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BOARD OF PHARMACY PUBLIC SESSION MINUTES ESSEX CONFERENCE ROOM, 7th FLOOR July 27, 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 Bender, at 124 Halsey Street, Essex Conference Room, 7th floor, on July 27, 2016 at 9:04 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 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, P.L.1975/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- 10:20a.m.
Stephen Lieberman, R.Ph.	
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Mitch Sobel, R.Ph.	
Linda Witzal, R.Ph.	

OTHERS IN ATTENDANCE

Megan Cordoma	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst
Jessica Kelley	Acting Executive Director DCU
Anthony Rubinaccio, R.Ph.	Executive Director
Jennifer Wasiewicz	Board Staff

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of July \$26,678 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 69
- Pharmacists licensed – 32 (20 by examination/score transfer and 12 by reciprocity)
- Out-of-State Pharmacies registered – 18
- In-State Pharmacies licensed – 5
- Pharmacists receiving immunization approval – 25
- Interns (foreign graduates) licensed – 1

V. OLD BUSINESS

1) Public Orders Filed

- a. Inspira Medical Center, Vineland, Final Consent Order, filed 6/29/16
- b. Ma'Leka Evans, Provisional Order of Discipline, filed 6/29/16
- c. Meredith Miranda, Summary Order of Suspension, file 6/29/16
- d. Teresa Acevedo, Provisional Order of Discipline, 06/29/16
- e. Amanda Bortz, Provisional Order of Discipline, filed 07/07/16
- f. Ahed Chhadeh, Provisional Order of Discipline, filed 07/07/16

2) Concierge Compounding Pharmaceuticals, Inc, Henderson, NV – additional requested information supplied

The Board received and reviewed the requested inspection reports. The most recent inspection was February 24, 2015, which predates the new owners taking over the pharmacy.

Thomas Bender moved, seconded by Edward McGinley to request an updated state inspection or a NABP VPP inspection and verify the relationship between the previous and current permit holders. The pharmacy must also provide the name of the new corporation and clarify that former owner is not a party to the new corporation. Motion passed 7-0.

VI. NEW BUSINESS

1) Assembly Bill, A3980

This bill requires certain health care professionals to meet continuing education requirements on topics related to prescription opioid drugs as a condition of renewal of a professional license, certification, or registration.

Richard Palombo moved, seconded by Mitch Sobel to support this bill and believes it is beneficial to learn about the risks and signs of opioid abuse, addiction and diversion. **Motion passed 6-1.** Stephen Lieberman was opposed.

2) **Assembly Bill, A3983**

This bill authorizes pharmacists to dispense up to a 90-day supply of certain prescription drugs pursuant to a valid prescription. Specifically, the bill would apply to 'prescriptions that authorize an initial quantity of less than a 90-day supply of the prescription drug, followed by periodic refills. The patient will be required to have completed an initial 30-day supply of the drug, unless the prescription is continuing a drug for which the patient was previously dispensed a 90-day supply. The bill would not apply to controlled dangerous substances, and would not authorize the total amount dispensed to exceed the total amount authorized under the prescription, including refills. The pharmacist will be required to notify the prescriber of the increased supply dispensed, and a pharmacist will not be permitted to dispense increased quantities of prescription drugs under the bill if the prescriber has explicitly indicated on the prescription that dispensing the medication in an initial amount, followed by periodic refills, is medically necessary, or has otherwise indicated that there is to be no change to the quantities authorized by the prescription.

Edward McGinley moved, seconded by Richard Palombo to support this Bill with comments. The Board believes that patients should be required to consent to the increased supply of medications being dispensed and that pharmacists should be required to provide counseling to patients about compliance with prescribed drug regimens. The Board believe that the requirement to notify the doctor should be removed. In addition, the Board believes that insurance companies and prescription benefit management companies need to provide coverage consistent with the bill's provisions. **Motion passed 7-0.**

3) **Assembly Bill, A3982**

This bill requires that every prescription for a controlled dangerous substance, prescription legend drug, or other prescription item be transmitted electronically using an electronic health records system. This requirement will take effect one year after the date of enactment.

Stephen Lieberman moved, seconded by Mahesh Shah that the Board supports the concept of increasing the use of e-prescribing but not making its use mandatory; the Board believes that prescribers should retain the ability to call in prescriptions and provide patients with a physical prescription (examples of reasons include

upcoming patient travel, patient chooses not to fill prescription). **Motion passed 7-0.**

4) Assembly Bill, A3984

This bill would add naloxone hydrochloride, and other opioid antidotes, to the list of prescription drugs that are to be monitored as part of the State's Prescription Monitoring Program (PMP). Although the PMP focuses on monitoring the dispensation of controlled dangerous substances in the State, and although opioid antidotes are not considered to be controlled dangerous substances information related to the dispensation of opioid antidotes is nonetheless relevant to determinations regarding the prescription and dispensation of controlled dangerous substances.

Mitch Sobel moved, seconded by Richard Palombo to oppose this bill because it will not aid the opioid epidemic and imposes hurdles to saving lives. **Motion passed 7-0.**

5) Assembly Bill, A3992

In order to protect against the occurrence of opioid addiction in student athletes, who regularly suffer from pain and injuries that necessitate the prescription of pain relief medications, this bill would establish certain limitations and requirements to restrict the prescription and dispensation of opioid medications to student athletes, and to provide, for the close monitoring of a student athlete's use of such medications.

Edward McGinley moved, seconded by Stephen Lieberman that the Board is neutral with respect to this bill but notes that the provisions should be expanded to all minors, and not limited to student athletes. **Motion passed 7-0.**

6) Senate Bill, S2402

This bill requires the Commissioner of Education, in consultation with the Commissioner of Health, to develop an educational fact sheet that provides information concerning the use and misuse of opioid drugs in the event that a student-athlete or cheerleader is prescribed an opioid for a sports-related injury. The bill requires school districts and nonpublic schools that participate in Interscholastic sports or cheerleading programs to distribute the fact sheet annually to the parents or guardians of student-athletes and cheerleaders, and to obtain a signed acknowledgement of the receipt of the fact sheet by the student and his parent or guardian.

Mitch Sobel moved, seconded by Richard Palombo that the Board is neutral with respect to this bill but notes that the bill's provisions should be expanded to include all minors. **Motion passed 7-0.**

7) **Senate Bill, S2387**

This Bill requires training of certain staff and health care professionals in interacting with individuals with developmental disabilities.

Edward McGinley moved, seconded by Linda Witzal that the Board of Pharmacy recognizes that there is a growing population of persons with developmental disabilities and there is a need for education. The Board determined to remain neutral on S2387 and noted that the bill lacks details concerning the type or amount of required training. **Motion passed 7-0.**

8) **Senate Bill, S3872**

This bill requires a preliminary finding of liability of professional malpractice by a panel of three experts appointed by licensing authority prior to institution of action.

Edward McGinley moved, seconded by Linda Witzal to support the intent of the bill to control costs and notes that there are many unanswered questions concerning the appointment of the expert panel, whether the panel's decision must be unanimous, and the impact of disparate decisions between the panel of experts and the Board. **Motion passed 7-0.**

9) **Jahnia Gainer** – Active Pharmacy technician, finalization of POD

Edward McGinley moved, seconded by Stephen Lieberman to finalize the POD without modification as the regular and certified mail was sent to the correct address of record but was returned unclaimed/unable to forward. No response was received and no issue of material fact was raised. **Motion passed 7-0.**

10) **Alexis Vega** - Active Pharmacy technician, finalization of POD

Stephen Lieberman moved, seconded by Linda Witzal to finalize the POD without modification as the regular and certified mail was sent to the correct address of record (certified mail was returned unclaimed/unable to forward and regular mail was not returned). No response was received and no issue of material fact was raised. **Motion passed 7-0.**

11) **Jamal Najib** – CE Audit POD

Edward McGinley moved, seconded by Linda Witzal to withdraw the POD as it was issued in error. **Motion passed 7-0.**

12) **Bergen Regional Medical Center** – waiver request

George Piltz of Bergen Regional Medical Center, presented the waiver to allow samples of the medication, Invega Sustena (injectable) and Vivitrol, to be dispensed in the hospital. Inpatient protocol is the same. Two doses can be administered to patients. The medication is specific to a physician and a patient and there is no charge for the first and second doses.

Richard Palombo moved, seconded by Mitch Sobel that after understanding program more fully, the Board determined no waiver is required. **Motion passed 8-0.**

13) **Bhumika Patel** – Reciprocity applicant - request for waiver of FPGEC

Mr. Patel has been licensed as a Pharmacist in Arizona since 2008 and in Michigan since April 2016. He has no discipline in any state. Mr. Patel passed the FPGEE in December 2004, and the score expired in 2012. Mr. Patel is requesting a waiver to reciprocate into New Jersey.

Edward McGinley moved, seconded by Stephen Lieberman to require Mr. Patel to pass the TOEFL examination and the Board will waive the FPGEC requirement. **Motion passed 8-0.**

14) **Amrit Chandra** – Pharmacist Reinstatement Application- review of work experience

Mr. Chandra has not worked as a pharmacist for 11 years, and only worked as pharmacy technician for one year a year ago.

Edward McGinley moved, seconded by Linda Witzal to require Mr. Chandra to take the NAPLEX and MPJE examinations. If he passes, this request will not need to come back before the Board. Mr. Chandra will need to comply with all of the Board's other reinstatement financial requirements. **Motion passed 8-0.**

15) **Patrick Okoye** – Reinstatement request

Mr. Okoye entered into a Consent Order in July 2013 for revocation of his Pharmacist license which allows him the right to reapply after his supervised release is completed.

Mahesh Shah moved, seconded by Edward McGinley to schedule Mr. Okoye for an Investigative Inquiry. **Motion passed 8-0.**

16) Victor Fakondo - Reinstatement request

Mr. Fakondo entered into a Consent Order in December 2010 for suspension of his Pharmacist license for five years.

Edward McGinley moved, seconded by Stephen Lieberman to schedule Mr. Fakondo for an Investigative Inquiry. **Motion passed 7-0-1.** Richard Palombo was recused due to due to his affiliation with Express Scripts (Medco).

17) Smiti Shah- Reciprocity applicant with disciplinary action

Chair Direct: Item tabled for further review by counsel.

18) Aaron Link - Reciprocity applicant with disciplinary action

Chair Direct: Item tabled for further review by counsel.

19) Empower Pharmacy – Out of State Pharmacy, sterile compounding – change of location application

Edward McGinley moved, seconded by Thomas Bender to request an updated complete inspection, either NABP VPP or Texas sterile compounding demonstrating compliance with USP 797, and the pharmacy's response to the FDA 483. **Motion passed 8-0.**

20) Compounding Docs, Inc. - Out of State Pharmacy, sterile compounding – change of location application

Edward McGinley moved, seconded by Thomas Bender to approve this application. **Motion passed 8-0.**

21) Clinical Solutions, Inc. - Out of State Pharmacy, sterile compounding application with discipline

Edward McGinley moved, seconded by Stephen Lieberman to approve this application. **Motion passed 8-0.**

22) Florida Pain & Rehabilitation Associates - Out of State Pharmacy, sterile compounding application

Edward McGinley moved, seconded by Mahesh Shah to approve this application.
Motion passed 8-0.

- 23) **Prescription Dispensing Laboratories, Inc.** - Out of State Pharmacy, change of location application with discipline

Edward McGinley moved, seconded by Linda Witzal for the Board office to request the pharmacy's Texas Inspection report for the new location and to obtain clarification between the old and new ownership. The Board office is to also request a copy of the FDA's 483 inspection reports and the pharmacy's response.
Motion passed 8-0.

- 24) **Fusion Specialty Pharmacy** – Out of State Pharmacy application – review of inspection report

Thomas Bender moved, seconded by Richard Palombo to approve this application. **Motion passed 8-0.**

- 25) **BriovaRX of Florida** – Out of State Pharmacy - change of ownership and name application with discipline

Edward McGinley moved, seconded by Mahesh Shah to approve this application.
Motion passed 8-0.

- 26) **Eastside Pharmacy dba Best Pet RX** – Out of State Pharmacy application, sterile compounding change of location application

Edward McGinley moved, seconded by Stephen Lieberman to approve this application. **Motion passed 8-0.**

- 27) **CentRX Pharmacy Northern Nevada** - Out of State Pharmacy application with discipline

Edward McGinley moved, seconded by Stephen Lieberman to approve this application. **Motion passed 8-0.**

- 28) **Accredo Health Group, Inc.,** - Out of State Pharmacy – request to begin sterile compounding

Edward McGinley moved, seconded by Mahesh Shah that the pharmacy must complete the sterile compounding affidavit and the application. The pharmacy must also obtain a NABP VPP Inspection report. **Motion passed 7-0-1.** Richard Palombo was recused due to his affiliation with Express Scripts.

29) FDA Guidance Document 503A – request for Board comment

Individual Board members can submit comments directly to Executive Director Anthony Rubinaccio.

30) Call for Resolutions and Roundtable Questions for NABP/AACP

The Board accepted this as informational.

VII. MITIGATION REQUEST

1) Teresa Ricioppo– Mandell’s Clinical Pharmacy, Somerset, NJ

Theresa Ricioppo responded on behalf of Mandell’s Clinical Pharmacy and requested mitigation of N.J.A.C. 13:39-11.19 and N.J.A.C. 13:39-11.21(a)8.

Mitch Sobel moved, seconded by Thomas Bender to deny the mitigation request as the citations are consistent with the Board of Pharmacy rules and regulations. **Motion does not pass 3-5.** Margherita Cardello, Edward McGinley, Mahesh Shah, Stephen Lieberman and Linda Witzal were opposed.

Edward McGinley moved, seconded by Linda Witzal to mitigate N.J.A.C. 13:39-11.21(a)8 to a warning, provided they utilize the labeling as presented to the Board and to remove the citation for N.J.A.C. 13:39-11.19(c) because the pharmacy only needs to prove sterility for 14 days and they have met that requirement. **Motion passed 5-3.** Mitch Sobel, Thomas Bender and Richard Palombo were opposed.

VIII. INFORMATIONAL

IX. COMMITTEE REPORTS

Edward McGinley updated the Board on the Rules and Regulations committee. They are in the midst of sunset review of the regulations and are holding weekly meetings to complete the process. With Rachel Glasgow’s assistance and guidance the committee has drafted responses to the comments received on the temperature control regulations. The next meeting will be held on August 11, 2016.

X. APPROVAL OF MINUTES

Stephen Lieberman moved, seconded by Margherita Cardello to approve the June 22, 2016 Public Session Minutes as amended. **Motion passed 8-0.**

XI. ADJOURNMENT

Stephen Lieberman moved, seconded by Mitch Sobel, to move into the Executive Session for review of 3 Complaints, 2 Old Business Items, 14 New Business Items, the Secretary's Report and Recommendation on Inspection Reports from, and the approval of the Executive Session Minutes. **Motion passed 8-0.**

At 12:10 p.m., Stephen Lieberman moved, seconded by Mitch Sobel, to adjourn the Public Session. **Motion passed 8-0.**