FINAL

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

December 12, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:19am

PRESIDING: Ryan Logan, Vice Chairman

MEMBERS PRESENT:
Jody H. Allen (arrived at 9:35am)
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott (arrived at 9:25am)
Sheila K. W. Elliott
Rafael Saenz
Cynthia Warriner

MEMBERS ABSENT:
Rebecca Thornbury
Ellen Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
David Brown, Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager
Heather Hurley, Licensing Specialist

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

APPROVAL OF AGENDA: The agenda was amended to table the presentation on the NABP E-profile participation to the March full board meeting and to include under regulatory actions, adoption of amended Guidance Document 110-1 to incorporate new licensing categories.

MOTION: **The Board voted unanimously to approve the agenda as amended (motion by Warriner, second by Saenz)**

APPROVAL OF MINUTES: A handout was provided for the November 16, 2016 Special Conference Committee minutes as the copy in the agenda packet contained a typographical error. The following minutes were considered for approval:

- September 7, 2016, Public Hearing of Scheduling Certain Chemicals
- September 7, 2016, Full Board Meeting
- September 7, 2016, Formal Hearing
- September 8, 2016, Special Conference Committee
- September 20, 2016, Special Conference Committee
- September 27, 2016, Special Conference Committee – Pilot Hearings
- October 3, 2016, Panel Formal Hearing
- November 14, 2016, Telephone Conference Call
- November 16, 2016, Special Conference Committee (handout)
- November 29, 2016, Regulation Committee (handout)
- December 6, 2016, Special Conference Committee (handout)

It was noted that the date on page 23 of the agenda packet for the September 7, 2016 Minutes of the Panel of the Board should read 2016, not 2014.

MOTION: **The Board voted unanimously to adopt the minutes from September 7, 2016 through December 6, 2016 as presented and amended. (motion by Warriner, second by Boone)**

PUBLIC COMMENTS: John Beckner, Senior Director of Strategic Initiatives at NCPA, spoke to the Board on behalf of the Virginia Pharmacists Association (VPhA). Mr. Beckner provided a letter written to the Board of Pharmacy from VPhA with comments on the enforcement of USP Chapter 800. The letter states that while VPhA appreciates the intent of the proposed Chapter 800, the proposed July 1, 2018 enforcement date would impact members and their patients greatly and they request a five-year delay or phased-in approach for enforcement by the Board of Pharmacy similar to that when USP Chapter 797 was introduced. He estimated renovation costs could range from $10,000 to $250,000 depending on the pharmacy's volume with the hazardous drugs (HD).

Jamin Engel, Pharmacy Manager at Sentara RMH Medical Center in Harrisonburg, provided comments regarding the implementation of USP Chapter 800. Mr. Engel provided comment regarding contradictory language found between Chapter 800 and Chapter 797. Examples include:

- Exemptions allowed within <797> for isolators (CACI/CAI) that are removed from engineering control configurations within <800>
- Low volume hazardous compounding exemptions currently within <797> and removed from <800>
- Closed-System Transfer Device (CSTD) requirements differ between documents
- Facility control considerations differ between documents

Mr. Engel stated he believes the contradictions could likely be addressed through the formation of a workgroup to develop board guidance on the issues. He also requested the Board to provide guidance to the

pharmacies for where there is no previous standard such as what standard to use for CSTD evaluation, as the NIOSH performance standard protocol is still in development. Also, what are the acceptable limits for HD surface contamination, as there are multiple wipe pad tests with varying levels of specificity that could alter results from facility to facility. Mr. Engel also stated that there may be opportunity for capital savings for facilities implementing new <797> and <800> standards.

DHP DIRECTOR'S REPORT:

Dr. Brown provided positive comments regarding the board member orientation day held in October. He reiterated information presented by Maria Everett from the FOIA Council that three or more members together discussing board business constitutes a meeting and a public notice must be given for such meeting. Dr. Brown spoke about the opioid public health emergency issued by the Department of Health and the statewide standing order for naloxone issued by Dr. Levine, State Health Commissioner. In 2015 there were 809 Virginians who died of opioid overdose and in 2016 that number is expected to be over 1000. The Board of Medicine has a buprenorphine workgroup and at the last meeting Delegate Pillion spoke to the workgroup about concerns with the diversion of buprenorphine. Dr. Brown stated DHP now has statutory authority to utilize PMP information to identify suspicious behavior in prescribing and dispensing opioids. Dr. Brown spoke about the website called VaAware in which DHP manages a section for prescribers and dispensers which contains information on continuing education and proper prescribing and dispensing.

REGULATORY ACTIONS:

- Regulatory Update: Ms. Yeatts provided a handout of a chart of pending regulatory actions for review by the board.
- Legislative Update: Ms. Yeatts stated there was no legislative update at this time.
- Adoption of Regulation to Schedule certain chemicals in Schedule I: There was a public hearing conducted at 9:10am this morning pursuant to requirements of §54.1-3443 of the Drug Control Act.

MOTION:

The Board voted unanimously to adopt an exempt action amendment of Regulation 18VAC110-20-322 as presented which places the following chemicals into Schedule I:
Classified as research chemicals:

- 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone),
- 4-chloro-alpha-Pyrrolidinavalerophenone (other name: 4-chloro-alpha-PVP),
- 4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP)
- 4-fluoro-alpha-Pyrrolidinoheptiophenone (other anme: 4-

fluoro-PV8),
- 1-(4-methyoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9), 4-allyloxy-3,
- 5-dimethoxyphenethylamine (other name: Allylescaline),
- 4-methyl-alpha-ethylaminopentiophenone

Classified as powerful synthetic opioids:
- N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl) piperidinyl]-propanamide (other name: para-fluoroisoputyryl fentanyl)

(motion by Warriner, second by Boone)

- Adoption of Chapter 21 recommendations from the Regulation Committee

The Board adopted a Notice of Intended Regulatory Action (NOIRA) related to the periodic regulatory review of Chapters 20 and 50 which was published on July 11, 2016 with a comment period until August 10, 2016. There were 5 comments; none relating to sections being amended at this meeting. Included in the NOIRA was a recommendation to divide Chapter 20 into two chapters: 1) Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians; and 2) Governing the Practice of Pharmacy. The Regulation Committee met on November 29, 2016 to consider the comments received and develop recommended amendments. It is the recommendation of the Regulation Committee to move the Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians into a new Chapter 21 and adopt the amendments to the regulations for pharmacists and pharmacy technicians as presented in the agenda packet. The Board then reviewed the recommended amendments provided in the agenda packet.

MOTION:

The Board voted unanimously to:
- **adopt the Regulation Committee's recommendation to divide Chapter 20 by moving Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians into a new Chapter 21;**
- **change references to Chapter "20" on page 55 and pages 63-68 of the agenda packet to "21";**
- **strike the pharmacy permit fee as listed in 18VAC110-21-20 C;**
- **not consider the language as presented in Regulations 18VAC110-21-50 and 18VAC110-21-70 at this time as staff needs to continue clarifying the language to ensure it satisfies the intent of the amendment;**
- **amend the proposed language in Regulation 18VAC110-21-90 C to read, "C. Of the 15 contact hours required for annual renewal, at least five hours shall be obtained in courses or programs that are live or real-time interactive. Included in the five hours, the following may be credited: 1. Maximum of one hour for attendance at a board meeting or formal**

hearing; or 2. Maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or foreign pharmacist applicant obtaining required hours of practical experience."; and,

- **adopt the other recommended amendments to the proposed Chapter 21 as presented.**
- **(motion by Warriner, second by Saenz)**

- Adoption of Regulatory Amendment to Allow CE Credit for Volunteer Hours

House Bill 319 passed by the General Assembly in 2016 amended 54.1-2400 (6) to require boards to promulgate regulations to allow for continuing education credit for individuals registered, certified, or licensed who delivery health care services, without compensation, to low-income individuals receiving health services through a health department or free clinic. The proposed amendments to Regulations 18VAC110-20-90 and 18VAC110-20-106 as recommended and presented by the Regulation Committee were discussed by the Board.

MOTION:

The Board voted unanimously to adopt as a fast-track action the following proposed amendments to 18VAC110-20-90 and 18VAC110-20-106 as recommended by the Regulation Committee:

- **Insert a new subsection D in 18VAC110-20-90 to read "Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacist, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.**
- **Insert a new subsection D in 18VAC110-20-106 to read "Up to one hour of the five hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacy technician, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic."**

(motion by Allen, second by Boone)

- Consideration of request to delay enforcement of USP Chapter <800>

Ms. Juran shared that the Regulation Committee discussed this issue in November, but had asked staff to further research this issue and provide additional information at the December full board meeting. She reported that during an informal poll of board members from 38 states attending the recent National Association of Boards of Pharmacy Interactive Member Forum meeting, only Idaho and another unknown state indicated

that it may delay enforcement of Chapter <800>, She is aware that North Carolina has decided they will not delay enforcement. Ms. Juran stated that a representative from USP indicated to her that FDA will not delay enforcement and that any state considering a delay would potentially put their licensees in violation of federal requirements.

MOTION: **The Board voted unanimously to develop a workgroup to draft guidance with regard to how to comply with USP Chapter <800>, similar to Guidance Document 110-36 which was developed to educate licensees on how to comply with Chapter <797>, and to not delay the enforcement of USP Chapter <800> past the effective date of July 1, 2018. (motion by Cathcart, second by Allen)**

MOTION: **The Board voted unanimously to begin educating the DHP inspectors and begin inspecting for compliance with USP Chapter <800> in 2017 in an attempt to educate pharmacists, but to not cite deficiencies or issue monetary penalties prior to the effective date of July 1, 2018. (motion by S. Elliott, second by M. Elliott)**

- Amend Guidance Document 110-38, requirement for non-resident pharmacies to submit current inspection report

Ms. Juran provided background on staff's request to amend Guidance Document 110-38 to only allow an opening inspection report for a newly opened pharmacy or a new location of an existing pharmacy if said pharmacy is not performing sterile compounding. If the facility is performing sterile compounding, staff recommends that the facility must provide an operational inspection to satisfy the requirement for obtaining initial registration or renewal as a nonresident pharmacy. She indicated this is consistent with North Carolina's position on the matter.

MOTION: **The Board voted unanimously to adopt the amendment of Guidance Document 110-38 as presented. (motion by M. Elliott, second by Allen)**

- Adopt amendments to naloxone protocol

Ms. Juran provided background on staff's recommended amendments to the naloxone protocol based on the statewide standing order recently issued by Dr. Levine, State Health Commissioner. The recommended amendment also allows a pharmacy to deliver the naloxone to an alternate delivery site such as a local health department if the counseling is provided by a physician, nurse practitioner, physician assistant, nurse, pharmacist, or an approved trainer of the REVIVE! training program at the alternate delivery site.

MOTION: **The Board voted unanimously to adopt the amendments to the naloxone protocol as presented and designate the protocol as a guidance document (motion by M. Elliott, second by S. Elliott)**

- Amend guidance document 110-1, categories of facility licensure

Ms. Juran presented the amended Guidance Document 110-1 that includes new facility categories for licensure, nonresident medical equipment supplier, outsourcing facility and nonresident outsourcing facility. During board discussions, it was noted that the language for in-state medical equipment suppliers should also be reworded to match what

is currently in statute.

MOTION: **The Board voted unanimously to adopt the amendments to Guidance Document 110-1as presented and directed staff to ensure the language for medical equipment suppliers is written consistently with the statute. (motion by Saenz, second by Boone)**

NEW BUSINESS:

- Consideration for requiring CE in a specific subject area in 2017

The Board discussed if a specific topic for continuing education should be mandated for pharmacists in 2017 as authorized in 54.1-3314.1 J. Some of the subject areas discussed were: opioid use, naloxone administration or opioid overdose prevention. The Board also discussed the number of CE units that should be required in this subject if they should decide to require as such. Staff reminded the Board that this requirement will not apply to pharmacy technicians as the law only addresses an ability to mandate up to 2 hours of CE in a specific subject for pharmacists.

MOTION: **The Board voted unanimously to require pharmacists to obtain 1 hour of continuing education credit in the calendar year 2017 in the subject of proper opioid use, opioid overdose prevention, or naloxone administration. (motion by Warriner, second by S. Elliott)**

REPORTS:

Chairman's Report

Ms. Thornbury was absent from this meeting and therefore, no Chairman's report was provided to the Board.

Report on the Board of Health Professions

Mr. Logan stated the Board of Health Professions has not met since the last Board of Pharmacy meeting and therefore, there is nothing to report.

Report on the PMP Advisory Panel

Jody Allen provided a report on the PMP advisory panel on which she and Ryan Logan participate. The PMP advisory panel recently developed criteria to recommend to Dr. Brown for identifying unusual prescribing and dispensing patterns and to provide this information to the Enforcement Division for investigation. The recommended criteria is prescribers and pharmacies with 10 or more patients with a morphine milligram equivalency (MME) greater than 1000 per day or a patient with greater than 2000 MME/day. The advisory panel will meet again in January 2017.

NABP Telepharmacy Task Force Meeting

Freeda Cathcart participated on the NABP Task Force for Telepharmacy in Chicago and this was to create a model act for telepharmacy that all states may utilize to develop law and regulation. The NABP Executive

Committee will consider the recommendations and NABP will report out on the issue at its annual meeting in May 2017.

NABP International Membership Task Force Meeting

Cynthia Warriner participated on the NABP International Membership Task Force in Chicago to consider the appropriateness of NABP expanding its international membership. The NABP Executive Committee will consider the recommendations and NABP will report out on the issue at its annual meeting in May 2017.

NABP Interactive Member Forum

Jody Allen participated on the NABP Interactive Member Forum in Chicago, a meeting that is held every other year. A representative from every state is there to collaborate on issues and share best practices. Many other countries were represented such as Canada and the Bahamas. Ms. Allen was a panelist on USP compounding issues. Other topics included: new board member orientation processes; pharmacist prescribing practices in Canada; allowance in Oregon for pharmacists to prescribe oral contraceptives; concerns with opioid overdoses; and expanded access to naloxone.

Report on Licensure Program:

Mr. Johnson reported the Board currently licenses 37,581 individuals and facilities. This is an increase of 743 over the 36,838 for same period in 2015. The Board issued 876 licenses and registrations for the period of September 1, 2016 through November 30, 2016. Inspectors conducted 451 facility inspections including 219 routine inspections of pharmacies: 57 (26%) resulted in no deficiency, 87 (40%) with deficiencies and 75 (34%) with deficiencies and a consent order. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012. Mr. Johnson reviewed the report of Inspection Deficiencies. It was noted that deficiency 142, regarding compliance with CQI requirements, is the most frequently cited deficiency. Other frequently cited deficiencies include deficiencies 13, 14, and 113 regarding drug inventories, deficiency 15 regarding the perpetual inventory, deficiency 109 regarding expired drugs, and 130a regarding the labeling of compounded drug products. There was an increase in Deficiency 7 regarding the submission of an application and undergoing an inspection prior to remodeling or changing the location of a pharmacy.

Report on 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 November 30, 2015; March 24, 2016; June 13, 2016; and December 8, 2016. For the final date, she reported that there were no cases at the entry stage; 75 at the investigation stage; 173 at the probable cause stage; 37 at the administrative proceedings division stage; seven at the informal stage; two at the formal stage; and 132 at the pending closure stage. She explained that these numbers involved all cases, including inspection and continuing education matters. Further, as noted on the handout, the numbers remain fairly consistent and she gave the received and closed case numbers for October 2016 (55/56) and November 2016 (37/40). Future reports will provide more

specific case-type information for the board members.

Executive Director's Report:

Regarding recent or ongoing projects, Ms. Juran reported that staff intends to begin using the NABP universal inspection form for all routine pharmacy inspections in February 2017. She indicated staff received positive feedback during the piloting of the form in August 2016. She reported on recent and upcoming meetings. She sought and received approval from the board to submit an application to NABP for the 2017 Fred T Mahaffey award for convening the pharmacy benefit manager oversight workgroup in 2016. She then provided on update on staffing issues.

SUMMARY SUSPENSION:

CYNTHIA LEE DORTON
Registration No: 0230-003720

Wayne T. Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

MOTION:

Upon a motion by Ms. Allen, and duly seconded by Mr. Boone, the Board voted 8-0 in favor of the motion that, according to the evidence presented, the continued practice by Cynthia L. Dorton, as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Cynthia L. Dorton to practice as a pharmacy technician be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Ms. Dorton for the indefinite suspension of her pharmacy technician registration for two years.

ADJOURN:

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

Ryan Logan, Vice-Chairman

3/21/17
DATE:

Caroline D. Juran, Executive Director

3/21/17
DATE: