or 8-11. A virtual meeting to provide recommendations for future protocols resulting from HB2079 will be tentatively convened on August 16 or 17th. Dr. St.Clair reminded everyone that the topic of remote order processing by pharmacy technicians was referred to the pharmacy technician workgroup for consideration.

PETITION FOR RULEMAKING 18VAC110-20-290; REQUEST TO SHORTEN EXPIRATION DATE OF SCHEDULE II PRESCRIPTIONS

Ms. Yeatts reviewed the petition starting on page 5 of the agenda packet. The committee reviewed the public comments received and discussed concerns related to shortening the expiration date to 7 days as it may impact the ability to partial dispense Schedule II prescriptions. This may impact individuals who obtain 90-day prescriptions and negatively impact patient access.

MOTION:

The committee voted unanimously to recommend to the full board in June to deny the petition for rulemaking to shorten the expiration date of Schedule II prescriptions. (Motion by St.Clair, seconded by Bolyard)

PERIODIC REVIEW OF CHAPTERS 20, 21, 30, 40, AND 50

Ms. Yeatts provided background of the boards' previous periodic review starting on page 16 of the agenda packet which was a comprehensive review of chapters 15, 20, 21, and 50 with amendments becoming effective December 11, 2019. She reminded the board that it must periodically review its regulations every 4 years. The board directed staff in December 2020 to publish a Notice of Periodic Review and to request comment on changes the public would like considered. No comments were received between January 4, 2021 and January 25, 2021. The committee reviewed comments received from the last periodic review on pages 36-37 that were either not included in the proposed regulations or not on sections being amended. The committee discussed each comment to determine if the subject should be included in the current periodic review.

Section 10, amend the definition of personal supervision to allow a pharmacist to not be physically present in the pharmacy but to supervise through the use of "real-time, two-way technology communication" between the pharmacist and the technician

The committee had some discussion about subsection 10 regarding personal supervision. The board expressed interest, but had some discussion about concerns regarding supervision of activities in the pharmacy. Mr. Rutkowski confirmed that it appears this subject could not be addressed through regulatory action since 54.1-3432 of the Code of Virginia references personal supervision of a pharmacist on the premises of the pharmacy.

Section 10, delete definition of "personal supervision" to allow audio-visual technology to supervision of compounding in retail pharmacies

Ms. Juran commented that use of audio-visual technology by a pharmacist on the premises of the pharmacy is currently being used to verify accuracy of compounded preparations. The committee agreed that this subject may need to be clarified in the regulation to ensure licensees are aware that this activity may occur.

Section 112, eliminate the current ratio of four pharmacy technicians to one pharmacist. Possibly allow the "prescription department manager" or "consultant pharmacist" to determine the number of technicians

The committee reviewed section 112. Staff shared on the screen a summary of the 2020 NABP Annual Survey that summarizes the Pharmacist to Pharmacy Technician ratio requirement in various states. There was some concern expressed for pharmacists supervising more than four pharmacy technicians at one time. Dr. St.Clair referenced information from George Mason, actions taken recently by Washington and Ohio, and expressed support for at least evaluating the subject. Dr. Lee commented that the board would need to decide if this was safe for the public. It was stated that discussions during the upcoming pharmacy technician workforce meeting may be helpful. The committee determined it would not recommend including this subject in the periodic review at this time.

Section 150, delete the square footage requirement and allow pharmacies to decide the amount of space "adequate to perform the practice of pharmacy." Allow for trailers or other moveable facilities in a declared emergency

Dr. Lee commented that the current square footage requirement does not appear to be burdensome. Staff shared that the board routinely exercises its existing ability to waive square footage requirements as needed and other requirements during a declared emergency. The committee did not believe this subject needed to be included in the periodic review.

Section 270, except for electronic prescriptions, only require written prescriptions for "controlled substances" to have a signature.

The committee had some discussion about section 270 and the requirement for signatures on written prescriptions. The committee expressed that more information on this subject may be needed to fully understand the request as a prescriber signature on a prescription appears to be a crucial element.

Section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.

The committee briefly discussed the ability for a pharmacist to alter prescriptions, change dosage form, complete missing information, and/or extend a maintenance drug. Dr. St.Clair stated that Ohio has some language on pharmacists addressing omissions, but that the language would need to be reviewed. Members stated this may be helpful in authorizing a pharmacist to change a prescription from tablets to liquid without needing to bother the prescriber. The committee recommended that it be included in the periodic review.

ACTION ITEM:

Ms. Juran will gather language from other states on this subject for the Board's consideration.

Section 270, amend the rule to not require data entry verification and prospective drug utilization review by a pharmacist who is dispensing an on-hold prescription at a future date

Staff commented that the current regulation requires the pharmacist to verify data entry verification at the time the prescription is placed on-hold. The committee expressed concern about not requiring a prospective drug utilization review by the dispensing pharmacist as the drug history may have changed since the time the prescription was first placed on-hold.

Section 355, amend to allow for using returns of dispensed drugs to be restocked for reuse in an automated counting device

Staff provided an overview of the current language related to the current process utilized when a dispensed drug is returned. Committee members expressed concern for recalls when placing returned drugs into an automated counting device as the lot numbers of these drugs would not be known.

Section 360, amend the regulation to allow pharmacy technicians to be involved in prescription transfers; pharmacist on duty should be able to delegate that task

ACTION ITEM:

The committee recommended that the subject of allowing pharmacy technicians to transfer prescriptions be forwarded to the Pharmacy Technician Workgroup for review so that more information may be obtained.

Section 420, change the provision of a seven-day supply of a drug in a unit dose systems in hospitals or long-term care facilities to allow for dispensing of a 14-day supply

The committee expressed concerns of risk associated with having a 14-day supply of multiple drugs being dispensed recognizing that drug changes and errors may occur during this time period.

In new chapter 21, section 10, strike the definition of PTCB and insert new definition for certification meaning any individual who has passed a certification exam administered by an organization accredited by the National Commission for Certifying Agencies.

The committee determined that this issue was addressed in recent regulatory amendments for pharmacy technicians.

Consideration of including a requirement for an e-profile identification number for facilities

Ms. Juran reminded the committee that if it is decided that the board will sign the NABP FDA MOU, facilities impacted would be required to have a NABP E-Profile ID. Ms. Juran confirmed that there is no cost for facilities to obtain an NABP E-profile ID and that staff would be able to communicate easier with NABP if this requirement was in place. The committee supported this concept.

Requirement for applicants to graduate from pharmacy school prior to taking examinations

Staff explained that NABP will not allow a candidate to schedule for taking the NAPLEX or MPJE until the board approves the applicant and the school has provided NABP with a transcript conferring the degree, therefore, this amendment is not necessary.

Change of timeframe for notification of a change in the PIC from 14 to 30 days

The committee had some discussion about the process of assigning a new PIC and the current 14-day allowance.

ACTION ITEM:

Ms. Juran will survey other states to assess their change of PIC notification requirements and report back to the board.

ADDITIONAL ITEMS CONSIDERED BY THE COMMITTEE:

Dr. St.Clair recommended that the board consider amending 18VAC110-20-550 to remove the restriction that a stat-drug box contain no more than 20 solid dosage units per schedule of Schedules II through V drugs. Allowing more flexibility with the contents of the boxes may be beneficial. The committee was supportive.

The committee also discussed requirements to reactivate a pharmacist license after a period of inactivity. Ms. Juran said that there is currently regulation that requires the passing of the MPJE prior to reactivating an inactive license after 5 years of inactivity. Ms. O' Halloran added that these individuals must also provide proof of 160 hours of practical experience as a pharmacy intern. No additional action was taken.

The committee had some discussion about background requirements for pharmacy owners. Ms. Juran recommended an amendment to 18VAC-110-20-110 to require certain disclosures by a pharmacy owner. The committee recommended that the board may want to require disclosure of similar information on pharmacy permit renewals as well.

Dr. St.Clair questioned if pharmacists and pharmacy technicians should report their current places of employment to the board. Since the board cannot currently collect this information electronically, no action was taken on this subject.

Staff questioned if 18VAC110-20-276 should be amended to require a pharmacy technician's program director to be a pharmacist or pharmacy technician. The committee was comfortable with the program director not being a pharmacist or pharmacy technician as long as they were not an instructor.

Ms. Juran asked the board to consider amending 18VAC110-21-190 to align with current NABP policies that a foreign graduate of pharmacy school obtain the FPGEC even if they complete a post-baccalaureate degree from an ACPE-accredited school of pharmacy. This will help to create parity among the states during the licensure endorsement process.

Ms. Juran asked the board to consider amendments to 18-VAC110-20-190 and 18VAC110-30-80 to prohibit a controlled substances registration or a physician selling license to be issued to a location in a private residence or dwelling. Enforcement Division has concerns with placing inspectors in a potentially dangerous situation when inspecting a private residence. This will align these regulations with other regulations impacting pharmacies, medical equipment suppliers, wholesale distributors, and other types of facilities.

MOTION:

The committee voted unanimously to recommend to the full board that it include the following items in the periodic review and solicit the public for other items following the June board meeting:

- **Section 10, delete definition of "personal supervision" to allow audio-visual technology to supervision of compounding in retail pharmacies**
- **Section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.**
- **Consideration of including a requirement for an e-profile identification number for facilities**
- **Change of timeframe for notification of a change in the PIC from 14 to 30 days**
- **Consider amending 18VAC110-20-550 to remove the restriction that a stat-drug box contain no more than 20 solid dosage units per schedule of Schedules II through V drugs.**
- **Amend 18VAC110-20-110 (J) to include allowance to consider prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the practice of pharmacy by the pharmacist-in-charge or immediate family members of the pharmacist-in-charge, and owners, directors, or officers**
- **Amend 18VAC110-21-90(A) by requiring FPGEC prior to obtaining pharmacist license through endorsement or score transfer and delete exemption from FPGEC in subsection D.**
- **Amend 18VAC110-20-690 and 18VAC110-30-80 to prohibit registration and permit from being issued to private dwelling or residence. (Motion by St.Clair, seconded by Lee)**

REVISION/RE-ADOPTION OF GUIDANCE DOCUMENTS 110-17 AND

Ms. Juran reviewed page 53 of the agenda packet and provided background information related to Guidance Document 110-2 and the licensing process for pharmacist. She recommended that the board amend the document to

110-2

meet NABP's policies which now requires the receipt of a college transcript prior to allowing the candidate to schedule for the NAPLEX or MPJE.

Ms. O'Halloran reviewed Guidance Document 110-7 beginning on page 50 of the agenda packet related to NABP confirmation of the graduation conferral date.

MOTION:

The committee voted unanimously to recommend that the full board adopt the revision to Guidance 110-17 as presented and 110-2 as presented and amended by changing on page two "and NABP has received a college transcript conferring the date of graduation" to "and NABP has received a college transcript indicating the graduation conferral date". (Motion by St.Clair, seconded by Bolyard)

FEEDBACK ON ACPE STANDARDS 2025

Ms. Juran indicated ACPE is soliciting feedback on its revised standards.

MOTION:

The committee voted unanimously to recommend that the full board provide supportive feedback on the 2025 ACPE Standards as presented. (Motion by Bolyard, seconded by St.Clair)

IDENTIFY SUBJECTS FOR POSSIBLE LEGISLATIVE PROPOSALS FOR 2022 GENERAL ASSEMBLY SESSION

There was some discussion regarding whether legislation was needed to support the recent regulatory amendment requiring a federal criminal background check for the responsible party of a wholesale distributor. Ms. Juran commented that staff was researching the ability for a responsible party to request his/her own background check through the FBI since staff could not, and then the responsible party forwarding this information to the board office. The committee was comfortable with monitoring this issue for now. No other subject for possible legislative proposal was offered.

ADJOURN:

With all business concluded, the meeting adjourned at approximately 12:45 PM.

Cheryl Nelson, Chairman

Caroline D. Juran, Executive Director

DATE

DATE

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, May 6, 2021
Virtually via WebEx

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 9:00 am.
PRESIDING:	Cheryl Nelson, Committee Chair
MEMBERS PRESENT:	Dale St. Clair, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Kiara Christian, Executive Assistant Jessica Kelley, DHP Adjudication Specialist David Robinson, DHP Adjudication Specialist
MEDICAP PHARMACY Permit No. 0201-004165	Banyo M. Ndanga, Pharmacist-in-Charge of Medicap Pharmacy ("Medicap") appeared as a representative to discuss allegations that Medicap may have violated certain laws and regulations governing its permit to conduct a pharmacy as stated in the January 6, 2021, Notice and continued on March 25, 2021. Medicap was represented by John Peterson, Esq.
Closed Meeting:	Upon a motion by Mr. St. Clair, and duly seconded by Ms. Nelson, 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 Medicap Pharmacy. Additionally, he moved that Mykl Egan, Ileita Redd, and Kiara Christian 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. Clair, and duly seconded by Ms. Nelson, the Committee unanimously voted to assess a monetary penalty against Medicap and to order an additional inspection of the facility.

SENTARA NORFOLK GENERAL HOSPITAL
Permit No. 0201-001014

Catherine Floroff, Pharmacist-in-Charge, Jon Horton, Pharmacy Operations Director, and Tim Jennings, Chief Pharmacy Officer, appeared as representatives of Sentara Norfolk General Hospital ("Sentara") to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the April 6, 2021 Notice. Sentara was represented by Jason Davis, Esq.

Closed Meeting:

Upon a motion by Mr. St. Clair, and duly seconded by Ms. Nelson, 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 Sentara Norfolk General Hospital. Additionally, he moved that Mykl Egan, Ileita Redd, and Kiara Christian 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. Clair and duly seconded by Ms. Nelson, the Committee voted unanimously to issue a monetary penalty against Sentara Norfolk General Hospital and to place the pharmacy on probation under terms and conditions.

ADJOURNED:

5:30 pm

Cheryl Nelson, Chair

Mykl Egan
Discipline Case Manager

Date

Date

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

Friday, May 7, 2021
Commonwealth Conference Center
Via WebEX Virtual Platform

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 09:03 AM.

PRESIDING: Kris Ratliff, Chairman

MEMBERS PRESENT:
Dr. Dale St. Clair
Dr. Bill Lee
Mr. Ryan Logan
Dr. Cheryl Nelson
Mr. Bernie Henderson
Mr. Jim Jenkins
Ms. Patricia Richards-Spruill
Dr. Sarah Melton
Mr. Glenn Bolyard

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

QUORUM: With ten (10) members of the Board present, a panel of the board was established.

MITCHELL A. KOHL, MD
Registration No.: 0241-000634

A formal hearing was held in the matter of Mitchell A. Kohl, MD to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia and to act on his application for reinstatement of his registration to practice as a practitioner for cannabis oil.

David Robinson, DHP Adjudication Specialist, presented the case via WebEx. He was assisted by Jess Kelley, DHP Adjudication Specialist.

Mitchell A. Kohl was present via WebEX and was not represented by counsel.

Joyce Johnson, DHP Senior Investigator, testified via WebEx on behalf of the Commonwealth.

Dr. Kohl testified in person on his behalf.

CLOSED MEETING:	Upon a motion by Dr. 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 the matter of Mitchell A. Kohl, MD. Additionally, she moved that 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.
DECISION:	Upon a motion by Mr. Jenkins, and duly seconded by Ms. Richards-Spruill, the panel voted 9-0 with one abstension (B. Henderson) to accept the Findings and Facts and Conclusion of Law as proposed by the Commonwealth and revised by the Board. Upon a motion by Dr. St. Clair, and duly seconded by Mr. Bolyard, the panel voted 10-0 to reinstate Dr. Kohl's registration as a practitioner for cannabis oil.
ADJOURN:	With all business concluded, the meeting adjourned at 11:51 AM.

Kris Ratliff, Chair	Caroline Juran, Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, May 13, 2021
Virtually via WebEx

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 10:00 a.m.

PRESIDING: Patricia Richards-Spruill, Committee Chair

MEMBERS PRESENT: William Lee, Committee Member

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

JERZEY DEBSKI
Pharmacist Applicant

Jerzey Debski appeared virtually to discuss his application for licensure as a pharmacist and that allegations exist to deny that application as stated in the April 29, 2021 Notice. Mr. Debski was not represented by counsel.

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 Jerzey Debski. Additionally, he moved that Mykl Egan, Ileita Redd, and Kiara Christian 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 grant Mr. Debski's application for licensure by endorsement under certain terms and conditions.

ADJOURNED: 11:08 a.m.

_____
Patricia Richards-Spruill, Chair

_____
Mykl Egan
Discipline Case Manager

_____
Date

_____
Date

Agenda Item: Regulatory Actions - Chart of Regulatory Actions
As of May 20, 2021

Board of Pharmacy

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*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Use of medication carousels and RFID technology [Action 5480] Proposed - *DPB Review in progress* [Stage 9236]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Implementation of legislation for pharmacists initiating treatment [Action 5604] Proposed - *DPB Review in progress* [Stage 9242]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 1093 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] Final - *Register Date: 5/10/21* *Effective: 6/9/21*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling of chemical in Schedule I [Action 5718] Final - *Register Date: 5/24/21* *Effective: 6/23/21*
[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] Proposed - *DPB Review in progress* [Stage 9243]
[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 [Action 5605] Proposed - *DPB Review in progress* [Stage 9244]
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Amendments resulting from SB976 of the 2020 General Assembly [Action 5629]

		Emergency/NOIRA - *Register Date: 3/1/21* *Comment ended: 3/31/21*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Response to petition for rulemaking [Action 5611] NOIRA - *Register Date: 3/1/21* *Comment ended: 3/31/21*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Registered agents and wholesale distribution [Action 5398] Proposed - *Register Date: 3/1/21* *Comment ended: 4/30/21*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Prohibition of products for vaping or inhalation with vitamin E acetate [Action 5452] Proposed - *Register Date: 5/24/21* *Comment closes 6/23/21*

Department of Health Professions
Regulatory/Policy Actions – 2021 General Assembly

EMERGENCY REGULATIONS:

Legislative source	Mandate	Promulgating agency	Board adoption date	Effective date Within 280 days of enactment
HB2079	Authorization for a pharmacist to initiate treatment certain drugs, devices, controlled paraphernalia, and supplies and equipment described in § 54.1-3303.1	Pharmacy	9/24/21	

EXEMPT REGULATORY ACTIONS

Legislative source	Mandate	Promulgating agency	Adoption date	Effective date
HB1988	Changes to pharmaceutical processors	Pharmacy	7/6/21	By Sept. 1st
HB2218/SB1333	Sale of cannabis botanical products	Pharmacy	7/6/21	By Sept. 1st
HB2218/SB1333	Revision of fee schedule for pharmaceutical processors and dispensaries to cover cost of new data system	Pharmacy	?	
SB1464	Deletion of sections of 322 with chemicals now scheduled in Code	Pharmacy	9/24/21	

NON-REGULATORY ACTIONS

Legislative source	Affected agency	Action needed	Due date
HB1304/SB830 (2020)	Pharmacy	To convene a workgroup composed of stakeholders including representatives of the Virginia Association of Chain Drug Stores, Virginia Pharmacists Association, Virginia Healthcareer Association, Virginia Society of Health-System Pharmacies, and any other stakeholders that the Board of Pharmacy may deem appropriate to develop recommendations related to the addition of duties and tasks that a pharmacy technician registered by the Board may perform.	November 1, 2021
HB1987	Boards with prescriptive authority	Revise guidance documents with references to 54.1-3303	As boards meeting after July 1
HB2079	Pharmacy (with Medicine & VDH)	To establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment available over-the-counter by pharmacists in accordance with § 54.1-3303.1. Such	Concurrent with emergency regulations

		protocols shall address training and continuing education for pharmacists regarding the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment.	
HB2079	Pharmacy (with Medicine)	To convene a work group to provide recommendations regarding the development of protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment by pharmacists to persons 18 years of age or older, including (i) controlled substances, devices, controlled paraphernalia, and supplies and equipment for the treatment of diseases or conditions for which clinical decision-making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, urinary tract infection, and group A Streptococcus bacteria, and (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. The work group shall focus its work on developing protocols that can improve access to these treatments while maintaining patient safety.	November 1, 2021
HB2218/SB1333	Pharmacy	To work on acquisition of a new data system/analysis of costs	

Future Policy Actions:

HB2559 (2019) - requires the Secretary of Health and Human Resources to convene a work group to identify successes and challenges of the electronic prescription requirement and offer possible recommendations for increasing the electronic prescribing of controlled substances that contain an opioid and to report to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2022.

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VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

General Notice

Comment period on pharmaceutical processor regulations

Date Posted: 5/6/2021

Expiration Date: 7/5/2021

Submitted to Registrar for publication: YES

60 Day Comment Forum is underway. Began on 5/6/2021 and will end on 7/5/2021

Notice of Public Comment Period

Board of Pharmacy

Regulations Governing Pharmaceutical Processors

In accordance with Chapters 205, 227, and 228 of the 2021 Acts of the Assembly, the Board of Pharmacy is providing an opportunity to comment on a draft of proposed regulations for pharmaceutical processors that will be considered for adoption as an exempt action.

The proposed regulations as drafted:

- Amend regulations as required by the 2021 legislation (those are highlighted in the attached document);
- Replace the references to "cannabis oil" with "cannabis products;" and
- Incorporate other amendments that are currently in effect as emergency regulations (those changes are shown with underlining or overstriking but are not highlighted).

https://www.dhp.virginia.gov/Pharmacy/pharmacy_laws_regs.htm

The 2021 legislation requires posting of a notice 60 days in advance of submittals for public comment and also requires amended regulations to be effective by September 1, 2021. Therefore, the Board of Pharmacy is scheduled to meet on July 6, 2021 with the intent of submitting regulations to the Register of Regulations by July 14, 2021 for publication on August 2, 2021 with an effective date of September 1, 2021.

Although the Board will receive public comment from May 6, 2021 to July 5, 2021, commenters are **strongly encouraged** to submit comments by June 18, 2021 in order to have them included in the Board's agenda package and adequately considered for the July 6th meeting.

Comments may be sent to: elaine.yeatts@dhp.virginia.gov

Elaine J. Yeatts

Agency Regulatory Coordinator

9960 Mayland Drive

Henrico, VA 23233

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(804) 367-4688

Contact Information

Name / Title:	Elaine Yeatts / *Agency Regulatory Coordinator*
Address:	9960 Mayland Drive Henrico, 23222
Email Address:	elaine.yeatts@dhp.virginia.gov
Telephone:	(804)367-4688 FAX: (804)527-4434 TDD: ()-

Agenda Item: Petition for rulemaking:

Included in your package are:

Copy of petition from Leslie Duval

Copy of Notice on Townhall

Copy of Comments on the petition

Copy of section 290 of regulations for which amendment requested

Board action:

To accept the recommendation of the Regulation Committee to deny the petition, or

To initiate rulemaking with publication of a NOIRA

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition. If the board has not met within that 90-day period, the decision will be issued no later than 14 days after it next meets.

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle initial, Suffix,) DuVal, Leslie J		
Street Address 4016 Laurel Rd	**Area Code and Telephone Number** 703-987-8720	
City Alexandria	**State** VA	**Zip Code** 22309
Email Address (optional) ljopharmd@yahoo.com	**Fax (optional)**	

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

18VAC110-20-290. Dispensing of Schedule II drugs.

A. A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than six months after the date on which the prescription was issued.

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

I propose that **opioid prescriptions** be valid for a shorter period of time than the current 6 month expiration date standard for all controlled substances. Several other states currently have shortened expiration dates for CII prescriptions, including DC, DE, HI, ID, IL, ME, MD, MA, MN, NV, RI, SC, VT, and WI (https://www.aafp.org/fpm/2011/1100/fpm20111100p16-rt1.pdf).

I am a retail pharmacist. My store is located very close to an Emergency Room and we receive opioid prescriptions quite often. Situations arise where an opioid is e-prescribed, received and filled at my pharmacy. A week goes by without the patient picking it up, so it is placed "on hold" in our system. The prescription itself is valid for 6 months. The patient comes after a month or 2 (or even 3 or 4) and wants the opioid prescription filled. In general, we refuse to fill an ER script after that amount of time due to the acute nature of ER visits. However, we have also had situations where the script is from a PCP or Pain Management but the PMP shows inconsistent use, a significant gap in therapy, or a dosage change and we are faced with the same dilemma: the script is in-date but therapeutically questionable due to time lapse.

The current CDC guidelines suggest dispensing no more than a 7 day supply for acute conditions. Several insurance policies limit dispensing to a 7 day supply for opioid naïve patients. I propose that *all* opioid prescriptions be valid for 7 calendar days from the date written: i.e. Monday-Sunday, Tuesday-Monday, etc...This way there is a clear definition of expiration with no argument that some months are longer or shorter. Furthermore, with electronic prescribing now the law (§ 54.1-3408.02 B), doctor offices arguably have a more efficient and better tracking system to determine when chronic patients are due for continuing prescriptions, and can therefore create a streamlined corresponding e-timeline for sending continuing opioid prescriptions.

In general, chronic opioid prescriptions are renewed monthly. E-prescribing provides the added benefit of "seeing" (and controlling) which pharmacy the patient frequents and offers an opportunity to establish a collaborative relationship with that pharmacy regarding that patient, to ultimately monitor usage in real time and enhance patient care. As mentioned before, we have had situations where continuing prescriptions for chronic conditions have been sent to the pharmacy but not picked up in a timely manner (or there is clarification needed and the prescriber does not respond in a timely manner), and it creates therapeutic timeline confusion as the chart is not reflecting what the patient is actually doing. Shortening the prescription validity window serves to open the communication between prescriber, pharmacy, and patient to address actual usage discrepancies, *which holds all parties more accountable.*

– The opioid epidemic continues. Decreasing the amount of time an opioid prescription is valid will significantly reduce the window of opportunity in which to fill a prescription and will curb potential abuse of opioids intended for acute, short-term medical issues, will afford enhanced monitoring of chronic usage, and increases accountability from all participants.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.

Authority provided in § 54.1-2400 of the Code of Virginia.

Signature: [signature] **Date:** 2-14-21

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VIRGINIA REGULATORY TOWN HALL

Secretariat Health and Human Resources

Agency Department of Health Professions

Board Board of Pharmacy

Edit Petition

Petition 338

Petition Information	
Petition Title	Dispensing of Schedule II drugs
Date Filed	2/23/2021 [Transmittal Sheet]
Petitioner	Leslie DuVal
Petitioner's Request	To require prescriptions for opioids to be valid for a shorter period of time than the current 6-month expiration standard for all controlled substances.
Agency's Plan	In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on March 15, 2021. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at **www.townhall.virginia.gov**; comment will be requested until April 14, 2021. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for June 4, 2021, and the petitioner will be informed of the Board's decision after that meeting.
Comment Period	Ended 4/14/2021 **3 comments**
Agency Decision	Pending

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

This petition was created by Elaine J. Yeatts on 02/23/2021 at 11:32am

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KAISER PERMANENTE®

Mid-Atlantic Permanente Medical Group, P.C.
Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc

Caroline Juran, RPh
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Richmond, VA 23233-1463

April 13, 2021

Re: Proposed Amendment 18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-290)

Dear Ms. Juran,

Thank you for the opportunity to provide comment on proposed new regulations 18VAC 110-20. Established in 1980, Kaiser Permanente is the trade name for the total health organization comprised of Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc., the Mid-Atlantic Permanente Medical Group, P.C., an independent medical group that features approximately 1,600 physicians who provide or arrange care for patients throughout the area, and Kaiser Foundation Hospitals, which contracts with community hospitals for the provision of hospital services to our patients. We provide and coordinate comprehensive health care services for approximately 780,000 members throughout the metropolitan area. Our organization operates thirteen pharmacies across ten medical facilities in the Commonwealth of Virginia with several more planned in the near future.

While we appreciate the Board of Pharmacy's commitment to ensure the safe dispensing of controlled substances, we have concerns about changing the current regulatory requirement. Kaiser Permanente takes seriously the potential inappropriate use of opioids has on the community. Our health plan undertakes a number of efforts to combat fraud, waste, abuse, and addiction. We understand that misuse of prescription opioids risks addiction and contributes to the opioid overdose epidemic. It is perhaps possible requiring prescriptions for opioids to be valid for a shorter period of time than the current 6-month expiration standard could help mitigate opioid abuse practices by reducing the opportunity for medication stockpiling. That said, we support the concept of dispensing opioids only in "good faith." To that end, pharmacists are strongly encouraged to use professional judgement when dispensing. Specifically, resources such as Prescription Drug Monitoring Programs or medication profiles and histories are valuable tools when determining the appropriateness of a prescription.

The current petition does not define what a "shorter period of time" entails or provide specific language to amend the current regulation. It is important patients still have adequate time to fill their opioid prescription – not all of which are CII – to ensure access to medication is not compromised. The Virginia Board of Medicine promulgated prescribing guidelines in their regulations, which set

parameters on supply limits, quantity limits and the strength of medication. When appropriately prescribed, there are many instances whereby patients may not be able to fill their prescriptions immediately. For example, prescribers may write prescriptions with a "do not dispense date" to prevent future gaps in therapy for the patient. Certain conditions such as sickle cell anemia, multiple sclerosis, and renal calculi (kidney stones) may warrant pain management approaches requiring intermittent use of opioids that result in a patient's delayed pursuit of filling a controlled substances prescription. Further, upon discharge from an acute care episode, patients may transfer to several different sites of care before released to the home setting. It is not until that time that the patients may fill their discharge medications.

For these reasons, Kaiser Permanente is taking a cautious approach and, respectfully, does not support the current petition as presented to amend 18VAC 110-20-290.

Feel free to contact me at monet.stanford@kp.org or (202) 465-6410 should any further inquiries arise. Thank you for your time and consideration.

Sincerely,

Monet M. Stanford

Monet Stanford, PharmD, PAHM
Pharmacy Government Relations and Regulatory Affairs
Kaiser Foundation Health Plan of Mid-Atlantic States, Inc.
4000 Garden City Drive
New Carrollton, MD 20785

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Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter

Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]

3 comments

All good comments for this forum Show Only Flagged

Back to List of Comments

Commenter: George Roberts Jr / Remington Drug Company 3/21/21 6:38 pm

Dispensing of Schedule II Medications

This petition request is not necessary. As a Standard of Practice, most if not all pharmacists would question a patient when filling a Schedule II medication if the date written is more than a few days before the date of the request to fill the prescription. The majority of Schedule II prescriptions are transmitted electronically so a pharmacist would have time to contact the provider or even call the patient to discuss the delay in filling a medication in this class. The major exceptions are medications for ADHD and pain management. In at least these two cases multiple prescriptions are issued on the same day with "Do Not Fill Dates" on the second and third prescriptions. In these situations the intent is communicated by the "Do Not Fill" dates. Currently, following a conversation with either the provider and/or the patient, a stale dated prescription could be filled based upon professional evaluation and clinical judgement by the pharmacist. This petition is an attempt, probably not the intention, to remove professional/clinical decision making on the part of a licensed pharmacist. Currently a pharmacist could refuse to fill the prescription, make clinical notes on the prescription/sign the prescription, and either keep the prescription (if requested by provider) or return the prescription to the patient. This petition would make the prescription invalid when presented for filling. What if the provider intended the prescription to be used "in case the previously treated condition presented suddenly"? This petition would not allow such an option. The petition is unnecessary and adds an excessive burden to the decision making ability of a pharmacist. I respectfully ask this petition not be considered for adoption.

CommentID: 97406

Commenter: Leslie DuVal 4/10/21 8:05 pm

CDC Guidelines

Current CDC guidelines for opioid prescribing are:

Acute pain-"Clinicians should prescribe the lowest effective dose of immediate release opioid and no greater quantity than needed *for the expected duration of pain severe enough to require opioids.* ***Three days*** *or less* is often sufficient; more than 7 days is rarely needed" (cdc.gov).

Chronic pain- "*Clinicians should evaluate benefits and harms with patients* ***within 1 to 4 weeks*** *of starting opioid therapy* for chronic use or of dose escalation. *Clinicians should evaluate benefits and harm of continued therapy with patients* ***every 3 months or more frequently***. If benefits do

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not outweigh the harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower doses or to taper and discontinue opioids"(cdc.gov).

Current VA law states:

"A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than *six months* after the date on which the prescription was issued"(18VAC110-20-290, law.lis.virginia.gov).

Decreasing the length of time during which an opioid prescription is viable for dispensing will more effectively align VA law with the CDC guidelines, and reinforce the current Virginia laws regarding treatment with opioids. This change will hold all parties more accountable for responsible opioid use.

Regarding acute prescriptions: the intention of any acute treatment is immediate mitigation or resolution. The CDC guidelines state that opioid prescriptions for acute conditions "should be for a quantity no more than the expected duration of pain severe enough to require opioids", and more than a 7 day supply is rarely required. Additionally, Virginia law currently states that "a prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a 7 day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record" (18VAC85-21-40, law.lis.virginia.gov). It therefore logically follows that a prescription issued for an acute condition should be filled immediately and a 7 day window from the date written is a reasonable time frame during which said prescription should be dispensed. Beyond 7 days the pain should either be at a level controllable by non-opioid measures, or the patient should be re-evaluated.

Regarding chronic prescriptions: the CDC guidelines state that (stable) patients should be re-evaluated at a minimum of every 3 months. Additionally, current Virginia law states that prescribers treating chronic pain "shall document the rationale to continue opioid therapy every 3 months" (18VAC85-21-70, law.lis.virginia.gov). It therefore is a reasonable expectation that a prescription issued for a chronic condition should be dispensed within 3 months from the date written.

Both scenarios support the argument that opioid prescriptions should be viable for less than 6 months. Additionally, opioid prescriptions are required to be electronically issued (54.1-3408.02, law.lis.virginia.gov), which affords clinicians tighter control over prescribing, determines where the opioid is dispensed, and allows greater visibility of patient compliance. This further upholds the recommendation of curtailing the expiration date of opioid prescriptions. The opioid epidemic continues. The intention of this petition is to block unnecessary dispensing of potentially therapeutically irrelevant opioids. I earnestly ask that this Board actively considers this petition.

References

cdc.gov. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016.MMWR. (www.cdc.gov/mmwr).

Administrative Code of Virginia. (law.lis.virginia.gov).

CommentID 97700

Commenter: Mark Hickman, on behalf of Virginia Society of Health-System Pharmacists 4/14/21 11:05 am

VSHP recommends referral to Regulation Committee

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The Virginia Society of Health-System Pharmacists (VSHP) supports a collaborative, multidisciplinary approach to opioid stewardship. This petition may not address systemic issues with current challenges that dispensing pharmacists encounter in enforcing or maintaining certain stewardship practices. VSHP understands the intent of the petition; however, this is a complex issue and deserves further consideration by the Regulation Committee, as well as the Board of Medicine. VSHP recommends referral of this matter to the Board of Pharmacy's Regulation Committee.

CommentID: **97708**

4B

18VAC110-20-290. Dispensing of Schedule II drugs.

A. A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than six months after the date on which the prescription was issued.

B. A prescription for a Schedule II drug shall not be refilled except as authorized under the conditions for partial dispensing as set forth in 18VAC110-20-310.

C. In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in § 54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner;

3. If the pharmacist does not know the practitioner, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a practitioner using the practitioner's phone number as listed in the telephone directory or other good-faith efforts to ensure the practitioner's identity; and

4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 54.1-3410 of the Drug Control Act, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail postmarked within the seven-day period or transmitted as an electronic prescription in accordance with federal law and regulation to include annotation of the electronic prescription with the original authorization and date of the oral order. Upon receipt, the dispensing pharmacist shall attach the paper prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to the pharmacist. Failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing practitioner.

D. 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 shall not add or change the prescriber's signature or make changes to the controlled substance prescribed, except for dispensing therapeutically equivalent drugs as permitted by law.

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Statutory Authority

§§ 54.1-2400 54.1-3307 of the Code of Virginia.

Historical Notes

Derived from VR530-01-1 § 6.3, eff. October 25, 1989; amended, Virginia Register Volume 9, Issue 4, eff. December 16, 1992; Volume 10, Issue 1, eff. November 4, 1993; Volume 11, Issue 21, eff. August 9, 1995; Volume 12, Issue 21, eff. August 7, 1996; Volume 15, Issue 8, eff. February 3, 1999; Volume 26, Issue 22, eff. August 4, 2010; Volume 36, Issue 6, eff. December 11, 2019.

Agenda Item: Amendments to Guidance documents 110-2 and 110-17

Staff Note:

Guidance documents and 110-2 and 110-17 have outdated language and need to be revised

Board action:

To accept the recommendation of the Regulation Committee for adoption of the revisions to guidance document 110-2 on information for applicants for pharmacist licensure and 10-17 on instructions for foreign applicants

VIRGINIA BOARD OF PHARMACY
Information for Applicants for a License as a Pharmacist

1. Licensure by Examination:

Application

The application is available on the Board of Pharmacy website at www.dhp.virginia.gov/pharmacy. Applications and fees are submitted online and received by the board the next business day.

Practical Experience Requirements

An applicant shall have accumulated a minimum of 1,500 hours of practical experience as a pharmacy intern. The applicant must have registered with the Board as a pharmacy intern prior to beginning to obtain practical experience. Credit will not be given for more than 50 hours in any one week, and not for less than an average of 20 hours per week averaged over a month. Practical experience that is gained within an ACPE-accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1,500 hours of practical experience, shall meet the Board's practical experience requirements for licensure as a pharmacist. All practical experience credit gained outside of an ACPE-accredited school of pharmacy program shall only be gained after successful completion of the equivalent of at least two semesters in an ACPE-accredited school of pharmacy, or in the case of graduates of foreign colleges of pharmacy (see Guidance Document 110-17), after obtaining the FPGEC and registering as a pharmacy intern. All practical experience shall be gained within the United States.

Certificates of Practical Experience

- For graduates of an ACPE-approved school of pharmacy, a "college Affidavit" form no longer needs to be submitted to the Board to document practical experience gained within the college experiential program~~, documentation should be recorded and certified under the "College Affidavit" section of the application. No further affidavits are needed for this experience~~. Graduation from an ACPE-approved school of pharmacy indicates that the student has obtained the required hours of practical experience. Confirmation of compliance with the practical experience requirement will be assessed by NABP through the receipt of a college transcript from the applicant prior to allowing the applicant to schedule for NAPLEX or MPJE.

- Affidavits of experience gained in Virginia, outside the college experiential program, must be signed by the supervising pharmacist and the original form must be sent to the board.

- Certificates or documentation of practical experience gained in another state outside of an ACPE-approved school of pharmacy experiential program must be certified by the board of pharmacy in that state and must be received by this Board directly from that state. This documentation must show actual dates of employment, total hours worked, place of employment and names of supervising pharmacists, and the certifying Board shall verify current, unrestricted licensure status of the supervising pharmacists~~. In the event that a state does not use internships to gain practical experience in pharmacy but relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the above information may be accepted in lieu of board certification.~~

Taking the NAPLEX

Applicants must directly register with and pay the required fee to the National Association of Boards of Pharmacy (NABP) in order to take the NAPLEX examination at www.nabp.pharmacy. NAPLEX is the competency assessment examination for initial pharmacist licensure that is accepted by all 50 states. the

District of Columbia, and Puerto Rico. An applicant may either take NAPLEX designating Virginia as the primary state of licensure, or register with NABP to score transfer to Virginia. The Board will notify NABP of a qualifying candidate's eligibility after reviewing the application for pharmacist licensure. The review is generally completed within five to seven business days. An applicant will not be allowed to schedule taking NAPLEX until he/she has been approved by the Board and NABP has received a college transcript indicating the date of graduation. Additional details about NAPLEX are also available on the NABP website.

2. Licensure by Endorsement (Reciprocity):

Virginia does allow licensure by a process called "endorsement" in which an applicant may transfer a pharmacist license from another state, provided the applicant's credentials for licensure in the other state meet Virginia's credentialing requirements with respect to education, practical experience, and required examinations, and provided grounds do not exist to deny an application such as disciplinary action by another state or criminal convictions. Applicants applying for licensure through endorsement should complete the following steps:

1. Follow NABP's instructions at www.nabp.pharmacy for submitting the application for licensure by endorsement to NABP. NABP will provide the board with relevant information regarding the applicant's licensure status, any criminal convictions, and any disciplinary action taken against the applicant. Please note that as of April 2018, NABP has transitioned from a paper application to an online application process for endorsement.
2. Submit to the Virginia Board of Pharmacy the Application for Pharmacist License by Endorsement found at http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm along with the required fee.
3. Follow NABP's instructions at www.nabp.pharmacy for submitting the application to take the Virginia Multistate Pharmacy Jurisprudence Examination (MPJE).

Once all steps have been completed and the board receives from NABP the applicant's relevant information for consideration, the board will notify NABP of the applicant's eligibility to take the MPJE.

3. Virginia Pharmacy Law Examination Required for Licensure by Examination or Endorsement:

As of July 1, 2016, Virginia ceased administering the Virginia Federal and State Drug Law Exam (FSDLE) and began requiring applicants for pharmacist licensure to successfully pass the Multistate Pharmacy Jurisprudence Examination (MPJE) administered by the NABP. Applicants must directly register with and pay the required fee to the NABP at www.nabp.pharmacy in order to take the MPJE. However, an applicant will not be allowed to schedule taking the MPJE until he has been approved by the Board. Approval from the Board is obtained after a review of the application for pharmacist licensure. Unless there are problems with an application, the application is generally approved within five to seven business days of receipt by the Board.

Detailed information about the MPJE, the registration process, scheduling an appointment to test, requirements on test day, and the MPJE blueprint, which contains a list of competency statements that comprises the topics covered on the exam, may be found at www.nabp.pharmacy .

4. Denial Of An Application For Grounds:

Grounds to deny a license may be found in §54.1-3316 of the Code of Virginia on the Board's website. If grounds exist to deny an application for licensure as a pharmacist, the application will not be approved by Board staff, and the applicant will be so notified and offered an opportunity to meet with an informal conference committee of the Board to determine if the license should be denied, issued, or issued conditionally. An applicant will not be allowed to take any required examinations if grounds exist to deny the application, until reviewed and approved by the Board.

Virginia Board of Pharmacy

INSTRUCTIONS FOR GRADUATES OF FOREIGN SCHOOLS OF PHARMACY

Each step of the following requirements to be eligible for a pharmacist license in Virginia must be completed in the order listed:

1. FPGEC Certification Program

Graduates of foreign colleges of pharmacy must first obtain the Foreign Pharmacy Graduate Equivalency Committee (FPGEC) certification from the National Association of Boards of Pharmacy (NABP). Virginia has no alternative to this process for certifying the equivalency of pharmacy education and proficiency in written and spoken English. The FPGEC certification shows the following:

a. That the person is a graduate of a foreign college of pharmacy and that the educational and licensure credentials have been evaluated and found to be valid and substantively equivalent to those in the United States;

b. That the person has successfully completed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).

c. That the person has successfully completed the written and oral communication ability tests of English as follows:

- **Beginning March 1, 2014, all new candidates for FPGEC Certification must complete** the Internet Based Test of English as a Foreign Language (TOEFL iBT) with a minimum passing score for each component as follows: Writing 24, Speaking 26, Listening 21, and Reading 22

- **Between April 1, 2010 and February 28, 2014, all new candidates for FPGEC Certification must complete** the Internet Based Test of English as a Foreign Language (TOEFL iBT) with a minimum passing score for each component as follows: Writing 24, Speaking 26, Listening 18, and Reading 21; scores for this exam will no longer be accepted from an international Educational Testing Service (ETS) test site location. These candidates who are unsuccessful in meeting all requirements for certification prior to June 1, 2014, must meet the new minimum score requirements of the TOEFL iBT in order to obtain certification.

2. Practical Experience Requirement

One must obtain at least **1500 hours** practical experience within the United States. **Prior to** gaining practical experience in Virginia for credit, a person must register with this Board as a **"pharmacy intern"**. The online application for registration as a pharmacy intern may be found at www.dhp.virginia.gov/pharmacy/pharmacy_forms. The applicant must submit the application, pay the required fee and provide the Virginia pharmacy location where the experience is to be gained as well as the name of the supervising pharmacist. Once the practical experience has been obtained, the pharmacy intern must submit an affidavit to the Board documenting the practical experience. These hours must meet the following requirements:

a. Credit will not be given for more than 50 hours in any one week or for less than an average of 20 hours a week averaged over a month.

b. A pharmacy intern shall be supervised by a pharmacist who holds a current, unrestricted license and assumes full responsibility for the training, supervision and conduct of the intern.

c. Practical experience gained in another state within the U.S. must be certified by that state's board of pharmacy and may require registration as a pharmacy intern with that state board.

d. A temporary intern registration may be issued without a social security number **for 90 days only**.

3. A Completed Application

Once the requirements of sections 1 and 2 above are completed, one may submit an application for licensure as a pharmacist. ~~If the application is approved, the applicant will be authorized~~ The applicant should also apply to take NAPLEX (if applying for initial licensure by examination) and the Multistate Pharmacy Jurisprudence Examination (MPJE) offered by NABP. If the applicant is approved, authorization to test will be granted by the Board. Detailed information about the NAPLEX and MPJE, the registration process, scheduling an appointment to test, requirements on test day, and both the NAPLEX and MPJE blueprints which contain a list of competency statements that comprise the topics covered on the exams may be found at www.nabp.pharmacy

a. If applying for initial licensure in Virginia by examination, an applicant must apply online and submit the required fee. The applicant may omit the college affidavit section.

b. If applying to transfer a pharmacist's license from another state within the United States (Licensure by Endorsement), an applicant must go through NABP's license transfer process . In order to be eligible to transfer a license from another state, an applicant must also have met the requirements of sections 1 and 2 above.

All forms required are available on the Board of Pharmacy website under Forms and Applications at http://www.dhp.virginia.gov/pharmacy/default.htm. FPGEC, NAPLEX and MPJE information may be found at www.nabp.pharmacy.

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

Scheduling Chemicals in Schedule I - Exempt action

Included in agenda package:

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

Amendments to regulation: 18VAC110-20-322

Staff Note:

A public hearing was conducted before the meeting this morning.

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

Board action:

Adoption of final regulation in sections 322

Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The virtual public hearing will be conducted at **9:05 a.m. on June 4, 2021.** Instructions will be included in the agenda for the board meeting, also on June 4th. Public comment may also be submitted electronically or in writing prior to June 4th to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified three (3) compounds for recommended inclusion into Schedule I of the Drug Control Act.

Based on its chemical structure, the following compound is 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-chloro-alpha-methylaminobutiophenone (other name: 4-chloro Buphedrone),** its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

3. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-enyl)indazole-3-carboxamide (other name: ADB-4en-PINACA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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. Synthetic opioids.

a. N-phenyl-N-(4-piperidinyl)-propanamide (other name: 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. N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (other name: Isotonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Research chemicals.

a. (2-ethylaminopropyl)benzofuran (other name: EAPB), 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. 2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 4-ethyl-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25E-NBOH), 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. 4-hydroxy-N-ethyl-N-propyltryptamine (other name: 4-hydroxy-EPT), 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. N-ethyl-1-(3-hydroxyphenyl)cyclohexylamine (other name: 3-hydroxy-PCE), 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.

f. 1-cyclopropionyl lysergic acid diethylamide (other name: 1cP-LSD), 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.

g. 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-Methoxymethamphetamine, PMMA), 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-(pent-4-enyl)-1H-indazole-3-carboxamindo]-3,3-dimethylbutanoate (other name: MDMB-4en-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butylindazole-3-carboxamide (other name: ADB-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.

c. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)indazole-3-carboxamide (other name: 5-chloro-AB-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indole-3-carbonyl}amino)-3-methylbutanoate (other names: MMB-FUBICA, AMB-FUBICA), 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 May 24, 2022, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioid. 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.

2. Compounds expected to have hallucinogenic properties.

a. 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.

b. 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.

c. 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.

d. 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.

e. 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.

f. 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.

3. Compounds expected to have depressant properties.

a 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.

b. 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.

c. 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.

4. Cannabimimetic agents.

a. 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.

b 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 October 27, 2022, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioids.

a. 1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

b. N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: para-chlorofentanyl, 4-chlorofentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

c. 2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene), 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.

d. N,N-diethyl-2-{[(4-ethoxyphenyl) methyl]-1H-benzimidazol-1-yl}-ethan-1-amine (other name: Etazene, Desnitroetonitazene), 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. Depressant.

5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agent.

Ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-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 December 23, 2022, unless enacted into law in the Drug Control Act.

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

1. Compound expected to have hallucinogenic properties.

4-chloro-alpha-methylaminobutiophenone (other name: 4-chloro Buphedrone), 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. Cannabimimetic agents.

a. ethyl-2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3-methylbutanoate (other names: 5-fluoro-EMB-PINACA, 5F-AEB), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-enyl)indazole-3-carboxamide (other name: ADB-4en-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

VIRGINIA HOSPITAL & HEALTHCARE ASSOCIATION

4200 INNSLAKE DRIVE, SUITE 203, GLEN ALLEN, VIRGINIA 23060-6772
P.O. BOX 31394, RICHMOND, VIRGINIA 23294-1394
(804) 965-1227 FAX (804) 965-0475

SENT VIA EMAIL (caroline.juran@dhp.virginia.gov)

May 11, 2021

Caroline D. Juran, RPh
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233

Re: Interpretation of New White Bagging/Brown Bagging Regulations (18VAC110-20-275)

Dear Ms. Juran:

We have previously exchanged e-mail correspondence regarding how the Board of Pharmacy will interpret and enforce the new regulations pertaining to white bagging and brown bagging. This letter summarizes our understanding of the Board's interpretation of the scope and applicability of the new Subsection F of 18VAC110-20-275 for the purposes of assisting our members to establish appropriate policies and procedures to comply with this requirement.

The text of the final regulations in Subsection F of 18VAC110-20-275 is:

> "The pharmacy and alternate delivery site shall be exempt from compliance with subsections B through E of this section if (i) the alternate delivery site is a pharmacy, a practitioner of healing arts licensed by the board to practice pharmacy or sell controlled substances, or other entity holding a controlled substances registration for the purpose of delivering controlled substances; (ii) *the alternate delivery site does not routinely receive deliveries from the pharmacy*; and (iii) compliance with subsections B through E of this section would create a delay in delivery that may result in potential patient harm…"

Our interpretation of this regulation is if the alternate delivery site *does* routinely receive deliveries from the pharmacy, then the pharmacy and alternate delivery site would *not* be exempt from compliance with subsections B through E of 18VAC110-20-275. This seems consistent with the March 22, 2019, Proposed Regulation Agency Background Document, in which the Board articulated in the economic impact section that the regulations would only affect "*Situations in which the delivery site does not routinely receive deliveries from the pharmacy.*" Furthermore, in the Final Regulation Agency Background document published May 18, 2020, the Board emphasizes the intent of the new Subsection F is to exempt parties in "*a case-by-case basis*" from the existing provisions of Subsections B through E, which are intended to protect patients when delivery of dispensed medications to an alternate delivery site *is* routine and normal practice.

Further, it is our understanding that when, as a condition of established policy, a pharmacy sends a variety of different drugs for all its patients, or all or a subset of its patients covered by a particular insurance policy or benefit, to an alternate delivery site as a standard practice, the alternate delivery site would be considered to routinely receive deliveries from the pharmacy. In this case, again, under the new regulations, subsections B through E of 18VAC110-20-275 would apply, including the requirement to have operating agreements and policy and procedure manuals in place.

We want to inform our members accurately and completely on the requirements for compliance with these regulations, and in which cases the new regulations apply. Also, alternate delivery sites that receive drugs for subsequent administration in white bagging arrangements such as those described above need clear regulatory guidance to refer to when challenged by pharmacies that decline or refuse to offer operating agreements or policy and procedure manuals needed to protect patients and establish stringent safeguards.

In summary, based upon our prior correspondence the explanation provided above, it is our understanding that the Board of Pharmacy would interpret the new regulations to mean that under circumstances where a pharmacy makes regular deliveries of a standardized list of multiple drugs to the same alternate delivery site over time, the circumstances would be considered routine and that compliance with subsections B through E of 18VAC110-20-275 would be required.

Please notify me if this understanding of the Board's interpretation is accurate.

Thank you for your assistance in this matter. You can reach me at cconnors@vhha.com and (804) 297-3194.

Sincerely,

Craig Connors

Craig Connors
Senior Director, Payor Relations

Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide

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

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

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

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

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

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

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
21b. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better.	54.1-3410.2		500
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas	54.1-3410.2		2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		5000

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

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

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		First documented occurrence and no drug loss = no penalty Drug loss or repeat = $ penalty 500
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	18VAC110-20-555	Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C)	First documented occurrence and no known patient harm = no penalty Repeat = $ penalty 250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
34. Combined with Deficiency 142 – 12/2013.			
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	18VAC110-20-395		250

Other Deficiencies

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

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

Deficiency	Law/Regulation Cite	Conditions
108. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold
110. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	

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

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

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

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

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

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

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

Security controls are reviewed on an ongoing basis.

• Knowledge of individual tape passwords is required to access backups, and access to the system is limited to users obtaining prior supervisory approval. To avoid inadvertent data disclosure, a special additional procedure is performed to ensure that all Privacy Act data are removed from computer hard drives. Additional safeguards may also be built into the program by the system analyst as warranted by the sensitivity of the data set.

• FTEs and contractor employees who maintain records are instructed in specific procedures to protect the security of records and are to check with the system manager prior to making disclosure of data. When individually identifiable data are used in a room, admittance at either federal or contractor sites is restricted to specifically authorized personnel.

• Appropriate Privacy Act provisions and breach notification provisions are included in applicable contracts, and the CDC Project Director, contract officers, and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to federal government or destroyed, as specified by the contract that includes breach notifications.

• Records that are eligible for destruction are disposed of using destruction methods prescribed by NIST SP 800–88. Hard copy records are placed in a locked container or designated secure storage area while awaiting destruction. Records are destroyed in a manner that precludes its reconstruction, such as secured cross shredding. Utilizing tbe HHS Security Rule Guidance Material found at *https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html,* electronic information will be deleted or overwritten using Department of Defense National Institute of Standards and Technology/General Services Administration (NIST/GSA) approved overwriting software that wipes the entire physical disk and not just the virtual disk. In addition, the physical destruction is obtained by using a National Security Agency/Central Security Service (NSA/CSS) approved degaussing device.

PHYSICAL SAFEGUARDS:

• Paper records are maintained in locked cabinets in restricted areas to which access is controlled by an electronic cardkey system and is limited to staff who have responsibility for conducting regulatory oversight.

• Electronic data files are stored in a restricted access location. The computer room is protected by an automatic sprinkler system and numerous automatic sensors (*e.g.,* water, heat, smoke, etc.) which are monitored, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer workstations, lockable personal computers, and automated records are located in secured areas.

RECORD ACCESS PROCEDURES:

An individual seeking access to records about that individual in this system of records must submit a written access request to the System Manager, identified in the "System Manager" section of this SORN. The request must contain the requester's full name, address, and signature, and DOJ identification number if known. To verify the requester's identity, the signature must be notarized or the request must include the requester's written certification that the requester is the individual who the requester claims to be and that the requester understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000. An accounting of disclosures that have been made of the records, if any, may also be requested.

CONTESTING RECORD PROCEDURES:

An individual seeking to amend a record about that individual in this system of records must submit an amendment request to the System Manager identified in the "System Manager" section of this SORN, containing the same information required for an access request. The request must include verification of the requester's identity in the same manner required for an access request; must reasonably identify the record and specify the information contested, the corrective action sought, and the reasons for requesting the correction; and should include supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURES:

An individual who wishes to know if this system of records contains records about that individual should submit a notification request to the System Manager identified in the "System Manager" section of this SORN. The request must contain the same information required for an access request and must include verification of the requester's identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

72 FR 35993 (July 2, 2007); 76 FR 4483 (Jan. 25, 2011), 83 FR 6591 (Feb. 14, 2018).

[FR Doc. 2020–23770 Filed 10–26–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0030]

Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the Food and Drug Administration; Availability

AGENCY: Food and Drug Administratiou, HHS.

ACTION: Notice of availability; withdrawal.

SUMMARY: Tbe Food and Drug Administration (FDA or the Agency) is announcing the availability of a final standard memorandum of understanding (MOU) entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration" (final standard MOU). The final standard MOU describes the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the MOU in investigating and responding to complaints related to drug products compounded in such State and distributed outside such State and in addressing the interstate distribution of inordinate amounts of compounded human drug products.

DATES: The announcement of the MOU is published in the **Federal Register** on October 27, 2020. FDA is withdrawing its revised draft standard MOU that published on September 10, 2018 (83 FR 45631), as of October 27, 2020.

ADDRESSES: Submit electronic comments on the final standard MOU to Docket No. FDA–2015–N–0030. Submit written comments on the final standard MOU to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fisbers Lane, Rm.

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1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the final standard MOU to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft document.

FOR FURTHER INFORMATION CONTACT: Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5169, Silver Spring, MD 20993–0002, 240–402–4078.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of tbe conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that (1) the drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products distributed outside such State; or (2) if the drug product is compounded in a State that has not entered into snch an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (5 percent limit) (see section 503A(b)(3)(B)(i) and (ii) of the FD&C Act). Another condition to qualify for the exemptions listed in section 503A of the FD&C Act is that the drug is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient (section 503A(a) of the FD&C Act). This MOU does not alter this condition.

Section 503A(b)(3)(B) of the FD&C Act directs FDA to develop, in consultation with the National Association of Boards of Pharmacy (NABP), a standard MOU for nse by the States in complying with section 503A(b)(3)(B)(i).

FDA is withdrawing the revised draft standard MOU entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration," which was issued in September 2018 (2018 revised draft standard MOU). The 2018 revised draft standard MOU is superseded by the final standard MOU.

II. Previous Efforts To Develop a Standard MOU

In the **Federal Register** of January 21, 1999 (64 FR 3301), FDA announced the availability for public comment of a draft standard MOU, developed in consultation with NABP (1999 draft standard MOU). Over 6,000 commenters submitted comments on the 1999 draft standard MOU. Because of litigation over the constitutionality of the advertising, promotion, and solicitation provision in section 503A of the FD&C Act,[1] the draft standard MOU was not completed. In 2013, section 503A of the FD&C Act was amended by the Drug Quality and Security Act (DQSA) (Pub. L. 113–54) to remove the advertising, promotion, and solicitation provisions that were held unconstitutional, and FDA took steps to implement section 503A, including to continue to develop the standard MOU. In the **Federal Register** of February 19, 2015 (80 FR 8874), FDA withdrew tbe 1999 draft standard MOU and issued the 2015 draft standard MOU for public comment. FDA received more than 3,000 comments on the 2015 draft standard MOU. In the **Federal Register** of September 10, 2018 (83 FR 45631), FDA withdrew the 2015 draft standard MOU and issued the 2018 revised draft standard MOU for public comment. FDA received 38 comments during the comment period on the 2018 revised draft standard MOU. By this notice, FDA is withdrawing the 2018 revised draft standard MOU and issuing a final standard MOU, which the Agency developed in consultation with NABP for use by the States in complying with section 503A(b)(3)(B).

[1] The conditions of section 503A of the FD&C Act originally included restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug and the solicitation of prescriptions for compounded drugs. These provisions were challenged in court and held unconstitutional by the U.S. Supreme Court in 2002. See *Thompson* v. *Western States Med. Ctr.*, 535 U.S. 357 (2002).

III. Final Standard MOU

In consultation with NABP, FDA bas developed a final standard MOU. FDA considered the comments submitted on the 2015 draft standard MOU and 2018 revised draft standard MOU, as well as comments on the MOU provisions it received in connection witb a draft guidance on section 503A of the FD&C Act entitled "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act" (2013 draft 503A guidance) (see 78 FR 72901, December 4, 2013). Below, FDA has summarized and discussed key provisions of the final standard MOU and, where appropriate, summarized changes that the Agency made in the final standard MOU. Drug products intended for veterinary use, repackaged drug products, biological products subject to licensure through a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262), and drug products compounded by outsourcing facilities under section 503B of the FD&C Act are not the subject of the final standard MOU.

A. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State

The final standard MOU provides that a State Board of Pharmacy or other appropriate State agency that enters into the MOU agrees to:

- Investigate complaints of adverse drug experiences and product quality issues relating to human drug products compounded at a pharmacy in the State and distributed outside the State. Investigations performed by the State Board of Pharmacy or other appropriate State agency under this MOU will include taking steps to assess whether there is a public health risk associated with the compounded drug product and whether such risk is adequately contained. Investigations will be performed pursuant to the State Board of Pharmacy's or other appropriate State agency's established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of the MOU;

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- If the complaint is substantiated, take action that the State Board of Pharmacy or other appropriate State agency considers to be appropriate and warranted, in accordance with and as permitted by State law, to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the problem, including the risk that future similar problems may occur;
- Maintain records of the complaints it receives regarding adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigation of each complaint, and any response to or action taken as a result of a complaint, beginning when the State Board of Pharmacy or other appropriate State agency receives notice of the complaint. The State Board of Pharmacy or other appropriate State agency will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.
- Notify FDA by submission to an Information Sharing Network or by email to *StateMOU@fda.hhs.gov* as soon as possible, but no later than 5 business days, after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a human drug product compounded at a pharmacy and distributed outside the State, and provide FDA with certain information about the complaint, including the following: name and contact information of the complainant, if available; name and address of the pharmacy that is the subject of the complaint; and a description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;
- Share with FDA, as permitted by State law, the results of the investigation of a complaint after the State Board of Pharmacy or other appropriate State agency concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue. This information includes the following: The State Board of Pharmacy's or other appropriate State agency's assessment of whether the complaint was substantiated, if available; and a description and the date of any actions the State Board of Pharmacy or other appropriate State agency has taken to address the complaint;
- Notify the appropriate regulator of physicians within the State of complaints of which the State Board of Pharmacy or other appropriate State agency receives that involve an adverse drug experience or product quality issue relating to human drug products compounded by a physician and distributed outside the State. The State Board of Pharmacy or other appropriate State agency will also notify FDA by submission to an Information Sharing Network or by email to *StateMOU@fda.hhs.gov* as soon as possible, but no later than 5 business days, after receiving the complaint of the following information, if available: Name and contact information of the complainant; name and address of the physician that is the subject of the complaint; and description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

The types of complaints of compounded drug products that should be investigated include any adverse drug experience and product quality issues. Even non-serious adverse drug experiences and product quality issues can be indicative of problems at a compounding facility that could result in product quality defects leading to serious adverse drug experiences if not corrected. For example, inflammation around the site of an injection can indicate drug product contamination from inadequate sterile practices at the compounding pharmacy. If the pharmacy or physician has inadequate sterile practices, other more serious contamination could result in serious adverse drug experiences.

The final standard MOU does not include specific directions to the State Boards of Pharmacy or other appropriate State agencies relating to how to conduct their investigation of complaints. Rather, as recommended by comments submitted to FDA previously, the details of such investigations are left to the State Board of Pharmacy's or other appropriate State agency's discretion. For example, a State Board of Pharmacy or other appropriate State agency may review an incoming complaint describing an adverse drug experience and determine that such a complaint does not warrant further investigation. In other cases, a State Board of Pharmacy or other appropriate State agency may determine that an incoming complaint contains insufficient information and investigate further to determine appropriate action.

The State Board of Pharmacy or other appropriate State agency signing the final standard MOU would agree to notify FDA about certain complaints and provide FDA with certain information about the complaints so FDA could investigate the complaints itself, or take other appropriate action. The 2018 revised draft standard MOU provided that notification would occur as soon as possible, but no later than 3 business days of receipt of the complaint. The final standard MOU provides that notification will occur as soon as possible, but no later than 5 business days after the State Board of Pharmacy or other appropriate State agency receives the complaint. This period will continue to facilitate early Federal/State collaboration on serious adverse drug experiences and serious product quality issues that have the potential to affect patients in multiple States, while providing for notification in a timeframe that is more feasible for the State Boards of Pharmacy or other appropriate State agencies. FDA increased the time for notifying FDA in the final standard MOU in response to comments expressing concern about having sufficient time to process complaints and notify FDA. We note that FDA has staff on call 24 hours a day to receive information in emergency situations.

Comments on the 2015 draft MOU expressed concern with certain provisions regarding States entering into the MOU and agreeing to take action not permitted by State law or implying that, after taking action, the State made a legal determination that a complaint had been resolved. The revised draft standard MOU clarified that the State should investigate and take action that the State considers to be appropriate with respect to the complaint in accordance with and as permitted by State law. FDA also clarified that, by signing the MOU, the State agrees to take steps to assess whether there is a public health risk associated with the compounded drug product and whether such risk is adequately contained rather than make definitive determinations of risk or confirm containment. The final standard MOU retains these revisions that addressed the concerns from comments on the 2015 draft.

B. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate

For purposes of the final standard MOU, a pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of)

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the facility in which the drug products were compounded during that same calendar year and the number of prescription orders for compounded human drug products that were dispensed (*e.g.*, picked up by a patient) at the facility in which they are compounded during that same calendar year (Fig. 1). This concept is called the 50 percent threshold.

Figure 1. Calculating an Inordinate Amount

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.

The final standard MOU provides that State Boards of Pharmacy or other appropriate State agencies that enter into the MOU will agree to:

- On an annual basis, identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the State Board of Pharmacy or other appropriate State agency, pharmacies that distribute inordinate amounts of compounded human drug products interstate.
- For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the State Board of Pharmacy or other appropriate State agency will identify, using data submitted to the Information Sharing Network or other available mechanisms, during that same calendar year:
  - The total number of prescription orders for sterile compounded human drug products distributed interstate;
  - The names of States in which the pharmacy is licensed;
  - The names of States into which the pharmacy distributed compounded human drug products; and,
  - Whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.
- Within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, the State Board of Pharmacy or other appropriate State agency will notify FDA, by submission to an Information Sharing Network or by email to *StateMOU@fda.hhs.gov*, and will include the following information:
  - Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;
  - The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year;
  - The number of prescription orders for compounded human drug products that were dispensed (*e.g.*, picked up by a patient) at the facility in which they are compounded during that same calendar year;
  - Total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;
  - Total number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year;
  - The names of States in which the pharmacy is licensed as well as the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and
  - Whether the State Board of Pharmacy or other appropriate State agency inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescriptions for individually identified patients during that same calendar year.
- If the State Board of Pharmacy or other appropriate State agency becomes aware of a physician who is distributing any amount of compounded human drug products interstate, it will notify the appropriate regulator of physicians within the State. The State Board of Pharmacy or other appropriate State agency will, within 30 days of identifying a physician who is distributing any amount of compounded human drug products interstate, also notify FDA by submission to an Information Sharing Network or by email to *StateMOU@fda.hhs.gov*.

Section 503A of the FD&C Act reflects Congress' recognition that compounding may be appropriate when it is based on receiving a valid prescription order or notation approved by the prescrihing practitioner for an identified individual patient. However, drug products compounded under section 503A are not required to demonstrate that they are safe or effective, have labeling that bears adequate directions for use, or

conform to CGMP. Congress, therefore, imposed strict limitations on the distribution of drug products compounded under section 503A to protect the public health and the integrity of the drug approval process.

In particular, Congress did not intend for compounders operating under these statutory provisions to grow into conventional manufacturing operations making unapproved drugs, operating a substantial proportion of their business interstate, without adequate oversight. Although other provisions of the FD&C Act (*e.g.*, the adulteration provisions regarding drugs prepared, packed, or held under insanitary conditions) apply to drugs compounded by State-licensed pharmacies and physicians that may qualify for the exemptions under section 503A of the FD&C Act, and although FDA may take action in appropriate cases against compounders whose drugs violate these provisions or that operate outside of the conditions in section 503A, Congress recognized that these compounders are primarily overseen by the States. However, if a substantial proportion of a compounder's drug products are distributed outside a State's borders, adequate regulation of those drug products poses significant challenges to State regulators. States face logistical, regulatory, and financial challenges inspecting compounders located outside of their jurisdiction. In addition, if a compounder distributes drug products to multiple States, it can be very difficult to gather the scattered information about possible adverse drug experiences or product quality issues associated with those drug products, connect them to the compounder, and undertake coordinated action to address a potentially serious public health problem.

Therefore, as a baseline measure, section 503A(b)(3)(B)(ii) of the FD&C Act limits the distribution of compounded drug products outside of the State in which they are compounded to 5 percent of the total prescription orders dispensed or distributed by a licensed pharmacist, pharmacy, or physician. It then directs FDA, in consultation with NABP, to develop a standard MOU that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products compounded in and distributed outside such State. Development of the standard MOU involves FDA describing what inordinate amounts means and providing a mechanism for addressing distribution of inordinate amounts of compounded human drug products interstate, as long as the State agrees to appropriately investigate complaints relating to drug products compounded in and distributed out of the State. The 5 percent limitation in section 503A(b)(3)(B)(ii) does not apply to drug products compounded in a State that has entered into the standard MOU under section 503A(b)(3)(B)(i).

In the 2015 draft standard MOU, FDA proposed that distribution interstate up to a 30 percent limit would not be inordinate, and that States entering into the MOU would agree to take action regarding pharmacists, pharmacies, or physicians that distribute inordinate amounts of compounded drug products interstate. FDA received a number of comments indicating that certain pharmacies, such as pharmacies located near State borders and home infusion pharmacies, distribute more than 30 percent of their compounded human drug products to patients interstate because, for example, the patients are located in another nearby State, or because few pharmacies compound a particular drug product to treat an uncommon condition for patients dispersed throughout the country. The comments noted that the proposed definition of inordinate amounts and the proposed provision in which States agree to take action could prevent such pharmacies from fulfilling patients' medical needs for the drug products that they supply. Other comments expressed concern about instances in which pharmacies are located near a State border and distribute compounded drug products to the other side of that border. FDA also received general comments questioning the Agency's basis for the 30 percent limit and indicating that it was too low. Some comments suggested that FDA increase the limit, including a suggestion to increase it to 50 percent.

The 2018 revised draft standard MOU addressed these comments in two respects. First, it removed the provision in the 2015 draft standard MOU that States agree to take action with respect to the distribution of inordinate amounts of compounded human drug products interstate. Second, it changed what is considered "inordinate amounts" from a 30 percent limit to a 50 percent threshold. In the final standard MOU, the States are not agreeing to take action with respect to distribution of inordinate amounts of compounded human drug products interstate, but, instead, to notify FDA of pharmacies that have distributed an inordinate amount of compounded human drug products interstate. The Agency does not intend to take action against a pharmacy located in a State that has entered into the MOU solely because the pharmacy has exceeded the threshold for inordinate amounts. Rather, the State Board of Pharmacy or other appropriate State agency entering into the final standard MOU agrees to collect further information on pharmacies that have distributed inordinate amounts interstate and provide this information to FDA to help inform Agency inspectional priorities. The State Board of Pharmacy or other appropriate State agency also agrees to notify FDA and the appropriate state regulator of physicians if it becomes aware of physicians distributing any amount of compounded human drug products interstate.

We note that States generally have day-to-day oversight responsibilities over State-licensed pharmacies, pharmacists, and physicians. In general, FDA considers a State-licensed pharmacy or physician to be primarily overseen by the State, which is responsible hoth for regulation of the compounder and protection of its citizens who receive the compounded drug products. However, as discussed above, if a substantial proportion of a compounder's drug products is distributed outside a State's borders, adequate regulation of those drugs poses significant challenges to State regulators. In such cases, although State oversight continues to be critical, additional oversight by FDA may afford an important public health benefit.

As stated above, the final standard MOU uses 50 percent as the threshold beyond which the amount of compounded human drug products distributed interstate by a pharmacy would be considered inordinate. The 50 percent threshold is the threshold that, with regard to pharmacies, triggers an information identification and reporting obligation once it is reached. The Agency believes that more than 50 percent is an appropriate measure of "inordinate amounts" because it marks the point at which pharmacies are distributing the majority of their compounded human drug products interstate, and the regulatory challenges associated with interstate distributors discussed above become more pronounced. At this point, the risk posed by the distribution practices of the compounder may weigh in favor of additional Federal oversight in addition to State oversight.

FDA recognizes that, in some cases, pharmacies may distribute more than 50 percent of a small quantity of compounded human drug products to contiguous States. Although such pharmacies have exceeded the inordinate amounts threshold in the final standard MOU, FDA would

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consider other information, such as the number of patients that will receive the compounded human drug products, if available, when assessing the pharmacy's priority for risk-based inspection. Accordingly, when a State Board of Pharmacy or other appropriate State agency identifies a pharmacy that distributes an inordinate amount of compounded human drug products interstate, the final standard MOU provides that the State entity will supply the Agency with certain information as described above. In addition, if the State Board of Pharmacy or other appropriate State agency becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the State entity will notify both the appropriate regulator of physicians within the State and FDA. FDA intends to use this information to prioritize its oversight of compounders based on risk, focusing on those that appear likely to distribute large volumes of compounded human drug products, particularly when the distribution is to multiple States, the drug products are intended to be sterile, and there is information about a lack of valid prescriptions for individually identified patients.

The calculation of inordinate amounts in the final standard MOU, with clarifying changes to the language, is the same as the calculation proposed in the 2018 revised draft standard MOU, with the exception of a change in the timeframe used in the calculation from 1 month to 1 year and removing drugs compounded by physicians from the calculation made by the State Board of Pharmacy or other appropriate State agency. The 2015 draft standard MOU provided that a compounder is considered to have distributed an inordinate amount of compounded drug products interstate if the number of units of compounded drug products distributed interstate during any calendar month is equal to or greater than 30 percent of the number of units of compounded and non-compounded drug products distributed or dispensed both intrastate and interstate by such compounder during that calendar month. FDA received comments noting that because the calculation includes both compounded and non-compounded drug products, in many cases, a substantial factor in whether a compounder has distributed an inordinate amount of compounded drug products interstate is whether the compounder offers non-compounded drug products. For example, under that policy, many specialty compounding pharmacies that engage in distribution of compounded human drug products interstate and only distribute compounded drug products would be able to distribute fewer compounded drug products interstate before reaching an inordinate amount than a pharmacy that also fills prescriptions for non-compounded drug products, even if both pharmacies produced the same amount of compounded drug products. After considering the public comments, FDA does not believe that including non-compounded drug products within the calculation of inordinate amounts would help address the public health concerns associated with sending compounded human drug products interstate that Congress sought to address in section 503A(b)(3)(B) of the FD&C Act. Non-compounded drug products were excluded from the calculation of inordinate amounts in the 2018 revised draft MOU. This final standard MOU maintains this exclusion.[2] FDA removed drug products compounded by physicians from the inordinate amount calculation to clarify that the State Board of Pharmacy or other appropriate State agency signing the MOU does not agree to gather information about the distribution of compounded drug products interstate by physicians or to calculate inordinate amounts of drug products compounded by a physician and distributed interstate. Instead, the State Board of Pharmacy or other appropriate State agency signing the MOU agrees that if it becomes aware that a physician is distributing any amount of compounded human drug products interstate it will notify the State authority that regulates physicians and FDA. This focus on States calculating inordinate amounts of pharmacy compounding reflects FDA's understanding and feedback from State regulators that the distribution interstate of compounded drug products mainly involves pharmacy compounders.

FDA received comments on the 2018 revised draft MOU expressing concern about calculating inordinate amounts by calendar month. After considering these comments and recognizing the possibility for significant monthly fluctuations, we have provided for annual calculation of inordinate amounts in the final standard MOU.

This 50 percent threshold does not function as a limit on the distribution of compounded human drug products interstate, but, instead, is a threshold for triggering information gathering about pharmacy distribution of compounded drugs by the State Board of Pharmacy or other appropriate State agency and provision to FDA. The information gathered will be considered by the Agency for the purpose of helping to inform its risk-based inspection priorities.

C. Definitions

Appendix A retains the definitions of "adverse drug experience," "serious adverse drug experience," "product quality issue," and "serious product quality issue" from the 2018 revised draft standard MOU.

To clarify the meaning of "distribution of inordinate amounts of compounded drug products interstate," the proposed definition of "distribution" in the 2018 revised draft standard MOU has been omitted and "distribution of compounded human drug products interstate" and "inordinate amounts" are defined. "Distribution of compounded human drug products interstate" means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the state in which the drug was compounded. A pharmacy has distributed an "inordinate amount" of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (1) The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (2) the number of prescription orders for compounded human drug products that were dispensed (*e.g.*, picked up by a patient) at the facility in which they were compounded during that same calendar year.

We received a number of comments on the 2015 draft standard MOU and the 2018 revised draft standard MOU stating that distributing and dispensing are mutually exclusive activities, such that if a drug product is distributed, it is not also dispensed, and vice versa. Some comments asserted, in particular, that a compounded drug product should not be considered to be "distributed" when it is provided pursuant to a prescription. Other stakeholders, however, agreed with the inclusion of drug products provided pursuant to a prescription within the definition of "distribution" and maintained that this interpretation was important to protect the public health.

After considering these comments and the public health objectives of section 503A(b)(3)(B) of the FD&C Act, FDA

[2] FDA also intends to exclude non-compounded drugs from the calculation of the 5 percent limit in section 503A(b)(3)(B)(ii).

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considers that when a drug is picked up at the facility in which it was compounded, dispensing, but not distribution, occurs for purposes of 503A(b)(3)(B).

FDA believes that in-person dispensing, where the transaction between the compounder and the patient is completed at the facility in which the drug product was compounded, is appropriately overseen, primarily, by the State outside the context of the MOU, regardless of whether the compounded drug product subsequently leaves the State. Such an intrastate, local transaction generally indicates a close connection among the patient, componnder, and prescriber. By contrast, transactions by mail often have a less direct nexus among the patient, compounder, and prescriber than in-person pick-ups and would be considered "distribution."

Drugs dispensed in-person that are later taken out of State will not contribute to reaching the threshold for inordinate amounts under the final MOU. Nor will complaints associated with compounded drug products dispensed this way and subsequently taken out of State be subject to the complaint investigation provisions of the final MOU. FDA expects that, in practice, the State in which the initial transaction occurred would handle such complaints. The State may, in its discretion, notify FDA of the complaint.

FDA is not persuaded by comments urging the Agency to interpret "distribution" and "dispensing" to be entirely separate activities for purposes of section 503A(b)(3)(B) of the FD&C Act. These comments recommend using definitions for these terms used elsewhere in the FD&C Act and FDA regulations, and generally conclude that distribution does not include the transfer of a drug pursuant to a prescription.

The conditions in section 503A, including section 503A(b)(3)(B), must be interpreted consistent with the prescription requirement in section 503A(a) of tbe FD&C Act. If we were to interpret the word "distribution" to apply only if a drug is provided without a prescription, it would mean that drug products compounded under section 503A of the FD&C Act are excluded from regulation under the MOU and the 5 percent limit, because to qualify for the exemptions under section 503A, a compounder must obtain a valid prescription order for an individually identified patient. For the reasons stated previously in this document, we believe this would achieve the opposite of what Congress intended. A compounded drug product may be eligible for the exemptions under section 503A of the FD&C Act only if it is, among other things, "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient."

Nor is there anything to suggest that Congress understood "distributed" and "dispensed" to be mutually exclusive categories rather than overlapping categories for purposes of section 503A. Section 503A(b)(3)(B) of the FD&C Act does not define "distribution" to exclude dispensing, which Congress has done elsewhere when that was its intention.[3] The definition proposed by comments would write an exclusion for dispensing, in its entirety, into the statute where Congress did not. Indeed, with respect to comments suggesting that drugs dispensed pursuant to prescriptions could not also be "distributed," we note that, in section 503A(h)(3)(B), Congress specifically contemplated that prescription orders could be "distributed" when it directed the Agency to count the number of prescription orders that pharmacists and prescribers distributed.

IV. Other Issues

A. Authority of State Boards of Pharmacy or Other Appropriate State Agencies

The 2018 revised draft standard MOU proposed that "States" would be the signatories of the MOU. In the final standard MOU, FDA clarifies the State party to the agreement, which is described as the "State Board of Pharmacy or other appropriate State agency." FDA received comments expressing concerns that the State entity signing the MOU (*e.g.*, the State Board of Pharmacy) may not have regulatory authority over physician compounding and could not agree to the MOU provisions regarding physicians as they appeared in the 2018 revised draft standard MOU. With regard to physician compounding, FDA has revised certain provisions from the 2018 revised draft standard MOU. Under the final standard MOU, a State Board of Pharmacy or other appropriate State agency would enter into the MOU on behalf of the State and agree to (1) notify FDA and the appropriate regulator of physicians within the State when it receives a complaint about adverse drug experiences or product quality issues associated with a human drug product compounded by a physician and distributed outside the State; and (2) if it becomes aware of a physician distributing any amount of compounded human drug products interstate, notify FDA and the appropriate regulator of physicians within the State.

B. Physician Compounding

It is FDA's understanding that physicians who compound drugs generally do so for their own patients, within their own professional practice, and provide them intrastate. FDA believes that, generally, physicians are not engaged in compounding that results in routine distribution of compounded drug products interstate.

Additionally, several comments advised that State Boards of Pharmacy do not oversee physician compounding and would not be able to agree to the provisions under the 2018 revised draft standard MOU with respect to oversight of physician compounding (collecting additional information to identify whether a physician compounder is distributing inordinate amounts of compounded drug products interstate, etc.). Accordingly, under the final standard MOU, State Boards of Pharmacy or other appropriate State agencies would agree to (1) notify FDA and the appropriate regulator of physicians within the State when they receive complaints about adverse drug experiences or product quality issues associated with a human drug product compounded by a physician and distributed outside the State; and (2) if they become aware of a physician distributing any amount of compounded human drug products interstate, notify FDA and the appropriate regulator of physicians within the State. The information provided to FDA will help inform Agency inspectional priorities with respect to physicians who compound human drug products and provide information to State regulators of physicians for appropriate action.

[3] In other (non-compounding) contexts, where it would further a regulatory purpose, Congress and the Agency have specifically defined "distribute" to exclude dispensing. See, for example, section 581(5) of the FD&C Act (21 U.S.C. 360eee(5)), which applies to Title II of the DQSA, and 21 CFR 208.3, which applies to 21 CFR part 208. Section 503A of the FD&C Act does not contain a similar definition, or a similar specific direction to exclude dispensing from the meaning of distribution. We also note that these definitions were adopted for provisions that focus on conventionally manufactured drug products, which assign different obligations to dispensers than to wholesalers, packagers, or other intermediaries in light of the different role that dispensers play with respect to product labeling and the drug distribution chain. In contrast, section 503A of the FD&C Act focuses on compounded drugs, and the reasons for defining "distribution" to exclude dispensing in Title II of the DQSA or part 208 do not apply.

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C. Development of a Standard MOU

A number of comments on the 1999 draft standard MOU, the 2013 draft 503A guidance, the 2015 draft standard MOU, and the 2018 revised draft MOU suggested that FDA negotiate MOUs with individual States, rather than develop a standard MOU. Section 503A of the FD&C Act requires the Agency to develop a standard MOU for use by the States. Furthermore, it would be impractical to develop an individualized MOU with every State, and creating individualized MOUs would create a patchwork of regulation of distribution of compounded human drug products interstate by compounders seeking for their drug products to qualify for the exemptions under section 503A of the FD&C Act. This would be confusing to the healthcare community, as well as regulators.

D. Exemptions From the Provisions Related to Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate

Some comments on the 2013 draft 503A guidance, the 2015 draft standard MOU, and the 2018 revised draft standard MOU requested that we consider exempting certain drug products or types of compounding entities from the threshold in the MOU and the 5 percent limit. For example, some comments recommended that we exempt nonsterile products.

American consumers rely on the FDA drug approval process to ensure that medications have been evaluated for safety and effectiveness before they are marketed in the United States. Drugs made by compounders, including those made at outsourcing facilities, are not FDA-approved. This means that they have not undergone premarket review of safety, effectiveness, or manufacturing quality. Therefore, when an FDA-approved drug is commercially available, FDA recommends that practitioners prescribe the FDA-approved drug rather than a compounded drug product unless the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product.

In section 503A of the FD&C Act, Congress enacted several conditions to differentiate compounders from conventional manufacturers and provided that only if the compounders meet those conditions can they qualify for the exemptions from the drug approval requirements in section 505 of the FD&C Act. One of those conditions relates to limitations and other measures to address distribution of compounded drug products interstate, and FDA intends to enforce those provisions to differentiate compounding that qualifies for the exemptions from conventional manufacturing in the guise of compounding that does not and will apply the conditions to all types of drugs and all categories of compounding.

E. Information Sharing Between the State Boards of Pharmacy or Other Appropriate State Agencies and FDA

The final standard MOU provides that State Boards of Pharmacy or other appropriate State agencies will agree to notify FDA of a complaint relating to a compounded human drug product distributed outside the State involving a serious adverse drug experience or serious product quality issue and provide information about those experiences and issues. The final standard MOU also provides that State Boards of Pharmacy or other appropriate State agencies will notify FDA if they identify a pharmacy that has distributed inordinate amounts of compounded human drug products interstate. In addition, State Boards of Pharmacy or other appropriate State agencies will notify FDA and the appropriate regulator of physicians within the State if the State entity becomes aware of a physician who is distributing any amount of compounded human drug products interstate, or if the State entity receives a complaint involving an adverse experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State.

FDA has entered into a cooperative agreement with NABP to establish an information sharing network that is intended to, in part, facilitate State information reporting to FDA by State Boards of Pharmacy or other appropriate State agencies that enter into the MOU with FDA addressing distribution of compounded drugs interstate.[4] The goal of this information-sharing and research initiative is to improve the management and sharing of information available to State regulators and FDA regarding State-licensed compounders and the distribution of compounded human drug products interstate to support better and more targeted regulation and oversight of compounding activities to help reduce risk to patients. This information will be important to help States to focus their limited resources on compounders for which they have primary oversight responsibility that present the greatest risk. It will also facilitate FDA's ability to determine when additional Federal oversight is warranted, such as when a large-scale compounder distributes drug products to multiple States, potentially causing significant and widespread harm if its products are substandard. FDA expects that the information sharing network will be designated by FDA for purposes of the MOU to collect, assess, and allow review and sharing of information pursuant to the MOU. FDA regularly posts, on its compounding website, information about enforcement and other actions related to compounders that violate the FD&C Act, and it is obligated to share certain information with States under section 105 of the DQSA. In addition to these measures, FDA is taking steps to proactively share information with States about complaints that it receives regarding compounded drug products, consistent with Federal laws governing information disclosure.

F. Enforcement of the 5 Percent Limit on Distribution of Compounded Human Drug Products Out of the State in Which They Are Compounded

In the 2013 draft 503A guidance, FDA stated that it does not intend to enforce the 5 percent limit on distribution of compounded human drug products outside of the State in which they are compounded until 90 days after FDA has finalized a standard MOU and made it available to the States for their consideration and signature. Most comments on the 2013 draft 503A guidance that raised this issue said this period was too short but did not recommend a specific alternative. A few comments recommended a different timeframe, one recommending 120 days and another recommending 365 days. The 1997 Senate Committee Report for the Food and Drug Administration Modernization Act suggests that a 180-day period for States to decide whether to sign might be appropriate.[5] In the notice of availability for the 2018 revised draft standard MOU, consistent with the 2015 draft standard MOU, the Agency proposed a 180-day period after

[4] See RFA–FD–19–025, available at *https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-19-025.html*.

[5] "[U]ntil the State . . . enters into a memorandum of understanding (MOU) with the Secretary or 180 days after the development of the standard MOU, whichever comes first, the [section 503A] exemption shall not apply if inordinate quantities of compounded products are distributed outside of the State in which the compounding pharmacy or physician is located." (U.S. Senate Committee Report)

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the final standard MOU is made available for signature before FDA will enforce the 5 percent limit in States that have not signed the MOU, and invited public comment on whether this was an appropriate timeframe. Some commenters on the 2018 revised draft standard MOU stated that more time may be necessary because some States may be required to enact new laws and promulgate new regulations before entering the MOU. Therefore, in response to these comments, FDA is providing a 365-day period for States to decide whether to sign the MOU before FDA intends to begin enforcing the 5 percent limit in States that do not sign. It is FDA's understanding that this extended timeframe corresponds to a full legislative cycle for most States and should, therefore, afford sufficient time for States to modify their laws and regulations, if necessary.

V. Paperwork Reduction Act of 1995

This MOU refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information have been approved under OMB control number 0910–0800.

VI. Electronic Access

Persons with access to the internet may obtain the final standard MOU at either *https://www.fda.gov/drugs/human-drug-compounding/regulatory-policy-information*, *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, or *https://www.regulations.gov*.

Dated: October 21, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23687 Filed 10–26–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a virtual meeting. The meeting will be open to the public. For this meeting, the TBDWG will review chapters and the template for the 2020 report to the HHS Secretary and Congress. The 2020 report will address ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, and interventions for individuals with tick-borne diseases; advances made pursuant to such research; federal activities related to tick-borne diseases; and gaps in tick-borne disease research.

DATES: The meeting will be held online via webcast on November 17, 2020 from approximately 9:00 a.m. to 5:30 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the TBDWG web page at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-11-17/index.html* when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC, 20024. Email: *tickbornedisease@hhs.gov;* Phone: 202–795–7608.

SUPPLEMENTARY INFORMATION: The registration link will be posted on the website at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-11-17/index.html* when it becomes available. After registering, you will receive an email confirmation with a personalized link to access the webcast on November 17, 2020.

The public will have an opportunity to present their views to the TBDWG orally during the meeting's public comment session or by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public comment should review instructions at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-11-17/index.html* and respond by midnight November 6, 2020 ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the 30 minute session. Written public comments will be accessible to the public on the TBDWG web page prior to the meeting.

Background and Authority: The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with Section 2062 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review federal efforts related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities. The TBDWG is required to submit a report to the HHS Secretary and Congress on their findings and any recommendations for the federal response to tick-horne disease every two years.

Dated: October 13, 2020.

James J. Berger,

Designated Federal Officer, Tick-Borne Disease Working Group, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2020–23693 Filed 10–26–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Listing of Members of the Indian Health Service's Senior Executive Service Performance Review Board (PRB)

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction of Performance Review Board Membership.

SUMMARY: The Indian Health Service published a notice in the **Federal Register** on October 14, 2020 listing members of the Indian Health Service's Senior Executive Service Performance Review Board. The membership listing failed to include Mr. Christopher Mandregan as a member of the Performance Review Board.

FOR FURTHER INFORMATION CONTACT: Nathan Anderson, Human Resources Specialist, 5600 Fishers Lane, Rockville, MD 20857, Phone: (605) 681–4940.

Correction

In the FR notice of October, 14, 2020, (85 FR 65062), the correction is to the alphabetical listing of Performance Review Board members:

Buchanan, Chris
Cooper, Jennifer
Cotton, Beverly
Curtis, Jillian
Driving Hawk, James
Grinnell, Randy (Chair)
Gyorda, Lisa
LaRoche, Darrell
Mandregan, Christopher
Redgrave, Bryce
Smith, Ben

April 27, 2021

Caroline Juran, Executive Director
Virginia Board of Pharmacy
Perimeter Center, 9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Caroline Juran,

We, the undersigned organizations, strongly urge your state board of pharmacy to take action immediately in determining if it can sign the FDA's Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) before the October 2021 deadline. If there are concerns about or impediments to signing by the October 2021 deadline, we urge you to contact the FDA *as soon as possible* to express your state's concerns and to request at least a two-year extension of the signing deadline, to October 2023. A letter to the FDA requesting such an extension was submitted April 16, 2021 and a copy of that correspondence is included here.

Already, several state boards of pharmacy have raised issues about the potential conflicts between the MOU and existing state laws regarding confidentiality of information. It is important that your board of pharmacy analyze now any legal restrictions which may exist under state law and take action to remedy those restrictions as quickly as possible. Some states have already determined corrective action cannot take place by the October 2021 deadline and will need to request an extension. If this is the case for your state, we urge you to echo to FDA our request for a two-year extension of the signing deadline.

The consequences of not signing the MOU are significant:

- For states that **do not sign** the MOU, a pharmacy in that state cannot send more than five percent of its human compounded prescriptions to patients out of state, which has significant impacts on the viability of compounding pharmacies and patients who live near state borders, have two residences, live in rural areas, or require a specialized compound from an out of state pharmacy for treatment.

- For states that **do sign** the MOU, a pharmacy can continue to fulfill the compounded needs of all their patients; however, those pharmacies that dispense/distribute more than fifty percent of their human compounded prescriptions out of state will be required to submit additional data to the state board of pharmacy. This additional information will be shared by the board of pharmacy with the FDA.

Please speak with compounders in your state about the implications of the MOU on their patients and practice. Clearly, there are negative implications for signing and not signing. Given the upcoming October 2021 deadline and the devastating impacts not signing the MOU would have on patients who rely on compounded treatments, we urge you to sign the MOU by October 2021 – or if unable to do so due to conflicts of law, to request at least a two-year extension to October 2023 from the FDA. If you have further questions, please contact Ronna Hauser, NCPA VP Policy & Government Affairs Operations, at ronna.hauser@ncpa.org.

Sincerely,

Alliance for Pharmacy Compounding (APC)
American Pharmacists Association (APhA)
National Community Pharmacists Association (NCPA)
PCCA

CC: National Association of Boards of Pharmacy

Enclosed in letter from APC, APhA, & NCPA

April 16, 2021

Dockets Management Staff: Docket No. [FDA-2015-N-0030]
Food and Drug Administration 5630
Fishers Lane, Room 106
Rockville, MD 20852

Submitted Electronically to FDA Docket No. [FDA-2015-N-0030]

The undersigned organizations represent thousands of pharmacy compounding professionals. We write today regarding the FDA's final Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) with the states regarding interstate distributions of compounded drugs. For the reasons discussed below, we respectfully request that the FDA delay enforcement of the final MOU until at least October 26, 2023.

We are concerned that multiple state boards of pharmacy, including but not limited to those in large states like Texas and Florida, have recently concluded that it will be necessary for their respective state legislatures to amend state law in order for the boards of pharmacy to be able to comply with the final MOU's requirements. Specifically, both Texas and Florida have state laws that protect the confidentiality of complaint information submitted to their state boards of pharmacy, and both boards have received legal opinions that those laws would need to be changed before the board could attest to the ability to comply with the final MOU.

To date, in some states the relevant laws have not been changed and it is unlikely that changes will be made and implemented before the October 26, 2021 enforcement date. Some states have biennial or part-time legislative sessions that do not align with the FDA's deadline for states to sign the final MOU. Florida is in the final two weeks of their legislative session, with no legislation pending to address the final MOU, and the next legislative session there does not begin until January 2022. Likewise, Texas is in the final six weeks of their biennial legislative session and the next legislative session in that state does not convene until January 2023.

According to the National Association of Boards of Pharmacy's FDA Compounding MOU Project data, Alabama, New Mexico, Wyoming, Idaho, and Tennessee have also indicated they are unable or unwilling to sign the final MOU. We understand that multiple other states are facing similar legal hurdles and budgetary concerns and are preoccupied with the COVID-19 pandemic as well. Therefore, these states will not likely be able to meet the FDA's deadline to sign the final MOU. States' boards have also expressed concerns about how many additional inspectors and/or other full-time employees will be needed to meet the final MOU's requirements.

Enforcement of a five percent cap beginning in October of this year will result in an unnecessary disruption of health care for thousands of patients and will put an enormous strain on the pharmacies that serve them. Patients who rely on compounded medications from pharmacies in states that cannot, or do not sign the final MOU by the October 26, 2021 deadline will be penalized by disruption

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of care and inability to receive therapy from their pharmacy of choice. States should be given more time to amend their laws and budget the necessary funds so they can sign and comply with the final MOU.

For these reasons, we respectfully request FDA delay its enforcement of the final MOU until, at least, October 26, 2023.

Thank you in advance for your consideration of this request.

If you have questions or would like to discuss the matter, please contact APC's Scott Brunner at scott@a4pc.org or at (404) 844-8607.

Sincerely,

Alliance for Pharmacy Compounding
American Pharmacists Association
National Alliance of State Pharmacy Associations
National Community Pharmacists Association

CC: National Association of Boards of Pharmacy

NABP
National Association of
Boards of Pharmacy

847/391-4406
Fax 847/375 1114

1600 Feehanville Dr
Mount Prospect IL 60056
help@nabp.pharmacy

April 27, 2021

Frances Gail Bormel, JD, RPh
Acting Director, Office of Compounding Quality and Compliance
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Sent via email: Frances.Bormel@hhs.fda.gov

Re: Request to Delay Enforcement of Section 503A(b)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act

Dear Ms Bormel:

The National Association of Boards of Pharmacy® (NABP®) writes to respectfully request that Food and Drug Administration (FDA) delay enforcement of Section 503A(b)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act until October 2022. Section 503A(b)(3)(B)(ii) reads:

> SEC. 503A. PHARMACY COMPOUNDING.
>
> (b) Compounded Drug.--
>
> (3) Drug product.--A drug product may be compounded under subsection (a) only if--
>
> (B) such drug product is compounded in a State--
>
> (ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician. [Page 111 STAT. 2330]

As you know, NABP, founded in 1904, represents the pharmacy regulatory and licensing authorities in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, The Bahamas, and all 10 Canadian provinces. NABP's mission is to serve as the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

In recent weeks, NABP has received comments from multiple member boards of pharmacy that the timeline is too short for them to take the action needed to sign the MOU by October 2021 and have asked about FDA delaying enforcement.

The majority of boards cite the burden that the coronavirus disease 2019 (COVID-19) pandemic has placed on them, causing a backlog in most, if not all, board activities and resulting in the need for boards to prioritize COVID-19-related actions above everything else.

Some boards also cite issues beyond those related to COVID-19. Several states have indicated that regulatory changes, which involve lengthy processes and require extensive public comment periods, are needed. Others have indicated that statutory amendments are necessary, and the legislatures are placing a great deal of focus on COVID-19-related legislation. In addition, states where legislatures only meet biennially, eg, Montana, Nevada, North Dakota, Texas, may not have appropriate changes in place until 2022 or even 2023.

Additionally, the potential lack of access for patients who rely on pharmacies that are located in states that cannot sign the MOU is of great concern to NABP and its member boards. In fact, at least one state has no in-state compounding pharmacies and its patients rely exclusively on interstate shipment for their needed medications. As a result, an October 2021 enforcement date may cause an interruption in therapy for these and other patients nationwide.

To summarize, NABP anticipates that an enforcement delay will give many states the time needed to take the necessary actions to sign the MOU. As you know, NABP is strongly supportive of the work that FDA has done to protect patients from high-risk compounders and would like as many states as possible to join in this effort. Association staff is hard at work developing the Information Sharing Network and will soon be onboarding several states that have decided to sign the MOU. NABP is pleased that patients in these states will soon benefit from the work put into this effort.

Thank you for your attention to this matter. NABP hopes that FDA will consider this request.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

cc: NABP Executive Committee

NABP Model Language

Definitions.

"NABP Information Sharing Network"[1] means the information sharing network developed by NABP that collects, assesses, and allows review and sharing of compounding pharmacy and physician information as described in the MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION.

"Person" means an individual, corporation, subsidiary, partnership, association, organization, affiliate organization, or any other legal entity, including government.

Notification.

(a) On an annual basis, and within 90 days of the beginning of the calendar year, all licensed Persons shall report to the NABP Information Sharing Network the following:

(1) Whether the licensed Person participates in the following activities during the identified calendar year:

(i) Human drug compounding – sterile;

(ii) Human drug compounding – nonsterile;

(iii) Patient-specific compounding; and

(iv) Non-patient-specific compounding.

(2) If a licensed Person is compounding sterile or nonsterile human drug products and is prompted by the NABP Information Sharing Network[2], the licensed Person shall also provide for the identified calendar year the following information[3]:

(i) Number of prescription orders for compounded human drugs the licensed Person sent out of the facility;

(ii) Number of prescription orders for compounded human drugs dispensed at the facility; and

(iii) Total number of prescription orders for compounded human drugs distributed interstate.

(3) If prompted by the NABP Information Sharing Network[4], the licensed Person shall provide the following additional information:

---

[1] The information sharing network was built by NABP pursuant to the NABP-FDA Cooperative Agreement to Develop a System for the Collection, Management, and Sharing of Information on Compounding Pharmacies Distributing Interstate.

[2] The Information Sharing Network will prompt the licensed Person for this information if the licensed Person indicates that it is compounding sterile or nonsterile human drug products.

[3] These three data points will allow the Information Sharing Network to determine whether the licensed Person is distributing inordinate amounts of compounded human drug products interstate, as described in the MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION.

[4] The Information Sharing Network will prompt the licensed Person for this additional information if it calculates that the licensed Person has distributed inordinate amounts of compounded human drug products interstate as described in the MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION.

(i) Number of prescription orders for sterile compounded human drugs distributed interstate;
(ii) Names of states into which the licensed Person distributed compounded human drugs during the year; and
(iii) Whether compounded human drugs are distributed without patient-specific prescriptions.

Virginia Board of Pharmacy
June 4, 2021
Licenses Issued

	11/1/19-1/31/20	2/1/20-4/30/30	5/1/20-7/30/20	8/1/20-10/31/20	11/1/20-1/31/21	2/1/21-4/30/21	License Count 5/20/2021
Business CSR	23	25	28	23	8	25	1,434
CE Courses	0	0	2	0	0	1	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	8
Medical Equipment Supplier	1	4	5	4	8	5	226
Nonresident Manufacturer	10	7	6	3	1	6	201
Nonresident Medical Equipment Supplier	14	9	5	11	9	8	347
Non-resident Outsourcing Facility	1	0	3	2	0	1	33
Non-resident Pharmacy	21	33	22	29	31	37	867
Non-resident Third Party Logistics Provider	17	14	5	12	15	10	150
Non-resident Warehouser	6	19	5	11	9	12	70
Non-resident Wholesale Distributor	8	8	11	5	10	20	624
Non-restricted Manufacturer	0	1	1	0	0	1	28
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmaceutical Processor	1	1	1	1	0	0	4
Pharmacist	187	120	309	301	178	175	15,777
Pharmacist Volunteer Registration	0	0	0	0	0	0	0
Pharmacy	11	10	12	7	8	11	1,764
Pharmacy Intern	43	160	76	177	99	107	1,506
Pharmacy Technician	485	345	333	447	482	424	13,012
Pharmacy Technician Trainee					149	1256	1,837
Pharmacy Technician Training Program	1	0	2	7	2	7	135
Physician Selling Controlled Substances	23	28	22	24	16	7	566
Physician Selling Drugs Location	3	6	5	4	2	4	163
Pilot Programs	1	0	1	0	1	0	24
Registered Physician For CBD/THC-A Oil	39	58	68	106	140	122	733
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	1	1	0	0	1	41
Third Party Logistics Provider	0	1	0	0	0	1	7
Warehouser	3	2	1	4	1	5	120
Wholesale Distributor	0	0	2	1	0	1	63
Total	**898**	**852**	**926**	**1,179**	**1,169**	**2,245**	**39,751**

Pharmaceutical Processors Report-June 4, 2021

- Dharma Pharmaceuticals, LLC completed a relocation of the pharmaceutical processor from the original Bristol location to a new location in Abingdon effective May 4, 2021.
- As has been reported in news media, Columbia Care, Inc. has entered into a purchase agreement with Green Leaf Medical of Virginia, LLC and Green Thumb Industries, Inc. has entered into a purchase agreement with Dharma Pharmaceuticals, LLC. Both purchases should be complete in June, 2021.
- Columbia Care of Eastern Virginia, LLC (Portsmouth) and Dalitso, LLC (Manassas) continue in the cultivation phase.
- The RFA for a pharmaceutical processor permit in Health Service Area I that was posted from September 25, 2020 to December 4, 2020 resulted in 26 applications being received. Currently the application review process is on hold due to a court order.
- The Board is receiving, on average, 800 to 1100 patient applications per week.
- The Board has two temporary staff employees assisting with the processing of applications and has completed interviews for two full time administrative specialist to support the program. Additionally, agency staff have been providing assistance with processing patient applications by working overtime hours for the Board.
- The Board continues to refine the scope of work for the new patient registration platform.
- The Board has completed a revision to the Regulations Governing Pharmaceutical Processors to address the 2021 legislative changes and posted the revision for public comment. The public comment period ends July 5, 2021

Pharmaceutical Processors Program-By the Numbers
As of 5/19/2021

Registered Practitioners	730
Registered Patients	21,807
Registered Parents/Guardians	155
Registered Agents	85
Registered Cannabis Oil Products	302

Discipline Program Report

Open Cases as of 5-14-2021:

	PC	APD	Investigation	FH	IFC	Pending Closure	Total #
Patient Care Cases	89	5	68	5	6	0	173
Non-Patient Care Cases	88	4	16	3	6	10	127
						Total:	**300**

- There are 89 patient care cases at Probable Cause compared to 57 reported for March 2021. Non-patient care cases at Probable Cause have also increased.
- Overall case load has increased by 36 cases since last reported.
- In-person disciplinary proceedings will resume on June 28, 2021.

Upcoming Disciplinary Proceedings:

June 28, 2021	IFC-C	Cheryl Nelson/Glenn Bolyard (for Dale St. Clair)
July 6, 2021	Formal Hearings	All Board Members
July 9, 2021	Formal Hearings	All Board Members
July 13, 2021	IFC-A	Patricia Richards-Spruill/Bill Lee
July 26, 2021	IFC-B	Glenn Bolyard/Dale St. Clair
August 12, 2021	IFC-C	TBD
August 16, 2021	Pilot Committee	TBD
August 24, 2021	IFC-A	TBD
September 2, 2021	IFC-B	TBD
September 17, 2021	IFC-C	TBD