FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

November 2, 2017
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:10am.

PRESIDING: Michael Elliott, Committee Chairman

MEMBERS PRESENT:
Sheila Elliott
Ryan Logan
Rafael Saenz
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst
Sylvia Tamayo-Suijk, Executive Assistant

APPROVAL OF AGENDA: An Amended Agenda was presented for review to include discussion of deficiency #9 regarding Enclosure as listed in Guidance Document 110-9 and amending Regulation 18VAC110-20-540 to allow naloxone in Emergency Drug Kits.

MOTION: **The Committee voted unanimously to approve the amended agenda as presented for the Regulation Committee meeting (motion by S. Elliott, second by Saenz).**

PUBLIC COMMENT: There was no public comment offered.

AGENDA ITEMS:

Amend Guidance Document 110-36, *Compliance with USP Standard for Compounding*

USP published a notification of intent to revise the effective date of Chapter <800> to December 1, 2019. The committee reviewed proposed changes to Guidance Document 110-36 which reflect the new implementation deadline date for compliance with Chapter <800>. The committee recommended that the Board begin the educational process through inspections within the next six months. Additionally, the committee recommended that the Guidance Document include USP's Frequently Asked Questions for Chapter <800> and a link to the National

Institute of Occupational Safety and Health (NIOSH).

- **MOTION:** **The Committee voted unanimously to recommend to the full board to amend Guidance Document 110-36 as presented, include USP's Frequently Asked Questions for Chapter <800>, add a link to the National Institute of Occupational Safety and Health (NIOSH) list, and begin the education process though inspections (which will not result in disciplinary action prior to the effective date of the chapter) within the next six months. (motion by Saenz, second by Thornbury)**

Discuss Piloting Changes to Physician Selling Inspection Program

The Board adopted Guidance Document 110-23, *Practitioners of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide* on March 26, 2014. At that time the board wanted to pilot the issuance of an expedited pre-hearing consent order at the conclusion of routine inspections which is akin to the process used for routine pharmacy inspections. The pilot was subsequently tabled until a legislative proposal authorizing the Board to permit the facilities from where physicians dispense could be passed. Mr. Johnson briefly reviewed Guidance Document 110-23, *Practitioners of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide.* The committee recommended removing the terms "major" and "minor" from the deficiency titles to be consistent with changes made in the recent past to Guidance Document 110-9, as well as removing Minor Deficiency #13 in light of a regulatory amendment (Sink with hot and cold running water not available within the immediate vicinity of the selling and storage area.) Additionally, the committee recommended that staff cross-walk the entire document to determine if additional edits were necessary based on regulatory amendments and to move forward with the process and implement a one year pilot program.

- **ACTION ITEM:** **The Committee requested staff to cross-walk Guidance Document 110-23 with Guidance Document 110-9 for consistency and with current regulations to determine if additional edits were necessary, and to present the full Board with a timeline for the start of the one year pilot program.**

- **MOTION:** **The committee voted unanimously to recommend to the full board that it amend Guidance Document (GD) 110-23 by striking "major" and "minor" from the deficiency titles and striking Deficiency #13, and to move forward with piloting for one year the issuance of expedited pre-hearing consent orders at the conclusion of routine inspections of practitioners of the healing arts to sell controlled substances when deficiencies listed in GD 110-23 are cited. (motion by S. Elliott, second by Logan)**

Adopt Regulation to Address White Bagging/Brown Bagging

The Committee revisited discussion regarding possible regulatory concepts to address patient-safety concerns with white bagging and brown bagging.

- **MOTION:** **The Committee voted unanimously to recommend to the full board to adopt a NOIRA to address white bagging and brown bagging that includes:**
  - **A definition of white bagging and brown bagging;**
  - **Prohibition of brown bagging of drugs requiring reconstitution or compounding prior to administration;**
  - **Requiring the specialty pharmacy participating in white bagging to notify the receiving pharmacy of the shipment to ensure appropriate coordination of patient care, to provide an estimated arrival date, to provide the name of the patient to whom the drug has been dispensed, and to provide the exact address where the product has been shipped. (motion by Saenz, second by Thornbury)**

Amend Regulation 18VAC110-20-390, *Kickbacks, fee-splitting, interference with supplier*

- **MOTION:** **The committee voted unanimously to recommend to the full board to amend 18VAC110-20-390 as presented which strikes the phrase in subsection A, "unless fully disclosed in writing to the patient and any third party payor". (motion by Saenz, second by S. Elliott)**

Consider Possible Disciplinary Action for Repeat Deficiencies

The Committee reviewed the chart of Repeat Deficiencies by Quarter from February 2014 to August 2017. Deficiency #15, Perpetual Inventory, was of some concern and there was discussion as to the cause of the repeats, how many are considered acceptable and how many repeats resulted from how many inspections. Ms. Elliott suggested that increasing the penalty fee from $250 to $750 might result in a decreased number of deficiencies.

- **MOTION:** **A motion to recommend to the full board to increase the penalty fee for Perpetual Inventory deficiency to $750 was made by Ms. Elliott, but died for lack of second.**

- **MOTION:** **The committee voted unanimously to request staff to continue monitoring the prevalence of repeat deficiencies, particularly the one involving perpetual inventories. (motion by Logan, second by Thornbury)**

- **ACTION ITEM:** **The committee requested that Mr. Johnson amend the licensure/inspection report he provides at the full board meetings to reflect the number of repeat deficiencies in the current quarter and cumulatively in all quarters listed on the report.**

Discuss Deficiency #9 regarding Enclosure as listed in Guidance Document 110-9, *Pharmacy*

Inspection Deficiency Monetary Penalty Guide

- **MOTION:**

The committee voted unanimously to take no action on deficiency #9. (motion by Logan, second by S. Elliott)

Amend Regulation 18VAC110-20-540, *Emergency Drug Kit*

Ms. Juran reported that the Department of Corrections would like the ability to have intranasal naloxone in the emergency drug kits. Currently, the regulation restricts the contents of the emergency drug kit to drugs for injection and inhalation, with some exception.

- **MOTION:**

The committee voted unanimously to recommend to the full board to take emergency action to amend 18VAC110-20-540 to include intranasal formulations of naloxone in emergency kits. (motion by Saenz, second by Thornbury)

ADJOURN:

With all business concluded, the meeting adjourned at approximately 12:10 pm.

Michael Elliott, Chairman

Caroline D. Juran, Executive Director

12/11/17
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