

(FINAL/APPROVED)

**VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN SUBSTANCES**

June 15, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:08a.m.

PRESIDING: Ellen Shinaberry, Chairman

MEMBERS PRESENT: Melvin Boone
Michael Elliott
Dinny Li
Ryan K. Logan
Empsy Munden
Rebecca Thornbury
Cynthia Warriner

MEMBERS ABSENT: Jody Allen
Sheila Elliott

STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David E. Brown, D.C., Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

QUORUM: With eight members present, a quorum was established.

CALL FOR COMMENT: Ms. Shinaberry called for comment to consider placement of the chemical substances N-(1-amino-3, 3-dimethyl-1-oxobutan-2yl)-1-(cyclohexylmethyl) indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA), methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (other name: 5-fluoro-AMB), 1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201), 1-4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144), 4-bromomethcathinone (other name: 4-BMC), and 4-chloromethcathinone (other name: 4-CMC) into Schedule I. John Prysbylski with the Department of Forensic Science stated that these six chemicals have been identified in forensic labs within Virginia and nationally. No additional public comment was provided.

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act 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.

ADJOURN:

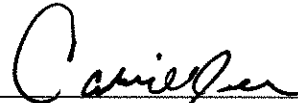
The public hearing adjourned at 9:15am.



Cynthia Warriner, Chairman

9/29/15

Date



Caroline D. Jufan, Executive Director

9/29/15

Date

FINAL/APPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

June 15, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15am

PRESIDING: Ellen B. Shinaberry, Chairman

MEMBERS PRESENT: Melvin L. Boone, Sr.
Michael Elliott
Dinny Li
Ryan Logan
Empsy Munden
Rebecca Thornbury
Cynthia Warriner

MEMBERS ABSENT: Jody Allen
Sheila Elliott

STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David Brown, Director, Department of Health Professionals
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

QUORUM: With eight members present, a quorum was established.

APPROVAL OF AGENDA: Ms. Shinaberry requested that an additional item be included on the agenda. She requested the Board consider whether it's an appropriate time to initiate a periodic review of regulations. Additionally, she stated that the Virginia Pharmacists Association requested that discussion regarding its letter to amend Guidance Document 110-36 be tabled until the September board meeting. Ms. Juran also asked the Board to disregard the minutes from the March 11, 2015 Special Conference Committee meeting that was included in the agenda packet since the minutes were previously approved at the March 24th full board meeting. The agenda was approved as amended.

APPROVAL OF MINUTES: Staff provided to the board amended handouts of the May 13, 2015

Telephone Conference Call draft minutes and the May 11, 2015 Regulation Committee Meeting draft minutes. Amendments of the Regulation Committee meeting draft minutes were suggested by several board members, including Ms. Warriner.

MOTION:

The Board voted unanimously to approve the minutes as amended for the meetings held between March 23, 2015 and May 13, 2015. (motion by Munden, second by Logan)

PUBLIC COMMENTS:

The Board reviewed written public comments from the following:

Janet Silvester, Pharm.D., M.B.A., FASHP, Vice President Accreditation Services, ASHP, wrote that she is in favor of the Pharmacy Technician Certification Board (PTCB) examination being a requirement for pharmacy technicians.

Amy Yarcich, MPA, Executive Director and Lisa Casler, MSW, CPhT, Director of Affiliate Services, of RxPartnership, expressed concerns with the Regulation Committee's proposed legislative proposal making the PTCB exam mandatory for pharmacy technicians especially in a free clinic setting.

Dominic A. Solimando, Jr., M.A., BCOP, FAPhA, FASHP, President, of Oncology Pharmacy Services, stated his concerns with the Board's consideration that closed system transfer devices not be recommended to extend the beyond use date (BUD) of single dose vials.

The following individuals addressed the Board during public comment:

Rafael Saenz, Administrator, Pharmacy Services, Assistant Dean, VCU School of Pharmacy-UVA Division, with University of Virginia Health System expressed his support for the Board's consideration in making the PTCB a requirement for pharmacy technician registration. He stated any consideration for the Board to potentially grant waivers for obtaining PTCB certification is premature as time is needed to develop educational and training resources. Mr. Saenz also commented that the University of Virginia Health System has been working with Piedmont Community College to implement a ACPE/ASHP-accredited pharmacy technician training program for individuals to obtain PTCB certification.

Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA) echoed comments made at the Regulation Committee concerning the Pharmacy Benefits Managers (PBMs) and stated that the VPhA was willing to assist the Board with the issue as it moves forward. He also gave an update regarding VPhA's meeting with Senator Warner in Washington, DC and reported that Sen. Warner's staff was pleased that the Board of Pharmacy was discussing the matter of PBMs. He stated the REVIVE! naloxone training will be offered at the VPhA's annual meeting in July and that meeting agenda will also address red flags for pharmacists to consider when dispensing controlled substances and armed

robberies of pharmacies.

William Shimmel, Associate Executive Director, with the Pharmacy Technician Certification Board (PTCB) offered comments regarding other states considering a requirement for PTCB. He stated that Louisiana decided to require the accreditation of pharmacy technician training programs in 2016 and to not wait until 2020. He reported that the development of accredited training programs has been positive; Louisiana went from having 5 training programs to 17.

H. Otto Wachsmann, Jr., pharmacist, Stoney Creek Pharmacy, expressed concerns that if the Board requires pharmacy technicians to become PTCB certified that he may not be able to find qualifying individuals to hire. He indicated he practices in a rural, low income area, and that some individuals may not be able to afford to obtain PTCB certification. He also questioned the need for all pharmacy technicians to receive training on sterile compounding since not all pharmacy technicians will practice in a pharmacy performing this activity. Additionally, regarding a possible review of PBMs, he recommended meeting with rural pharmacists to get an understanding of the concerns they have in regards to patients' ability to access drugs safely in a rural community.

Rafael Saenz, Administrator, Pharmacy Services, Assistant Dean, VCU School of Pharmacy-UVA Division, with University of Virginia Health Systems addressed concerns with the cost and affordability of obtaining PTCB certification. He stated that Texas which has a large rural population has made it affordable and accessible for pharmacy technicians in these areas to obtain PTCB certification.

DHP DIRECTOR'S REPORT:

Dr. Brown reminded the Board of the upcoming DHP board member training program to be held September 28, 2015 and encouraged attendance. The Governor's Task Force on Prescription and Heroin Abuse was well represented by both the Board of Pharmacy and DHP. He stated that DHP will be taking the lead on developing a resource website, one of the recommendations adopted by the Task Force. The Task Force will finalize the implementation plan on June 16th. A regional meeting of neighboring states is scheduled in Abingdon, VA in September to discuss prescription drug and heroin abuse issues. Additionally, a conference is scheduled this November in Roanoke to communicate the Task Force's activities. Dr. Brown stated he discussed with Secretary Hazel the oversight of PBMs. It was agreed that a broad-based workgroup needs to be organized and that it would be headed-up by DHP. The workgroup will likely consist of various agencies and key stakeholders. He stated that the workgroup could discuss issues and areas of concern; any recommendations would be relayed to Secretary Hazel. The meeting date for this workgroup has yet to be determined.

REGULATORY ACTIONS:

- CONSIDERATION OF ANY SCHEDULING ACTION FROM PUBLIC HEARING:

Ms. Yeatts requested that the Board consider whether the chemicals discussed during the public hearing should be placed into Schedule I. The possible scheduling of the following substances are:

MOTION:

The Board voted unanimously to adopt an exempt regulatory action to strike the following three chemicals from regulation that were placed into law by the 2015 General Assembly:

- N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA);
- N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AMB); and
- 3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA)

and to place the following six chemicals identified by the Department of Forensic Science into Schedule I:

- N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA);
- methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (other name: 5-fluoro-AMB);
- -naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: 5-fluoro-NY-3201);
- 3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144);
- 4-bromomethcathinone (other name: 4-BMC); and,
- 4-chloromethcathinone (other name: 4-CMC). (motion by Warriner, second by Logan)

- REGULATION UPDATE:

Ms. Yeatts reviewed the chart of regulatory actions included in the agenda packet. A majority of the regulations have been approved and will go into effect in July 2015. Ms. Yeatts stated that the regulatory action for collection sites for the disposal of unused drugs was currently in comment period until July 1st.

- REVENUE AND EXPENDITURE ANALYSIS:

Ms. Yeatts reported that the required revenue and expenditure analysis has been performed as indicated in the letter from Dr. Brown included in the agenda packet. Dr. Brown recommended that no action to change license fees be taken at this time.

- REPORT FROM REGULATION COMMITTEE:

The Board was provided an update on the 2016 Legislative Proposals discussed at the Regulation Committee meeting that was held on May 11, 2015.

2016 LEGISLATIVE PROPOSALS:

- THIRD PARTY LOGISTIC PROVIDERS, WHOLESALE DISTRIBUTORS, TRACK AND TRACE REQUIREMENTS:

Ms. Juran reminded the Board that Title II of the Drug Quality and Security Act preempts state boards from licensing third party logistic providers as wholesale distributors, a licensing model currently used by this Board. Additionally, the federal law preempts state pedigree requirements which do not comply with federal track and trace requirements for drug distribution. The Regulation Committee recommended the Board adopt the legislative proposal, with definitions for “co-licensed partner” and “track and trace”, to require wholesale distributors to comply with federal track and trace requirements; create three new licensing categories to include in-state and nonresident third party logistics providers and non-resident manufacturers; clarify that manufacturers may distribute drug without an additional license as a wholesale distributor; and clarify the use of bulk drug substances in compounding as presented in §54.1-3410.2 F.

MOTION:

The Board voted unanimously to adopt the legislative proposal as recommended by the Regulation Committee and presented to require wholesale distributors to comply with federal track and trace requirements; create three new licensing categories to include in-state and nonresident third party logistics providers and non-resident manufacturers; clarify that manufacturers may distribute drug without an additional license as a wholesale distributor; and clarify the use of bulk drug substances in compounding as presented in §54.1-3410.2 F. (motion by Thornbury, second by Warriner)

- NON-RESIDENT MEDICAL EQUIPMENT SUPPLIERS:

The Regulation Committee recommended that the Board adopt a legislative proposal to create a new licensing category for non-resident medical equipment suppliers.

MOTION:

The Board voted unanimously to adopt the legislative proposal as recommended by the Regulation Committee and presented to create a new licensing category for non-resident medical equipment suppliers.

- PTCB CERTIFICATION

The Board discussed the Regulation Committee’s recommendation for adoption of a legislative proposal to require Pharmacy Technician

REQUIREMENT:

Certification Board (PTCB) certification for initial registration as a pharmacy technician and to include the word “initially” in section B of the draft proposal prior to the word “registered”. The proposal has a suggested delayed implementation date of July 2017. The Board discussed various subjects such as the impact the legislative proposal could have on high school students obtaining registration as a pharmacy technician, cost of training programs obtaining accreditation, cost of persons completing an accredited training program, and the impact on free clinic pharmacies. Ms. Yeatts stated that the Board could not “waive” the initial PTCB exam cost to pharmacy technicians working as volunteers in free clinics since it was not a Board-issued exam but could consider “reimbursing” the fee. Additionally, she stated that this policy decision did not need to be addressed in statute. It was recommended that the phrase “and the first examination fee for the Board-approved examination” be stricken in section F of the proposed language, along with “If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination.” William Shimmel from PTCB stated PTCB does not have a minimum age requirement, but does require a high school diploma or GED prior to obtaining PTCB certification. Additionally, he stated currently there are six states to include Texas, Louisiana, North Dakota, Wyoming and South Carolina that require pharmacy technicians to obtain PTCB certification. There are twenty-one states that currently accept either state-required training or PTCB certification. Ms. Shinaberry stated that she believes there is sufficient time for pharmacy technician training programs to obtain accreditation prior to 2020 and that a sufficient number of programs will do so.

MOTION:

The Board voted unanimously to adopt the legislative proposal as amended to require certification from the Pharmacy Technician Certification Board (PTCB) as a prerequisite for initial registration as a pharmacy technician, to waive the initial application fee for board registration and subsequent renewals fees for a limited-use pharmacy technician registration who works exclusively in a free clinic pharmacy, and to propose a delayed implementation date of July 1, 2017. (motion by Warriner, second by Munden)

**ADDITIONAL LEGISLATIVE
ISSUES CONSIDERED BY
REGULATION COMMITTEE:**

- VAWD accreditation

Ms. Juran gave the Board some background information regarding the Verified-Accredited Wholesale Distributors (VAWD) which is an accreditation issued by the National Association of Boards of Pharmacy (NABP). It was reported that the Regulation Committee determined that it would not recommend to the full board at this time to require VAWD since federal regulations supporting the Drug Supply Chain Security Act have not been fully implemented, but that the Board may wish to revisit

this topic in the future.

- Separate license for pharmacies performing sterile compounding:

Ms. Juran reported that counsel advised that it could not authorize or prohibit a pharmacy from performing sterile compounding based on a licensing model using a subcategory of the pharmacy permit via regulation. The Board discussed the possible need to submit a legislative proposal to create an additional licensing category for those pharmacies performing sterile compounding. It was decided not to adopt such a legislative proposal at this time, but that the Board may revisit this issue later.

**RECOMMENDED
LEGISLATIVE PROPOSALS
FROM PMP ADVISORY
COMMITTEE:**

- Expanded access and reporting requirements:

Ms. Yeatts stated that the Regulation Committee heard legislative proposals that were drafted by the Prescription Monitoring Program (PMP) Advisory Committee. The PMP Advisory Committee recommended a legislative proposal to amend §54.1-2523 to expand a pharmacist's ability to access PMP data when consulting on a specific patient and not simply dispensing a drug. A second legislative proposal recommends changing the reporting requirement from within 7 days of dispensing to within 24 hours of dispensing or the next business day whichever comes later.

MOTION:

The Board voted unanimously to support the recommended legislative proposals from the Prescription Monitoring Advisory Committee (motion by Warriner, second by Thornbury)

**CLOSED SYSTEM
TRANSFER DEVICES TO
EXTEND BUD OF SINGLE
DOSE VIALS:**

Ms. Juran reported that the Regulation Committee had discussed whether closed system transfer devices (CSTD) should be allowed to extend beyond use dates (BUD) of single dose vials. It was suggested in the committee meeting that perhaps CSTDs should be allowed for this purpose if site-specific testing was maintained to demonstrate its successful use to safely extend the BUD without contamination. Ms. Juran reported that she contacted USP to ensure this recommendation would be consistent with USP allowances and determine what criteria should be included in any site-specific testing. USP indicated that the use of CSTDs for this purpose is not addressed. The Board further discussed the 2014 compounding workgroup's recommendation to amend Guidance Document 110-36 to not recommend the use of closed system transfer devices to extend the BUD of single dose vials. It was recommended to include the compounding workgroup's recommendation in Guidance Document 110-36 and to monitor USP addressing this issue in a future revision.

MOTION:

The Board voted to include the 2014 compounding workgroup's recommendation in Guidance Document 110-36 indicating that a closed system transfer device should not be used to extend the beyond use date (BUD) of a single dose vial to exceed the 1 hour assigned BUD when punctured outside of an ISO Class 5 environment or the 6 hour assigned BUD when punctured within and not removed from an ISO Class 5 environment. (motion by Munden, second by Logan) (Warriner abstained)

NEW BUSINESS:

- **ADOPTION OF NALOXONE PROTOCOL:**

Ms. Juran reviewed with the Board HB 1458 and the draft language for the naloxone protocol that would allow a pharmacist to dispense naloxone pursuant to a standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opiate overdose. She indicated the draft language resulted from a meeting and collaboration with staff from the Virginia Department of Health, Board of Medicine, Department of Behavioral Health and Developmental Services, the Department of Criminal Justice Services, the Prescription Monitoring Program, the Department of Health Professions, and the Board of Pharmacy.

MOTION:

The Board voted unanimously to adopt the naloxone protocol as presented. (motion by Thornbury, second by Warriner)

- **REQUEST FROM VPHA TO AMEND GUIDANCE DOCUMENT 110-36**

At the request of VPhA, the Board tabled the request to amend Guidance Document 110-36 until the September Board meeting.

- **2014 VIRGINIA WORKFORCE REPORT:**

- **Pharmacist report and pharmacy technician reports:**

Elizabeth Carter, PhD, Executive Director, Healthcare Workforce Data Center, provided the Board with a summary of the workforce survey information collected from pharmacists and pharmacy technicians during the 2015 licensure renewal cycle. Dr. Carter also showed the Board where it can view additional information collected and presented by the Healthcare Workforce Data Center at www.vahwdc.tumblr.com

REQUEST FOR PERIODIC REGULATORY REVIEW:

Ms. Shinaberry requested that a periodic regulatory review be initiated by the Regulation Committee this year. It was stated that such a review usually takes a year to complete.

MOTION: **The Board voted unanimously to have the Regulation Committee initiate a periodic regulatory review this Fall. (motion by Thornbury, second by Munden)**

REPORTS:

CHAIRMAN'S REPORT: Ms. Shinaberry gave a brief report on upcoming events. She stated that Ms. Munden, Ms. Thornbury, Ms. Warriner, Ms. Juran and herself attended the NABP 111th Annual Meeting that was held in New Orleans, May 16th-May 20th. She also stated that the Virginia Board of Pharmacy received the Fred T. Mahaffey award during the awards dinner on May 19th. NABP and AACP will be holding the districts 1 and 2 meeting this year in New Hampshire, September 24th -September 26th. She encouraged attendance, if possible.

BOARD OF HEALTH PROFESSIONS: Ms. Shinaberry gave an update on recent activities of the Board of Health Professions. Dental hygienists scope of practice is still under review and they are awaiting comment from the Board of Dentistry. There will be an upcoming public hearing for a proposed funeral licensing category.

LICENSURE PROGRAM: Mr. Johnson reported the Board currently licenses 35,105 individuals and facilities. The Board issued 967 licenses and registrations for the period of March 1, 2015 through May 31, 2015. Inspectors conducted 363 facility inspections including 161 routine inspections of pharmacies: 42 (26%) resulted in no deficiency, 48 (30%) with deficiencies and 71 (44%) with deficiencies and a consent order. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012.

DISCIPLINARY PROGRAM: Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report comparing the case stages between the four report dates of September 9, 2014; December 8, 2014; March 24, 2015; and June 12, 2015. For the final date, open cases were none at the entry stage; 55 at the investigation stage; 138 at the probable cause stage; 6 at the administrative proceedings division stage; 5 at the informal stage; two at the formal stage; and 123 at the pending closure stage for a total of 329 cases.

EXECUTIVE DIRECTOR'S REPORT: Ms. Juran reported on the NABP 111th Annual Meeting that was held in New Orleans May 16th-May 20th. She provided a brief overview of resolutions passed and officers elected. The Virginia Board of Pharmacy received the Fred T. Mahaffey Award for its exceptional contributions to the protection and welfare of the public health, specifically in addressing concerns with compounding. Ms. Juran then provided an update on the DEA Pharmacy Diversion Awareness Conference that was held May 30th and 31st. She provided a presentation on board-related activities at the conference. She reported that an Epinephrine Workgroup met on May 27th as required pursuant to SB1167. VDH, DHP and other various

because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Munden, second by Logan)

MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Munden, second by Warriner)

MOTION:


Upon a motion by Mr. Boone and duly seconded by Mr. Elliott, the Board voted 8-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Janet R. Underhill, a pharmacist.

ADJOURN:

With all business concluded, the meeting concluded at approximately 12:36 pm.



Cynthia Warriner, Chairman



Caroline D. Juran, Executive Director

9/29/15
DATE:

9/29/15
DATE: