(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

May 3, 2019
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: Cynthia Warriner, Committee Chairman

MEMBERS PRESENT:
Rafael Saenz
Glen Bolyard, Jr.
Kristopher Ratliff

STAFF PRESENT:
Caroline D. Juran, Executive Director
Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP (Exited 11:19AM)
Ellen B. Shinaberry, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General
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: Christina Barille, Executive Director of Virginia Pharmacist Association (VPhA), provided comment to the committee on behalf of VPhA and VSHP (Virginia Society of Health-System Pharmacists). Ms. Barille provided support of legislation requiring completion of an accredited pharmacy technician training program. She offered a suggested amendment to §54.1-3321 in the legislative proposal option 2 provided in the agenda packet (pp. 98-100). She said that this option accomplishes the goal of requiring completion of either an accredited training program or a widely accepted federal or state-provided program, allowing the board to retain control over training criteria, and avoiding overly specific or restrictive accreditation or training standards in the Code of Virginia. Ms. Barille also expressed opposition to a legislative proposal authorizing telepharmacy at this time. She expressed concerns regarding the lack of pharmacist personal supervision. She shared that VPhA is currently working with VDH to research access issues and that a report will be published next year to provide findings. She also expressed opposition for any possible discussions to eliminate the current pharmacist to

pharmacy technician ratio as VPhA believes the ratio is there to keep the patients safe. Handout from VPhA-VSHP provided.

Jessica Langley, Executive Director of Education and Advocacy for the National Healthcareer Association (NHA), provided comment in support of advancement of pharmacy technician education and employer-based training programs. She shared concerns for the draft legislative proposals which could result in a decline in access to training programs.

Jan Kuhn, Assistant Professor at VCU, provided comment to the committee regarding the topic of brown bagging and its impact on the treatment of hemophilia. She expressed concern with the recommended language for 18VAC110-20-275 subsection G that reads: "An exception to this requirement may be made for patients with hemophilia who may require emergent blood factor treatment." She shared that some hemophilia treatments are not blood factor treatments. She also provided examples of when blood factor medications are given in a non-emergent outpatient setting, as a part of best practice. She recommended deleting the word "emergent" and changing "blood factor treatment" to "hemophilia medication". Staff encouraged her to please submit formal comment on the subject during the next open public comment period on this regulatory action.

John Beckner, Senior Director of Strategic Initiative for the National Community Pharmacist Associations (NCPA) shared comment with the committee regarding pharmacy technician training requirements. He shared that they currently represent 353 pharmacies in Virginia and that the requirement for pharmacy technician training programs to be ACPE/ASHP-accredited would be too restrictive. He said that imposing this requirement would create access issues for pharmacy technician training. Instead, he asked that the committee expand the regulatory language to include military, Department of Education, and employer-based pharmacy technician training programs, as well as recognize prior pharmacy technician work experience from other states.

Jeenu Phillip, Senior Manager of Pharmacy Affairs for Walgreens and member of the Florida Board of Pharmacy, supported comments provided by Ms. Langley and Mr. Beckner. Mr. Phillip expressed concerned over limitations the board may encounter if only allowing programs that have been accredited through ASHP/ACPE. He asked that the committee discuss available options. He suggested the board not eliminate employer-based programs, but rather beef them up.

Lauren Paul, Senior Director of Pharmacy Regulatory Affairs for CVS Health, offered comment in support of the petition for rulemaking regarding labeling of dispensed prescriptions and requested the committee move forward with the proposed language amending 18VAC110-20-275. She said that this would decrease patient confusion.
Natalie Nguyen, Legislative Committee Chairman for Virginia Society of Health-System Pharmacists (VSHP) offered comment in support of the

legislative proposal requiring completion of an ASHP/ACPE-accredited pharmacy technician training program. She commented that the standards represent minimum standards.

Dylan Bishop, Esq., representing Cannabis Business Association of Virginia (CBAV), provided comment to the committee on the pharmaceutical processor regulations. He requested the committee remove the prohibition to use telemedicine when initially consulting a patient on use of CBD or THC-A oil and in the first year of treatment. CBVA also recommended that the proposed regulations surrounding laboratory testing require Cannabis plant materials be tested once processed and ready for human consumption. With respect to 18VAC110-60-30, CBVA suggested requiring all labs used by pharmaceutical processors to be accredited and registered by the board. CBAV provided recommended changes with regard to 18VAC110-60-300. Handout provided.

Staff provided the Committee with written comments submitted by Political Capital and by Virginia Medical Cannabis Coalition regarding the pharmaceutical processor proposed regulations and NACDS opposing standardized pharmacy technician training programs.

Update on Regulatory/Policy Actions

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet and provided updates to the following actions:

- Brown Bagging and White Bagging- under review by DPB
- E-Profile ID Requirement to go into effect June 26, 2019
- Scheduling of Chemicals into Schedule I effective June 26, 2019
- Delivery of Prescriptions- under review by DPB

Ms. Juran added that the drug gabapentin will change from a Schedule VI drug to a Schedule V drug effective July 1, 2019. She also advised the Committee that law authorizing the registration of nurse practitioners and physician assistants for issuing written certifications takes effect July 1, 2019. Ms. Yeatts also shared that legislative action requiring the board to promulgate emergency regulations on the pharmaceutical processor regulations cannot be addressed until the final replacement regulations become effective later this year. She shared that the emergency regulations will expire in August and that discussions regarding the promulgation of emergency regulations would likely not occur prior to the September board meeting.

Recommendation on Proposed Regulations for Labeling Dispensed Prescriptions

The draft proposed regulations provided in the agenda packet amended 18VAC110-25-275(B) to clarify requirements for the policies and procedure manual when a pharmacy delivers a dispensed drug to another pharmacy. Additionally, it stated that the identity of the pharmacy solely involved in the holding of a prescription for pick-up or further delivery is not required on the prescription label when that pharmacy has not shared in other filling or dispensing functions. Mr. Bolyard recused himself

from the discussion and vote since he is employed by CVS Pharmacy and the petition for rulemaking was submitted by CVS. There was much discussion regarding whether both pharmacies' names should be listed on the label or not. It was determined that the pharmacy holding the drug for delivery to the patient, that did not otherwise have a role in the dispensing of the drug, did not need to have its name listed on the prescription label.

- **MOTION:**

The committee voted unanimously to recommend to the full board that it adopt the proposed regulatory amendment as presented. (motion by Saenz, second by Ratliff)

Recommendation on Final Regulations for Pharmaceutical Processors

Ms. Yeatts reminded the Committee that a public comment period is open on this subject until May 17, 2019, but that they could consider the comment received thus far. Ms. Juran and the Committee reviewed recommendations offered by staff in the agenda packet and took written comment received thus far into consideration. Additionally, Ms. Juran provided a handout of other recommended amendments based on written comments received the day before the meeting. Many recommendations were offered by the board.

The committee also had discussion regarding 18VAC110-60-60(A)(6) and whether a violation of law pertaining to marijuana should be incorporated into the language. It was determined that no action is necessary at this time.

There was a brief discussion regarding use of perimeter alarms. It was determined that no changes to security system requirements were needed at this time.

- **MOTION:**

The committee voted unanimously to recommend to the full board that it adopt the following recommendations:

- **18VAC110-60-310(2) – change the record-keeping requirement for maintaining the patient's self-assessment of the use of the oils from two years to three years to be consistent with other recordkeeping requirements;**
- **18VAC110-60-10, "90-day supply" – strike "which cannot exceed 60 fluid ounces";**
- **18VAC110-60-20(D) – insert fee for "change of ownership not requiring criminal background check" equal to $100 and fee for "change of ownership requiring criminal background check" equal to $250;**
- **18VAC110-60-285:**
  - **Strike (A)(5) that reads "5. Any other active ingredient that constitutes at least 1% of the batch used in the product";**
  - **In (B), change "97% to 103%" to "90% to 110%" to be consistent with statutory change involving range**

for THC;

- **18VAC110-60-290(2)(e) - insert at the end "based on stability testing";**
- **18VAC110-60-295 – strike all language as it is duplicative with 18VAC110-60-310**
- **18VAC110-60-300:**
  - **In (B), insert at the end "and terpenes profile."**
  - **In (B), insert "1. For purposes of the active ingredient analysis, a sample of the cannabidiol oil or THC-A oil product shall be tested for:**
    - **Tetrahydrocannabinol (THC);**
    - **Tetrahydrocannabinol acid (THCA);**
    - **Cannabidiols (CBD); and**
    - **Cannabidiolic acid (CBDA)";**
  - **In (D), strike "include Cannabis in a cannabidiol oil or THC-A oil product or" and insert after "sell", "cannabidiol oil or THC-A oil product" and strike "it" after "product";**
  - **In (F)(2), strike "Cannabis" and insert after "sample", of cannabidiol oil or THC-A oil product";**
  - **In (F)(3), strike "Cannabis" and insert after "sample", of cannabidiol oil or THC-A oil product";**
  - **In (F)(3), in the chart, change "Limits uG/KG BW/Day" to "Limits parts per million (ppm)" and change the limit of Arsenic to "<10 ppm", change the limit of Cadmium to "<4.1 ppm", change the limit of Lead to "<10 ppm", and change the limit of Mercury to "<2 ppm";**
  - **In (F)(4), replace "Cannabis" with "cannabidiol oil or THC-A oil product";**
- **18VAC110-60-310:**
  - **In (C)(2), strike "or kind of" and insert after "THC-A oil", "that was registered with the board pursuant to 18VAC110-60-285";**
  - **In (C), insert a new (6) that reads "A terpenes profile and a list of all active ingredients, including:**
    - **Tetrahydrocannabinol (THC);**
    - **Tetrahydrocannabinol acid (THCA);**
    - **Cannabidiols (CBD); and**
    - **Cannabidiolic acid (CBDA)";**
  - **In (C), insert a new (7) that reads "A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, and chemical residue analysis;"**
  - **In (C)(12) which will be renumbered to (14), after "based on", insert "stability testing and";**
  - **Insert a new (D) that reads "D. A pharmaceutical processor shall not label cannabidiol oil or THC-A oil products as "organic" unless the Cannabis plants**

have been organically grown and the cannabidiol oil or THC-A oil products have been produced, processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.;

- **Staff should also draft language for consideration in June that incorporates salmonella testing similar to Louisiana's requirement, a requirement for residual solvent testing, and further clarify requirements for establishing an expiration date based on stability testing and for complying with §54.1-3442.7(D) regarding requirements for THC-A products.**

(motion by Ratliff, second by Bolyard)

Recommendation on Number of Patients associated with Registered Agents Emergency/Exempt Actions-Regulations for Pharmaceutical Processors

Ms. Yeatts explained that emergency regulations may not be promulgated until the legislative changes and the final replacement regulations are in effect. The Committee deferred this discussion to a later meeting.

Consideration of Possible 2020 Legislative Proposals

Pharmacy Technician Education Standards

After much discussion, the Committee agreed that there should be a standard in place for pharmacy technician training and that military education should be permissible. Ms. Warriner shared her support of education standards.

MOTION:

The Committee voted unanimously to recommend to the full Board to adopt the draft legislative proposal option #1 regarding pharmacy technician education standards with the following amendments:

- **§54.1-3321(C) should read: "To be registered as a pharmacy technician, a person shall: (i) submit to the Board an application and fee established in regulation to obtain a pharmacy technician registration; (ii) satisfactory evidence that he ~~is of good moral character and~~ has ~~satisfactorily~~ successfully completed a training program accredited by the Association of Health-Systems Pharmacists and Accreditation Council for Pharmacy Education or other Board-approved accrediting body with substantially similar standards or federal services pharmacy technician training program and (iii) successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or National Healthcareer Association ~~that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board~~."**
- **Staff should draft language for consideration in June,**

authorizing issuance of a pharmacy technician registration to an out-of-state applicant through credentialing as detailed in regulation which could specify a minimum number of years of experience practicing as a pharmacy technician combined with national certification.
(motion by Saenz, second by Bolyard)

Compounding of Essentially Copies

Ms. Juran shared that the draft legislative proposal attempted align state law with current federal requirements that prohibit the compounding of essentially copies of commercially available drug products.

- **MOTION:** **The committee voted unanimously to recommend to the full Board to adopt the legislative proposal on compounding of essentially copies as presented. (motion by Ratliff, second by Bolyard)**

Telepharmacy

Ms. Warriner shared her concerns and that she would like to review the population study report on access that will result from the work between VPhA and VDH prior to endorsing telepharmacy. Mr. Saenz said that he would feel more confident with telephamacy if pharmacy technician education standards were enhanced. Mr. Bolyard said that it was too soon to move forward on the subject. Mr. Ratliff said that he currently lives in a rural area and does not see an immediate need for telepharmacy at this time.

- **MOTION:** **The Committee voted unanimously to recommend to the Board to take no action at this time. (motion by Bolyard, second by Ratliff)**

White Bagging/Brown Bagging

There was some discussion that a legislative proposal may not be needed on this subject at this time, but that staff could send a letter to pharmacies when the final regulations are effective on white bagging/brown bagging to highlight the need for compliance.

- **MOTION:** **The Committee voted unanimously to recommend to the full Board to take no action on a legislative proposal regarding white bagging/brown bagging at this time. (motion by Saenz, second by Bolyard)**

ACTION ITEM: **Staff should send a letter to pharmacies when the final regulations on white bagging/brown bagging are effective to highlight the need for compliance.**

Consideration of Comments Received during Periodic

Ms. Yeatts indicated that the Board currently has thirteen regulatory packets under administrative review and that it may be advisable to not

Regulatory Review that Exceeded the Scope of the NOIRA

adopt another Notice of Intended Regulatory Action until some of the current regulatory actions have become final. She also shared that the Board had previously received comment that Pharmacy was the only board with regulatory restrictions regarding the number of people that could be supervised. She then reviewed the information on pages 126 and 127 of the agenda packet that referenced other boards with similar supervisory restrictions. The Committee then reviewed the list of comments on page 125 of the agenda packet that were received during the periodic review regulatory public comment period that were deemed outside of the scope of the Notice of Intended Regulatory Action for the periodic review process. Ms. Juran clarified that the list should have also included a request to change the deadline for pharmacist-in-charge changes from 14 days to 28 days. Mr. Ratliff recommended including on the list an ability for a pharmacist to change a dosage form, e.g., capsules to tablets, without a requirement to contact the prescriber. There was brief discussion of the following subjects, in particular: In section 10, amend the definition of "faxed prescription" to allow an electronic image; In section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription to change dosage form; and, Consider amending change of PIC requirements from 14 days to 28 days. There was general consensus that the Regulation Committee will consider the topics on the list at a future meeting.

ADJOURN:

With all business concluded, the meeting adjourned at approximately 2:56 pm.

Rafael Saenz, Chairman

6-5-19
DATE

Caroline D. Juran, Executive Director

6/5/19
DATE