FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

May 26, 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 9:03am

PRESIDING: Ellen B. Shinaberry, Chairman

MEMBERS PRESENT: Cynthia Warriner
Melvin L. Boone Sr.

NON-COMMITTEE MEMBERS PRESENT: Freeda Cathcart – arrived at 9:30am

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
Elaine J. Yeatts, Senior Policy Analyst
Jim Rutkowski, Assistant Attorney General

APPROVAL OF AGENDA: The agenda was approved as presented.

PUBLIC COMMENT: Theodore F. Adams, III, Director, Virginia State Government Relations at McGuireWoods Consulting LLC, representing his client Surterra Holdings, Inc., urged the committee to adopt a regulatory advisory panel to promulgate regulations for pharmaceutical processors to produce and dispense cannabidiol oil and THC-A oil. Mr. Adams stated that Surterra Holdings wishes to participate on the panel as they have experience to offer regarding issues with security and purity of the oil.

Roy Scherer, an advocate for reform of marijuana laws, encouraged the Board to appoint a regulatory advisory panel for the promulgation of regulations for pharmaceutical processors producing and dispensing cannabidiol oil and THC-A oil. He stated that he would like to participate on the panel. Mr. Scherer shared a personal story with the committee about how the medical use of this oil would have helped a friend during a terminal illness.

Tim Musselman, Executive Director of the Virginia Pharmacists Association, discussed three items with the committee. Regarding the agenda topic to designate promethazine with codeine as a drug of concern, Mr. Musselman stated that although this drug is an older drug that has been around a long time, he believes it is still a drug that is

widely abused and its abuse seems to come in waves. Secondly, Mr. Musselman asked the committee to consider the cost of specialty drugs when discussing what action should be taken, if any. Lastly, Mr. Musselman stated that the Virginia Pharmacists Association is not in favor of a legislative proposal to remove the restriction of one prescription per blank. He stated that prescriptions containing more than one prescription order can be difficult to read and could possibly contribute to dispensing errors.

Beth Collins, Senior Director of Government Relations and External Affairs for the Americans for Safe Access, urged the committee to appoint a regulatory advisory panel for the development of regulations for the production and dispensing of cannabidiol oil and THC-A oil. Ms. Collins stated she would like to see the panel review other states' guidelines for the production of cannabis as well as the Americans for Safe Access 2015 report for Patient Focused Certification, the Regulator's Program Guide for Medical Cannabis. Ms. Collins also requested that a patient representative be appointed to the regulatory advisory panel and a representative from the Americans for Safe Access.

Julia Whiting, MD, mother of a daughter with intractable epilepsy, provided comment urging the committee to appoint a regulatory advisory panel to develop regulations for the production and dispensing of cannabidiol oil and THC-A oil. She recommend the panel include patient representation.

Alexander Pytlarz, pharmacist from northern Virginia and representing Virginia Pharmacists Association, commended the Board on its commitment to compounding best practices and offered to serve as a resource, if needed.

Baylor Rice, pharmacist and owner of South River Compounding Pharmacy and Vice-President of the International Academy of Compounding Pharmacists, provided comment in support of the agenda topic discussion regarding the reporting of adverse drug events, however, added that this should be for all drugs and not just for compounded drugs. Mr. Rice commended the Board for keeping cannabis within the purview of the Board of Pharmacy and volunteered to participate on a regulatory advisory panel to develop regulations for the dispensing and production of cannabidiol oil and THC-A oil.

Paul Lyons, MD, a physician in Winchester with experience with compassionate use trials with the FDA offered his assistance to the committee in the development of regulations for the dispensing and production of cannabidiol oil and THC-A oil. Dr. Lyons emphasized the importance of a proper diagnosis. He has experience treating epileptic patients and with reporting requirements.

Catherine Gurley and Ben Gurley, mother and son, offered comment based on personal experiences with the difficulties of obtaining

cannabidiol oil from other states. The Gurleys expressed concerns with obtaining oils that do not appear to be consistent in potency and therefore, do not produce the same desired effect of lessening seizure activity. Additionally, they commented that the administration of one oil in the past resulted in severe seizure activity that could have been life-threatening. They urged the committee to regulate the production of cannabidiol oil and THC-A oil in a manner that would ensure consistency in quality and potency.

AGENDA ITEMS:

- Chart of Regulatory Actions

Ms. Yeatts reviewed the chart of regulatory actions with the committee members and provided a status update for each action.

- Consideration for convening a Regulatory Advisory Panel (RAP) and Discussion of Emergency Regulations for Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil

Ms. Yeatts reviewed the guidelines outlined in Regulation 18VAC110-11-70 for the committee to form a regulatory advisory panel. Ms. Yeatts suggested that the Board could post a notice on Regulatory Town Hall for interested parties to request to be on the panel. Ms. Warriner inquired about the size of the panel, to which Ms. Yeatts replied is normally about 9 or so people. Ms. Yeatts also indicated the panel would need to meet two to three times prior to the September Board meeting. Requests to participate on the panel should be sent to Ms. Juran. Ms. Yeatts also reminded the public and committee of several points: The Department of Health Professions is a non-general fund agency and must cover its expenses through licensure fees; SB701 requires the pharmaceutical processors to be inspected quarterly; and, SB701 must be reconsidered by the 2017 General Assembly prior to enactment of the law and any supporting regulations.

MOTION:

The Committee voted unanimously to form a regulatory advisory panel for the discussion of emergency regulations for pharmaceutical processors to produce and dispense cannabidiol oil and THC-A oil, and for the board chairman to appoint participants to the panel. (motion by Warriner, second by Boone)

- Fast-Track Regulations for Amending Regulations for "Public Participation Guidelines (PPG)"

Ms. Yeatts provided explanation that there has been a statutory change in the public participation guidelines that allows a person to be accompanied by and represented by counsel or other representative and that the Board of Pharmacy needs to amend the Regulation regarding public comment to conform to the new statute.

MOTION:

The Committee voted unanimously to recommend to the full Board to adopt a fast track action to amend the regulation for public participation guidelines to conform to a recent amendment of the Administrative Process Act by allowing a person to be accompanied and represented by counsel or other representative. (motion by Warriner, second by Boone)

- Adoption of Re-

Ms. Juran reported that staff has received questions and comments

Proposed Regulations on Setting Certain Conditions on Work Hours for Pharmacists

regarding the proposed language adopted by the board in March that suggest the language does not accurately represent the board's intention of prohibiting a pharmacy permit holder from requiring a pharmacist to work longer than 12 continuous hours. Current wording appears to allow the pharmacist to work longer than 12 continuous hours as long as the permit holder provides six hours of off-time between consecutive shifts. Staff suggested the committee consider adopting a re-proposed amendment that would, except in an emergency, prohibit a pharmacy permit holder from requiring a pharmacist to work longer than 12 continuous hours and require the permit holder to allow at least 6 hours of off-time between consecutive shifts. Ms. Warriner agreed that the re-proposed amendment is consistent with the board's original intent. If adopted by the full board, an additional 30-day comment period would be provided.

MOTION:

The Committee voted unanimously to recommend to the full Board to adopt as presented the re-proposed amendment of Regulation 18VAC110-20-110 that states, "Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break." (motion by Boone, second by Warriner)

- Adoption of Regulation for Nonresident Medical Equipment Suppliers

Ms. Juran provided an overview of HB527, passed during the 2016 General Assembly, authorizing the Board to register nonresident medical equipment suppliers. The legislation will become effective July 1, 2016 and therefore, the board cannot adopt regulation until the September full board meeting. The board will need to adopt regulation to establish licensure fees for nonresident medical equipment suppliers. The proposed fees for nonresident medical equipment suppliers will be the same for resident medical equipment suppliers.

MOTION:

The Committee voted unanimously to recommend to the full board, at the September full board meeting, to amend Regulation 18VAC110-20-20 to establish licensure fees for nonresident medical equipment suppliers that are consistent with in-state medical equipment suppliers. (motion by Warriner, second by Boone)

- Request to Consider Adding Promethazine with Codeine as a Drug of Concern

The Virginia Pharmacists Association requested at the March full board meeting that the board deem promethazine with codeine a drug of concern thus making dispensations of the drug reportable to the Prescription Monitoring Program. During the discussion of whether promethazine with codeine met the definition in §54.1-2519 for "drug of concern", where there has been or there is potential for abuse, Ms. Juran reported the Department of Forensic Science indicated that promethazine with codeine appeared in only 14 cases out of approximately 30,000 cases during fiscal year 2015. There was some discussion that abuse of this drug may occur in waves. Promethazine with codeine is placed in Schedule V and is not currently collected by the Virginia PMP that only

collects information on drugs in Schedules II-IV. There was discussion that 31 state PMPs, including those states that border Virginia, collect information of drugs in Schedules II-V and that perhaps the law should be amended to require dispensers in Virginia to report dispensation information for drugs in Schedules II-V. This would directly address any concerns of abuse for drugs in Schedule V, including promethazine with codeine.

MOTION:

The Committee voted unanimously to recommend to the full board that it recommend to the Prescription Monitoring Program Advisory Committee that it submit a legislative proposal to amend the term "covered substance" in §54.1-2519 and §54.1-2520 to include Schedule V. (motion by Warriner, second by Boone)

- Discussion of White Bagging and Brown Bagging

The Pharmacy Benefit Manager Workgroup agreed that the Board of Pharmacy should address identified issues of concern regarding white bagging and brown bagging including the promulgation of regulation to reduce the potential for patient harm and promote consistency within the processes. During the full board meeting in March it was agreed that the Regulation Committee should discuss the issues of white bagging and brown bagging. Ms. Juran provided information on a resolution recently passed at the National Association of Boards of Pharmacy annual meeting regarding the issues of white bagging and brown bagging. The resolution calls for NABP to conduct a study to review and define the practices of white bagging and brown bagging and recommend regulatory language, if necessary, to assist boards in overseeing and addressing the accountability and safety of medications dispensed and administered via these methods. There was discussion that it may be advantageous to learn the outcome of NABP's work prior to taking action on this issue.

MOTION:

The Committee voted unanimously to recommend to the full board that it gather additional information from NABP as it performs its study of white bagging and brown bagging, and consider possible regulatory action on this issue at a later time. (motion by Boone, second by Warriner)

- Discussion of Specialty Drugs

As stated in the 2015 Pharmacy Benefit Manager (PBM) Workgroup Report, members representing pharmacists, pharmacies and the Medical Society of Virginia generally supported the Board of Pharmacy in considering the issue of specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug. PBM Workgroup members representing health plans and PBMs did not support this policy option. Board counsel opined at the March 2016 full board meeting that the Board does not presently have the authority to define "specialty drug" in regulation. Counsel recommended that the term be defined in statute or that the General Assembly could give the Board the authority to define the term in regulation. There was discussion that defining the term "specialty drug" in the Drug Control Act will not necessarily require insurers to comply with this definition and that an amendment of laws impacting insurers may also be necessary. There was

also discussion that this was a critical issue of patient concern regarding access to needed medications that were otherwise available at local pharmacies.

MOTION:

The Committee voted unanimously to recommend to the full board that it convene an ad hoc committee to further review possible options for addressing concerns with specialty drugs as identified by the Pharmacy Benefit Manager Workgroup; members should include those PBM Workforce members who supported the Board of Pharmacy addressing concerns with specialty drugs. (motion by Warriner, second by Boone)

- Consider 2017 Legislative Proposal Removing One Prescription per Blank Prohibition

A constituent of Senator Ebbin requested the Board of Pharmacy remove the one prescription per blank prohibition which would require a statutory amendment. Committee discussion on the subject involved the use of electronic prescribing, that instruction may be necessary for programming systems to print only one prescription per blank, and the difficulty in reading handwritten prescriptions with multiple prescription orders on a single blank which could contribute to dispensing errors and patient harm.

MOTION:

The Committee voted unanimously to recommend to the full board that it take no action at this time to advance a legislative proposal to remove one prescription per blank prohibition. (motion by Warriner, second by Boone)

- Consider 2017 Legislative Proposal to Clarify Collaborative Practice Authority

Ms. Yeatts explained that the statement in §54.1-3300.1 that "nothing in this section shall be construed to supersede the provisions of §54.1-3303" appears to conflict with the authorization in the law for a pharmacist to implement, modify, continue, or discontinue drug therapy pursuant to written or electronic protocols and therefore, has led to questions as to how a pharmacist may legally perform these activities. The committee considered a legislative proposal intended to clarify and support the existing authority in law which would allow a pharmacist to issue a prescription to implement, modify, continue, or discontinue drug therapy pursuant to a collaborative practice agreement.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt a legislative proposal to amend the last sentence of §54.1-3300.1 to read "Notwithstanding the provisions of §54.1-3303, a pharmacist may issue a prescription to implement, modify, continue, or discontinue drug therapy pursuant to written or electronic protocols within a collaborative practice agreement." (motion by Warriner, second by Boone)

- Consider 2017 Legislative Proposal for Requiring PTCB Certification for Initial Pharmacy Technician Registration

This legislative proposal was first adopted by the board in 2015, but was not advanced to the General Assembly due to a significant amount of negative public comment received by several entities. Concerns centered around PTCB's 2020 Initiative such as requiring a pharmacy technician trainee to obtain practical experience in two separate practice settings which could impact the employment of the trainee. Since then, PTCB has

decided it will not require practical experience in two practice settings. There was also some concern expressed with the availability of ASHP-accredited pharmacy technician training programs. Information from PTCB indicating an increase in the number of training programs was provided in the agenda packet.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt a legislative proposal requiring Pharmacy Technician Certification Board (PTCB) certification for initial pharmacy technician registration with a delayed effective date of July 1, 2018. (motion by Warriner, second by Boone)

- Consider 2017 Legislative Proposal for Requiring Temperature Monitoring Devices

At the March 2016 full board meeting, Michael Rush, Executive Director of Global Health Policy at Temptime Corporation requested the Board consider a legislative proposal requiring temperature sensitive medications shipped via mail to be accompanied with a device to monitor temperature during shipping. There was discussion regarding USP requirements which currently requires those shipping drugs to do so in an appropriate manner to ensure the drugs are stored at appropriate temperatures. Ms. Juran also stated that she was informed that the Georgia bill, HB132, referenced in the agenda packet was amended prior to Governor's signature and no longer requires shipments of drugs to include a temperature monitoring device.

MOTION:

The Committee voted unanimously to recommend to the full board that it take no action at this time on a legislative proposal requiring shipment of drugs to include a temperature monitoring device. (motion by Shinaberry, second by Boone)

- Consider 2017 Legislative Proposal for Addressing Compounding Best Practices

Ms. Juran highlighted certain best practices in Pew Charitable Trust's report summarizing Best Practices for State Oversight of Drug Compounding that it may wish to consider requiring in a legislative proposal. There was discussion regarding adverse event reporting for compounded drugs and ability for the Board to seize or quarantine a compounded product if there is a suspected cause for patient harm. Ms. Warriner expressed concern for the board possibly incurring costs associated with storing and possibly destroying seized drugs. She also concurred with the public comment provided that the board should not require adverse event reporting of compounded drugs without requiring adverse event reporting of all drugs. Ms. Shinaberry requested that Ms. Juran and Mr. Johnson comment on the best practice of inspecting sterile compounding pharmacies annually. Ms. Juran stated that current staffing levels would not allow sterile compounding pharmacies to be inspected annually if inspectors continue to inspect all non-compounding pharmacies every two years. She indicated they will continue to monitor inspection frequencies and may consider moving to a risk-based inspection schedule. The Board also discussed its current authority to embargo a drug product and its experience in requiring a recall through issuance of consent orders.

MOTION: **The Committee voted unanimously to recommend to the full board that it take no action at this time on a legislative proposal to require adverse event reporting or authorize the board to seize or quarantine drug, or require recalls. (motion by Warriner, second by Boone)**

ADJOURN: With all business concluded, the meeting adjourned at approximately 12:15 pm.

Ellen B. Shinaberry, Chairman

6/14/16
DATE

Caroline D. Juran, Executive Director

6/14/16
DATE