FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE MEETING ON DELIVERY OF PRESCRIPTION DRUG ORDERS (HB1956), GUIDELINES FOR COUNSELING ON DRUG DISPOSAL (HB2046), AND GUIDANCE FOR COMPLYING WITH USP CHAPTER <800>

September 18, 2017
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 10:17 a.m.

PRESIDING: Ellen Shinaberry, Chairman

MEMBERS PRESENT:
Jody Allen
Melvin L. Boone, Sr.
Sheila K. W. Elliott (arrived at 10:50 a.m.)
Ryan Logan

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Sylvia Tamayo-Suijk, Executive Assistant

APPROVAL OF AGENDA: The agenda for the Ad Hoc Committee meeting included topics such as discussion of HB1956- Delivery of Prescription Drug Orders, developing guidance for complying with USP Chapter <800> and discussion of HB2046- Guidelines for Counseling on Drug Disposal.

MOTION: **The Committee voted unanimously to approve the agenda. (motion by Allen, second by Boone)**

PUBLIC COMMENTS: John Beckner, representing the National Community Pharmacists Association (NCPA), provided comments on USP Chapter <800>. He stated that implementation will create a substantial economic impact and will change how members practice. Mr. Beckner stated that full compliance by July 1, 2018 will be too difficult and proposed a delay in the enforcement. He proposed the creation of a task force to offer specific recommendations. He stated that NCPA supports the inclusion of temperature monitoring devices for mail order deliveries.

Hunter Jamerson, attorney representing EPIC Pharmacies, mirrored the comments of John Beckner and requested a stay of enforcement of Chapter <800>. EPIC is in favor of HB1956 since temperature monitoring devices provide patient safety and are useful and inexpensive

tools. He stated that there is no duty for mail order pharmacies to monitor temperature during delivery.

Mike Rush, Executive Director, Global Health Policy for Temp Time, shared with the Committee, some excerpts from letters written by patients who receive temperature sensitive prescription medications via mail order. He stated that he was surprised to learn that Virginia law does not require temperature control devices in mail order deliveries and would like assurance that temperature sensitive biologics are not compromised if delivered by mail order.

Michelle Satterlund, McGuire Woods Consulting, provided comment regarding legal action taken in 2016 by patients in California who have received temperature sensitive medications without monitoring devices. She stated that several states have passed rules and regulations requiring temperature monitoring devices and she requested that the Board include some regulation to ensure that patients have some method of knowing if the medications have been compromised.

R. Scott Woods, Senior Director, State Affairs at Pharmaceutical Care Management Association, commented that they believe there are already existing federal and state laws and regulations that ensure the safe delivery of mail order medications.

Jamin Engle, pharmacist at Sentara Regional Medical Center, commented on some confusion of definitions between USP <797> and <800>. He addressed the difference in definitions of a segregated compounding area, the low-risk level with 12 hour or less beyond use dating (Hood within a non-ISO Class 7 area) and containment isolators. Mr. Engle requested additional guidance for Guidance Document 110-36 as it relates to wipe sampling and medical surveillance, dosage formulation changes and closed-system transfer devices. He requested that the Board extend the enforcement grace period for facility and engineering controls due to significant capital expenditure and project planning requirements.

Cheri Garvin and Alexander Pytlarz, Leesburg Compounding Center requested a delay until 2021 in the implementation of USP <800> in order to review the impact it will have in patient access, interpretation of the standards and the impact on its practice sites. They voiced concerns about patient access to hazardous products as facilities may simply cease compounding and these products may not be available. They stated that implementation is very expensive and the cost will be passed on to consumers. Availability of equipment, HVAC vendors, consultants and contractors in order to become compliant is also a concern.

Baylor Rice, pharmacist and owner of South River Compounding Center, echoed the comments of John Beckner and several others regarding concern for the implementation of USP Chapter <800>. Mr. Rice also commented that the NIOSH list may not be up to date.

Kyle Shreve, representing Virginia Association of Health Plans echoed previous comments opposing a mandate for temperature monitoring devices. He stated such a mandate does not protect against waste. In addition, the annual projected $400,000 cost of implementation will be passed on to consumers.

John Sisto, representing Express Scripts, stated that the requirement of temperature sensitive devices only serves to identify a problem after it arises and suggested that proper packaging and effective delivery is more useful. He urged the Committee to consider the use of continuous quality improvement in order to identify the problem before it occurs.

William Lee, Systems Director, Carilion Clinic, voiced his concerns on the limitation of the one-mile radius for delivery of sterile compounded products. He commented that renovation of 8 or 9 pharmacies to meet compliance with chapter <800> would require them to shut down or to bring in a costly mobile facility.

Kevin Tolley, pharmacist and co-owner of Dan's Wellness Pharmacy, requested an extension of the enforcement of USP <800> due to financial concerns and the limited availability of persons necessary to make the required changes. He stated that he renovated in 2015, would need to do so again, and would like to know what the rules are on the subject.

Two pharmacists from We Care Pharmacy shared that they had already spent $500,000 to become compliant with USP <800> and were concerned about ongoing operational costs. They discussed the $60,000 cost for garments and disposal of personal protective equipment and ongoing HVAC costs related to exhausting air. They requested that the Board review and limit the number of drugs on the NIOSH list and possibly require only certain classes of drugs.

Michelle Satterlund and Mike Rush responded to specific questions from the Committee and staff. It was explained that the devices vary in capability and price. The lesser expensive devices monitor for an excursion in temperature, but do not indicate the amount of time the drug was exposed to that excursion. More expensive devices, often used by manufacturers of biological drugs that are temperature-sensitive, are customized to the drug and may be more informative in determining if a drug's efficacy has been compromised. Mr. Rush stated temperature monitoring devices should be mandated for biological drugs that are temperature sensitive, in particular.

DISCUSSION OF HB1956:

Ms. Shinaberry provided an overview of the materials in the agenda packet, to include three letter from legislators. Delegate Orrock's letter submitted on behalf of the Health, Welfare and Institutions Committee requested the board to consider the issue related to any variances that may exist between mail-order and hand-delivered prescription medications, and to inform him of any recommendations by November 2017. Letters

from Delegates Peace and Head requested the board respond to fact-finding questions. The committee agreed that staff should prepare responses to these fact-finding questions. Ms. Shinaberry stated excerpts from minutes of May 2016 and June 2016 were also included in the agenda packet which is when this matter was first deliberated on by the Board.

Ms. Juran explained that all pharmacies must ensure drugs are dispensed and transported in a manner that provides for appropriate temperature storage or else the drug may be deemed adulterated under State and federal law. Drug manufacturers generally provide for allowable excursions in temperature during the transport and storage of drugs. Without knowing how long a drug was maintained at a temperature excursion, it is difficult to know if the drug has been negatively affected. There is no data to share with the Board on consumer complaints to DHP on this subject.

Ms. Elliott stated the necessity to err on the side of the patient so that they receive the drug they need safely and in accordance with the manufacturer's instructions.

Ms. Allen stated that the lack of data regarding consumer complaints does not warrant a mandate to require temperature control devices and suggested that pharmacies be proactive by using appropriate packaging and shipping.

MOTION:

The Committee voted to recommend to the full board that no action be taken to mandate temperature monitoring devices, but recommended that the Board develop guidance for pharmacies that highlights the importance for using appropriate packaging materials when delivering temperature-sensitive drugs, to include temperature monitoring devices, if warranted. (motion by Allen, second by Boone; opposed by Ms. Elliott)

DISCUSSION OF USP <800>

The Committee discussed that §54.1-3410.2 requires sterile and non-sterile compounding be performed in compliance with USP-NF standards, and therefore, the law requires compliance with chapter <800> on its effective date of July 1, 2018. There was much discussion regarding concerns for licensees being able to comply by July 1, 2018. Ms. Shinaberry recommended the convening of a task force to develop guidance on how to comply. Ms. Juran reminded the committee of the numerous frequently asked questions USP has published on <800> and expressed concern for the board's ability to convene a task force in a timely manner due to other scheduled meetings and availability.

ACTION ITEM:

The Committee requested Ms. Juran to research with USP the questions raised during public comment regarding confusion in understanding requirements in chapter <800> and any immediately submitted to her following the meeting, to potentially include in an amended guidance document, in lieu of convening a task force.

Based on her findings the Board will later determine if a task force is necessary for developing guidance on complying with chapter <800>.

MOTION: **The Committee voted unanimously to recommend to the full board that inspectors begin citing deficiencies as of July 1, 2018, but impose no monetary sanctions. Beginning January 1, 2019, monetary sanctions (to be established at a later date) should be imposed for non-compliance with the non-physical standards of chapter <800>, e.g., list of hazardous drugs received or stored in the pharmacy, performance of assessment of risk, etc. Beginning July 1, 2019, monetary sanctions (to be established at a later date) should be imposed for the physical and engineering standards of Chapter <800>. (motion by Allen, second by Elliott)**

DISCUSSION OF HB2046: The Committee discussed creating a guidance document to address the points which a pharmacist should review with a patient regarding proper disposal of controlled substances.

MOTION: **The Committee voted unanimously for staff to create a guidance document regarding the disposal of controlled substances for Board consideration which should include resources of information on the subject. (motion by Logan, second by Boone)**

ADJOURN: With all business concluded, the meeting adjourned at approximately 1:30pm.

Ellen B. Shinaberry

Ellen Shinaberry, Committee Chairman

9/26/17

DATE:

Caroline D. Juran, Executive Director

9/26/17

DATE: