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BOARD OF PHARMACY PUBLIC SESSION MINUTES HUDSON CONFERENCE ROOM, 6th FLOOR SEPTEMBER 28, 2016

I. CALL TO ORDER

The Open Session of the New Jersey Board of Pharmacy was called to order by the Board President, Mr. Thomas F.X. Bender, at 124 Halsey Street, Hudson Conference Room, 6th floor, on September 28, 2016 at 9:00 a.m. All members were duly notified of the time, place and all pertinent materials were provided to the members.

II. SUNSHINE LAW ANNOUNCEMENT

President Thomas F.X. Bender read a statement that the newspapers and appropriate elected officials had been notified of the meeting according to the requirements of the Open Public Meetings Act N.J.S.A., Chapter 231, PL1975/C.10:4-8.

III. ROLL CALL

Thomas F.X. Bender, R.Ph.	President
Richard Palombo, R.Ph.	Vice President
Margherita Cardello, R.Ph.	Late Arrival- 11:30 a.m.
Stephen Lieberman, R.Ph.	
Edward G. McGinley, R.Ph.	Excused Absence
Mahesh Shah, R.Ph.	
Mitch Sobel, R.Ph.	
Linda Witzal, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio	Executive Director
Jodi Krugman	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst
Jessica Kelley	Acting Executive Director DCU

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of August, the following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 107
- Pharmacists licensed – 137 (127 by examination/score transfer and 10 by reciprocity)

- Out-of-State Pharmacies registered –18
- In-State Pharmacies licensed – 5
- Pharmacists receiving immunization approval – 55
- Interns (foreign graduates) licensed – 4

Executive Director Anthony Rubinaccio asked all pharmacists and employers to bear with the Board as we work diligently to review and process Immunization applications.

V. OLD BUSINESS

1) Public Orders Filed

2) Carrie McGuire – response to POD

Richard Palombo moved, seconded by Stephen Lieberman to finalize the POD without penalty or suspension as Ms. McGuire passed away. **Motion passed 5-0-1.** Thomas Bender was recused due to an affiliation with Walgreens.

3) Robert Ecker - response to POD

Thomas Bender moved, seconded by Mahesh Shah to accept the Attorney General's recommendation and finalize the POD. **Motion passed 6-0.**

4) Kaba Fusion- Out of State Pharmacy application- sterile compounding- additional information

The Board received and reviewed the requested additional information.

Richard Palombo moved, seconded by Mitch Sobel that the pharmacy must obtain an in state sterile compounding inspection or NABP VPP inspection. This application will remain pending. **Motion passed 6-0.**

5) Empower Pharmacy - Out of State Pharmacy change of location application- sterile compounding- additional information

The Board received and reviewed additional requested information.

Richard Palombo moved, seconded by Stephen Lieberman to approve this application. **Motion passed 6-0.**

6) I/M/O Howard Dukes

Mr. Dukes is seeking reinstatement of suspended registration for failure to cooperate.

Stephen Lieberman moved, seconded by Linda Witzal to allow Mr. Dukes to reinstate contingent upon payment of the \$250 fine. Once reinstated, the Board

can consider underlying discipline. **Motion passed 6-0.**

VI. NEW BUSINESS

1) Assembly Bill, A3910

This Bill establishes procedures for pharmacists to seek approval to dispense alternative products in place of the prescribed epinephrine auto-injector devices.

Linda Witzal moved, seconded by Richard Palombo that the Board supports the bill if it is amended to provide immunity from liability for the pharmacist as long as the procedures are followed. The Board further notes that although it supports this particular bill, it is wary of this type of individualized drug bill re-occurring for all drugs that undergo price increases. **Motion passed 6-0.**

2) Assembly Bill, A4169

This Bill would require the Division of Consumer Affairs to establish an electronic monitoring system for pain management agreements, to be linked to, and used in association with, Prescription Monitoring Program.

Mahesh Shah moved, seconded by Mitch Sobel that the Board opposes this bill as it will discourage prescribers from entering into pain management agreements, the requirements are burdensome, and the bill impinges upon a patient's rights to privacy and patient confidentiality. **Motion passed 6-0.**

3) Assembly Bill, A4094

This Bill would require epinephrine auto-injectors to be packaged and sold as single units.

Richard Palombo moved, seconded by Mitch Sobel that the Board supports the bill if it is amended to have the manufacturer produce both the single unit and double unit and the decision as to which to order is left to the patient and practitioner. **Motion passed 6-0.**

4) Prescription blanks – being revised to address Physician Assistant and Optometrist changes in health care facility

Regulatory Analyst Rachel D. Glasgow informed the Board that, due to changes to the laws governing the prescription authority for Optometrists and Physician Assistants, the New Jersey Prescription Blanks Program revised the Healthcare Facility (HCF) New Jersey Prescription Blank. Through March 31, 2017, practitioners may write valid prescriptions on either the old or the new healthcare facility prescription blanks. Starting April 1, 2017, practitioners must use the

new healthcare facility blank to issue prescriptions for their patients.

The Board accepted this as informational.

5) **Fouad Masri** – FPGEC waiver request

Mr. Masri is requesting a waiver for an alternative pathway to allow him to qualify for FPGEC Certification. Mr. Masri cannot obtain the required documentation due to the conflict in his home country of Syria and doing so would pose a risk to his family. He did not obtain licensure in Syria, but does have recommendation from the health association, so under current rules he is not eligible for the FPGEC.

Mitch Sobel moved, seconded by Linda Witzal to deny the waiver request and allow the NABP process take its course or Mr. Masri can apply for refugee or asylum status. **Motion passed 6-0.**

6) **Nicole Novitsky** - requesting NAPLEX testing accommodation

This item was moved to the Executive Session.

7) **Ralph Ypil** – requesting NAPLEX testing accommodation

This item was moved to the Executive Session.

8) **Monica Taing** - requesting NAPLEX and MPJE ADA testing accommodation –

This item was moved to the Executive Session

9) **N.J.A.C. 13:39 Proposed Readoption, Amendments, and New Rules**

Regulatory Analyst Rachel D. Glasgow provided an overview of the sunset review process and discussed the proposed amendments, new rules, and repeals. The Board's rules are scheduled to expire on May 17, 2017. The Board undertook a thorough review of its rules to decide if any changes were necessary as a result of industry trends or developments, new laws, corrections or updates to citations and references, and clarification of existing rules/practices. Board members individually reviewed the rules and submitted suggested changes for the Rules & Regulations Committee to consider. During the discussion of the Committee's recommendations, the Board projected the proposed rule text onto the wall so that the members of the public could follow the discussion. After the review and discussion, the Board approved for proposal the readoption of N.J.A.C. 13:39 with amendments, new rules, and repeals.

Richard Palombo moved, seconded by Linda Witzal to approve the committee recommendation for proposal, with one minor adjustment noted. Board President, Thomas Bender will be permitted to answer questions and have his decisions ratified at next board meeting. Regulatory Analyst Rachel D. Glasgow is

authorized to make some suggested changes per the rule process. **Motion passed 6-0.**

10) Robert Bernstein – response to Continuing Education verification

The Board received and reviewed Mr. Bernstein’s response to the POD he received after failing to provide documentation of the required continuing education credits for his biennial renewal after affirming he had completed the on his renewal application. He did not obtain any pharmacy credits, however he did submit continuing education credits related to his medical license. Mr. Bernstein request the Board mitigate the fine and allow him to surrender his license.

The Attorney General recommends to finalize the POD without modification as Mr. Bernstein had no pharmacy credits and answered “yes” to continuing education question on his renewal.

Stephen Lieberman moved, seconded by Mahesh Shah to modify the POD and impose a fine of \$3,000 for failure to complete his continuing education credits and allow for a payment plan. The Board will allow Mr. Bernstein to surrender his license and remind him that if he wants to reinstate, will need to complete the required education credits. The \$1,000 fine for misrepresentation will be removed. **Motion passed 6-0.**

11) James Park - response to Continuing Education verification

The Board received and reviewed Mr. Park’s response to the POD he received after failing to provide documentation of the required continuing education credits for his biennial renewal after affirming he had completed all 30 credits on his renewal application.

The Attorney General recommends to finalize the POD without modification.

Mitch Sobel moved, seconded by Stephen Lieberman to accept the Attorney General’s recommendation and finalize the POD without modification except to permit a payment plan for penalties. **Motion passed 6-0.**

12) Kamal Moorjani – request for modification of the Consent Order

Mr. Moorjani is requesting the requirement that he provide a copy of his Consent Order to all employers where a pharmacy license is required and that each employer notifies the Board that he has received it and is aware of the exclusion/debarment status be removed.

Richard Palombo moved, seconded by Mahesh Shah to grant Mr. Moorjani’s request. **Motion passed 6-0.**

13) Bayshore Pharmacy – request for determination

Bayshore Pharmacy is requesting the Board make a determination regarding the need for electronically received CII prescriptions to have the quantity written in both numbers and words on schedule II prescriptions which are received electronically.

The Board of Medical Examiners regulation, N.J.A.C. 13:35-7.2(d)(5) requires words as well as numbers to be written on hardcopy prescriptions to represent the quantity of medication to be dispensed. There are some concerns raised that PBMs are requiring the alphabetic representation of quantity to be included on electronic prescriptions as well; however these e-scribe systems may not be able to accommodate this requirement due to current technological design constraints. The rules for prescriptions submitted electronically require the same standards be followed as those that are in place for hardcopy prescriptions.

Mitch Sobel moved, seconded by Richard Palombo, for the DCA to discuss with the BME this situation and the Board's desire to change N.J.A.C. 13:39-7.11(e) to accommodate a carve-out to address the alphanumeric requirement for electronic schedule II prescriptions in the BME regulation N.J.A.C. 13:35-7.2(d)(5) which reads:

"Words, in addition to numbers, to indicate the drug quantity authorized if the prescription is for a Schedule II controlled substance, for example: ten (10) Percodan; or five (5) Ritalin 5 mg"

If the BME is amenable to the proposed change, DCA will amend the proposed pharmacy regulations to accommodate this change. In the interim, Director Rubinaccio will respond to this inquiry that at this point in time, it would appear that this current restriction will prohibit us from any mandating of electronic C-II prescriptions. The rules must be followed as written. **Motion passed 6-0.**

14) Village Pharmacy – Out of State Pharmacy – request to remove restrictions on shipping CSPs to New Jersey

Village Pharmacy is requesting that the Board remove the restriction on shipping compounded sterile product into New Jersey that were imposed as a result of a Consent Order imposed by their home state of Massachusetts in 2013. The Massachusetts Board of Pharmacy has removed all of the restrictions.

Stephen Lieberman moved, seconded by Richard Palombo to remove the restrictions pending verification from Massachusetts that they have lifted the restrictions. **Motion passed 7-0.**

15) Paqosa Specialty Pharmacy - Out of State Pharmacy application with discipline

In 2006 Paqosa Specialty Pharmacy was cited for failure to report a change the pharmacist in charge and in 2011 the pharmacy was cited for failure to submit the required PMP data for two separate one week periods during September and December. Both of the violations occurred prior to the current ownership group taking over the pharmacy.

Stephen Lieberman moved, seconded by Mahesh Shah to approve this application.
Motion passed 7-0.

VII. MITIGATION REQUEST

n/a

VIII. INFORMATIONAL

1) NABP District I & II meetings

The NABP AACP District I & II meeting was held on September 15-17, 2016 at the Greenbrier Resort in White Sulphur Springs, West Virginia. New Jersey was represented by Board members Edward McGinley, Thomas Bender, Richard Palombo, Margherita Cardello, Linda Witzal and Executive Director Anthony Rubinaccio.

This meeting was designed for NABP and AACP members, and registered pharmacists in all practice settings. The sessions focused on regulations related to naloxone/substance abuse and the integration of this content into the pharmacy curriculum, a roundtable discussion covering current pharmacy topics, a panel discussion on pharmacists' recovery, the pharmacists' scope of practice, and minimizing pharmacy errors.

- 2) Board Members Mitch Sobel and Linda Witzal represented the Board at a DEA Pharmacy Diversion Awareness Conference (PDAC) on September 18 and 19, 2016 at the Hyatt Regency, 2 Albany Street, New Brunswick, New Jersey. The attendees were predominantly pharmacists and pharmacy technicians from the state of New Jersey. The DEA has held seventy-five PDACs throughout the country (since late 2011). The PDACs were designed to educate pharmacists and pharmacy technicians about the problem of pharmaceutical drug diversion (as it relates to pharmacies) and things they can do to prevent diversion from their stores.

IX. COMMITTEE REPORTS

X. APPROVAL OF MINUTES

Public Session minutes for August 24, 2016

Richard Palombo moved, seconded by Mitch Sobel to approve the August 24, 2016 Public Session minutes as amended. **Motion passed 7-0.**

XI. ADJOURNMENT

Stephen Lieberman moved, seconded by Mahesh Shah for the Board to move into the Executive Session for review of 3 Complaints, 4 Old Business Item, 12 New Business Items, the Secretary's Report and Recommendation for Inspection Reports, and the approval of the August 24, 2016 Executive Session Minutes.

Motion passed 7-0.

At 12:12 p.m., Mitch Sobel moved, seconded by Richard Palombo, to adjourn the Public Session. **Motion passed 7-0.**