(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE

May 11, 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 9:05AM.

PRESIDING: Cynthia Warriner, Committee Chairman

MEMBERS PRESENT:
Michael Elliott
Ryan Logan
Empsy Munden
Ellen Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Jim Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather W. Hurley, Administrative Assistant

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented.

PUBLIC COMMENT: Stephen F. Eckel, Clinical Associate Professor, Vice-Chair, Graduate and Post-Graduate Education, Division of Practice Advancement and Clinical Education for University of North Carolina School of Pharmacy addressed the Board concerning the topic of the use of closed system transfer devices (CSTD) to extend beyond use dates (BUD) of single dose vials. Dr. Eckel requested that board guidance not be made stricter than USP Chapter 797 and allow for the use of CSTDs to extend the use of SDVs beyond 6 hours when punctured and stored within an ISO 5 environment. He indicated this can be beneficial during drug shortages. He reported that the University of North Carolina has been conducting research with CSTDs to extend BUDs and it has shown no sign of contamination. This research has been forwarded to the USP and Dr. Eckel stated he has had continuous open dialogues with them.

Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA) brought four issues to the committee's attention. First was the topic of issuing of a separate license for sterile compounding. Mr. Musselman requested that if such a requirement is approved it should apply to non-resident pharmacies as well as the in-state pharmacies. Secondly, he stated that VPhA supported amending the law for the registration of pharmacy technicians that would require them to take the Pharmacy Technician Certification Board exam (PTCB). However, the pharmacy technicians currently registered with the Board should be grandfathered. Thirdly, he commented regarding the Prescription Monitoring Program draft legislative proposal that would change the reporting time from 7 days to 24 hours. He requested that the committee consider an allowance for vendors to assist the pharmacies so that they could meet the 24 hour deadline. Lastly, he spoke on the subject of the

pharmacy benefit management companies (PBMs) and stated that the major concern is the clinical aspect. He stated that there have been issues with delays in treatment because of the PBMs and their prior authorization system. Additionally, he discussed with the board written comment provided by VPhA which summarized numerous negative interactions Virginia pharmacists have had with PBMs. The question to be addressed is who is making the decisions regarding the patient's care and who has the oversight. Mr. Musselman referenced regulations where he feels the Board has jurisdiction to regulate the PBMs. He requested that the committee recommend proposed regulations that would allow the Board to take regulatory action against PBMs.

Otto Wachsmann, Jr., Stony Creek Pharmacy, addressed the committee with his concerns regarding PBMs and the impact they have on the small rural pharmacies. Mr. Wachmann stated he knew of several rural pharmacies closing down due to mail order pharmacies taking over. There have been issues with the PBMs calling patients at work and on their cell phones, asking them to use the mail order pharmacies instead of going to their local community pharmacy. He also addressed the issue of the pre-authorization process being cumbersome and it may take the patient days to get their medication. Mr. Wachsmann stated that patient safety is in jeopardy and that there needs to be oversight by the Board of Pharmacy.

Adam Chesler, Director of Strategic Alliances, Pharmacy Technician Certification Board (PTCB) stated that he would be available to answer any questions the committee may have regarding the PTCB exam and what is required of PTCB pharmacy technicians. He explained that currently PTCB does not require a training program, but he agrees that having pharmacy technicians PTCB certified will assist with standardizing educational requirements across the board. PTCB will require completion of an ASHP-accredited training program beginning in 2020.

Hunter Jamerson, Esq., Macaulay & Burtch, representing the Virginia Academy of Family Physicians commented that he has been currently working closely with health plans on prior authorization issues. Mr. Jamerson also briefly discussed a letter that he submitted on behalf of EPIC Pharmacies, a network that consists of over 300 community pharmacies in the Commonwealth. Their concerns are the credentialing processes, the increase of drugs classified in a "specialty" drug tier and how the PBMs inform their patients that they have to use mail order pharmacies to obtain these "specialty" drugs. A majority of the community pharmacies are unable to participate in a PBM network. This creates limits on where the patient can get their prescriptions, therefore, compromising patient access. EPIC requests that the Board regulate the PBMs as well, not just the mail order pharmacies.

Kerri Musselman, Director of Bon Secours Pharmacy, expressed concerns with PBMs based on personal experiences involving prior authorizations and certain drugs inexplicably being deemed specialty drugs. She referenced an example wherein a PBM classified enoxaparin as a specialty drug, but did not classify the lesser expensive drug, heparin,

as a specialty drug even though heparin requires more intensive treatment monitoring. She indicated it was a difficult process to navigate as a pharmacist and expressed concern for those patients who do not have her level of understanding of PBMs. She feared these patients may not being able to receive their medications in a timely manner.

David Creecy, Poquoson Pharmacy, shared concerns regarding PBMs. He stated that there were issues with drug accessibility as well as patient safety. There is also the concern with people having to pay out of pocket who cannot afford their medication, but cannot wait for approval of a prior authorization. Mr. Creecy gave several examples of patient safety issues that include being denied their medication, not being given the correct medication, or not being trained on how to use the medication properly. Mr. Creecy requests that the mail order pharmacies or non-resident pharmacies be held to the same standards as in-state pharmacies when it comes to inspections and sterile compounding.

USE OF CLOSED SYSTEM TRANSFER DEVICES TO EXTEND BEYOND USE DATES OF SINGLE DOSE VIALS:

The committee discussed the compounding working group's recommendation to amend Guidance Document 110-36 to prohibit the use of closed system transfer devices (CSTD) to extend the beyond use dates of single dose vials beyond 6 hours when punctured and stored within a ISO class 5 environment. A response from USP in the agenda packet was also highlighted which indicated that USP does not address the use of CSTDs to extend BUDs of single dose vials. Ms. Shinaberry recommended that CSTDs be allowed to extend BUDs of single dose vials if site-specific testing was maintained to demonstrate its successful use to safely extend the BUD without contamination. Ms. Juran indicated she would contact USP to ensure this recommendation would be consistent with USP allowances and determine what criteria should be included in any site-specific testing. Information will be shared with the full board at the June board meeting.

EMERGENCY REGULATIONS FOR OUTSOURCING FACILITIES:

Ms. Yeatts reviewed HB 1739 with the committee regarding the statutory framework. She reported that the Board may begin drafting regulations, but may not adopt them until after July 1, 2015 when HB 1739 becomes effective. Therefore, the earliest the Board can adopt regulations will be at the September full board meeting.

MOTION:

The committee voted unanimously to recommend the following amendments to the draft proposed regulations for outsourcing facilities:

- **In 18VAC110-20-215 C, 2, b, strike "active" in the first two lines, add an "s" to "ingredient", and add "or lot number" at the end of subsection. (motion by Warriner, second by Elliott)**

MOTION:

The committee voted unanimously to recommend to the full board at the September 2015 full board meeting that it adopt the draft

proposed regulations for outsourcing facilities as amended. (motion by Munden, second by Elliott)

EMERGENCY REGULATIONS FOR PERMITTING DISPENSING FACILITIES FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES:

Ms. Yeatts reviewed with the committee HB 2192 which passed during the 2015 General Assembly session and the draft proposed regulations included in the agenda packet.

MOTION:

The committee voted unanimously to strike section B within the proposed 18VAC 110-30-20 concerning the alarm requirements for physicians who dispense no more than five different topical Schedule VI drugs for cosmetic use and for staff to continue to follow guidance on this subject within Guidance Document 110-12. (motion by Shinaberry, second by Munden)

MOTION:

The committee voted unanimously to amend 18VAC110-30-90 number 5 to clarify "immediate vicinity" by replacing the terms with "twenty feet" and adding at the end of the phrase "and not located within an exam room or restroom." (motion by Logan, second by Munden)

MOTION:

The committee voted unanimously to increase the proposed renewal permit fee in 18VAC110-30-15 C, 2 to $240 and to recommend to the full board at the September 2015 full board meeting to adopt the proposed regulations regarding the licensing of physician dispensing locations as amended. (motion by Shinaberry, second by Munden)

REGULATIONS FOR PACE FACILITIES:

The committee reviewed HB 1733 that was approved during the 2015 General Assembly session regarding PACE facilities. Ms. Yeatts stated that that the current regulations for Community Services Boards (CSBs) and Behavioral Health Authorities (BHAs) could be amended to include PACE facilities. The committee was presented with the draft regulatory language for consideration.

MOTION:

The committee voted unanimously to recommend to the full board in September 2015 to adopt the proposed regulations for PACE facilities. (motion by Munden, second by M. Elliott)

POSSIBLE LEGISLATIVE PROPOSALS:

Third Party Logistic Providers, Wholesale Distributors, Track and Trace Requirements, etc.:

Ms. Juran presented to the committee possible legislative proposals for the upcoming General Assembly session. The proposals were on the following topics: replace current pedigree requirements with a requirement for wholesale distributors to comply with federal track and trace requirements; create licensure categories for third-party logistic providers, non-resident third-party logistic providers, non-resident manufacturers, and nonresident medical equipment suppliers; whether

wholesale distributors should be required to obtain Verified-Accredited Wholesale Distributors accreditation (VAWD); clarification that a manufacturer may ship without obtaining a wholesale distributor permit; and, the consideration of creating a separate permit for those pharmacies that compound sterile drugs. The Board requested counsel to research whether the Board may identify sterile compounding pharmacies through a subcategory of the pharmacy permit in regulation, in lieu of creating a new licensing category in statute. The Board also requested staff to research definitions for "co-licensed partner" and "track and trace" that could be incorporated into the proposed legislative proposal.

MOTION:

The committee voted unanimously to recommend to the full board in June 2015 to adopt the legislative proposal, with definitions for "co-licensed partner" and "track and trace" to be added, 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 Shinaberry, second by Munden)

Nonresident Medical Equipment Suppliers:

MOTION:

The committee voted unanimously to recommend to the full board in June 2015 to adopt a legislative proposal that would create a new licensing category for nonresident medical equipment suppliers. (motion by Elliott, second by Shinaberry)

Separate License for Pharmacies Performing Sterile Compounding:

MOTION:

The committee voted unanimously to request counsel to research whether the board could identify pharmacies that perform sterile compounding through a subcategory of the pharmacy permit via regulation, in lieu of creating a separate licensing category. (motion by Munden, second by Shinaberry)

- Consideration to require VAWD for wholesale distributors and/or manufacturers:

Ms. Juran gave a brief overview of the Verified-Accredited Wholesale Distributors (VAWD) accreditation that is offered through the National Association of the Boards of Pharmacy (NABP). The committee determined that it would not recommend to the full board at this time to require VAWD since 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.

- PMP legislation:

Ralph A. Orr, Program Manager, Prescription Monitoring Program (PMP) gave a brief update on the PMPs current legislative proposals for the 2016 General Assembly. 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. Mr. Orr also stated that the

PMP committee recommends changing the reporting requirement from within 7 days of dispensing to within 24 hours of dispensing. With respect to the proposal for reporting within 24 hours of dispensing or the next business day whichever comes later, the committee questioned whether the language referred to the next business day for the Department or the dispenser. Additionally, the committee questioned if simply requiring reporting within 24 hours was sufficient and therefore, the PMP may wish to consider deleting the allowance for reporting within the next business day.

CONSIDER REQUIREMENT FOR PHARMACY TECHNICIAN CERTIFICATION BOARD (PTCB):

Ms. Juran reminded the committee that the full board briefly discussed at the December 2014 full board meeting whether it should require PTCB certification as a prerequisite for pharmacy technician registration and referred the matter to the Regulation Committee for further consideration. The committee discussed minimal educational standards for pharmacy technicians, grandfathering those already registered as pharmacy technicians, and the possible elimination of the state and ExCPT pharmacy technician exams. There was consensus that a pharmacy technician should still be allowed to enroll in a Board-approved pharmacy technician training program and perform duties of a pharmacy technician for up to 9 months while working to complete the process for obtaining board registration as a pharmacy technician. Those pharmacy technicians already registered should not be required to obtain PTCB certification. Additionally, there was agreement that the allowance for a limited-use pharmacy technician registration for practicing in a free clinic should remain and that the fee for the initial PTCB examination should be waived, along with initial application fee for board registration and subsequent renewals fees.

MOTION:

The committee voted unanimously to recommend to the full board in June 2015 to adopt a legislative proposal that would amend 54.1-3321 to require new applicants for registration as a pharmacy technician to obtain certification from the Pharmacy Technician Certification Board (PTCB) as a prerequisite to registration and allow the fee for the initial PTCB examination to be waived, along with the initial application fee for board registration and subsequent renewals fees, for a limited-use pharmacy technician registration. (motion by Munden, second by Logan)

OVERSIGHT OF PHARMACY BENEFITS MANAGERS:

Ms. Warriner reviewed the comments and concerns made regarding Pharmacy Benefit Managers (PBMs). Many of the comments provided referenced concerns with patient safety, an increased number of drugs requiring prior authorizations or classified as specialty drugs, and patient access to medications. At Dr. Brown's request, Ms. Warriner summarized her participation on a NABP Task Force in October 2014 concerning PBMs. The committee expressed concern for those persons employed by PBMs who determine or communicate information regarding drug coverage. Ms. Juran stated that this is a large, complex subject affecting multiple healthcare professions, not simply pharmacists, and any oversight would likely involve multiple governing bodies. She recommended the committee consider asking Dr. Brown or Secretary Hazel to form a work group of various stakeholders to review the possible lack of oversight for PBMs. Dr. Brown commented that the issue was indeed complex, involving more entities than just the Board of Pharmacy

and that access, safety and cost were areas that could be addressed with a broader work group. After discussion, Dr. Brown agreed that he and Ms. Juran would contact Secretary Hazel to explore possible next steps.

ADJOURN: With all business concluded, the meeting adjourned at 2:28pm.

Cynthia Warriner, Committee Chairman

5/16/15
Date

Caroline D. Juran, Executive Director

6/15/15
Date