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BOARD OF PHARMACY PUBLIC SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR January 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 F.X. Bender, at 124 Halsey Street, Monmouth Conference Room, 7th floor, on January 27, 2016 at 9:15 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.	Excused Absence
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Linda Witzal, R.Ph.	
Mitch Sobel, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director, Board of Pharmacy
Jodi Krugman	Deputy Attorney General
Jessica Kelley	Board Staff
Jennifer Wasciewicz	Board Staff

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of December, \$255,877 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 270
- Pharmacists licensed – 53 (35 by examination/score transfer and 18 by reciprocity)
- Out-of-State Pharmacies registered – 31
- In-State Pharmacies licensed – 8
- Pharmacists receiving immunization approval – 35
- Interns (foreign graduates) licensed – 5

The Executive Director corrected the amount report from the month of November to \$294,398.

Farleigh Dickenson University School of Pharmacy is obtaining ACPE accreditation and invited the Board members to attend.

V. OLD BUSINESS

1) Public Orders Filed

- a. Sanjay Patel, R.Ph. – Complaint – (12/17/15)
- b. Sanjay Patel, R.Ph. – Notice of Hearing and Notice to File Answer (12/18/15)
- c. Nicole Ardite, R.Ph. – Order Granting Unrestricted License (01/08/16)

2) Randall Higgins, R.Ph. – Request for unrestricted license

Edward McGinley moved, seconded by Stephen Lieberman to grant Mr. Higgins an unrestricted license to practice pharmacy, effective immediately, January 27, 2016. **Motion carried 6-0-1.** Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

3) Nuclear Diagnostic Products – Request for waiver of N.J.A.C. 13:39-11.21

Upon review of this request at the October 28, 2015 meeting, the Board requested a better explanation as to the concern and reason for the waiver request and clarification as to the process of labeling with examples of labels currently being used.

The pharmacy explained, “Since we are a nuclear pharmacy our label requirement is already listed under 13:39-12.2 General Requirements for Pharmacies Providing Radiopharmaceutical Service. Radiopharmaceuticals must have a date and time of calibration due to the nature of radioactive decay and since they are short lived they must also have a use by date with a time as well. Adding more information to this label as per 13:39-11.21 Information required to appear on the prescription label would only cause confusion to the end user, in particular the requirement of date and time of preparation since there would be another date and time on an already crowded label.”

The pharmacy provided four (4) labels as examples for the Board’s consideration. Two (2) labels are sent with the radiopharmaceutical to the end user, one (1) label is kept in house as a copy, and one (1) label is placed around the barrel of the syringe.

Thomas Bender moved, seconded by Mitch Sobel to deny the waiver request, suggesting that they provide an auxiliary or supplemental label to accompany the device. **Motion did not carry 2-5.**

Richard Palombo moved, seconded by Linda Witzal to grant the waiver request. **Motion did not carry 4-3.**

Edward McGinley moved, seconded by Stephen Lieberman to grant the waiver for label 4, the label around the barrel of the syringe, but the remaining three (3) labels need to maintain all required information. **Motion carried 5-2.** Thomas Bender and Mitch Sobel were opposed.

VI. NEW BUSINESS

- 1) **Bill A4919-** Opioid antidote reserve stock for first responders and hospital pharmacies

This bill requires county health departments to maintain reserve stock of opioid antidotes and dispense such reserve stock to first responders and hospital pharmacies, on interim basis, in order to ensure uninterrupted supply.

Edward McGinley moved, seconded by Richard Palombo to support the bill. **Motion carried 7-0.**

- 2) **Proposed Rule Review on Medication Therapy Management** – Mahesh Shah, R.Ph.

Board member Mahesh Shah, R.Ph. discussed medication therapy management (MTM) services and how they are increasingly being used to boost medication adherence and patient outcomes while reducing adverse events and unnecessary health care costs. However, Board of Pharmacy regulations do not directly address the provision of MTM services.

Mahesh Shah moved, seconded by Mitch Sobel to refer this discussion to the rules and regulations committee. **Motion carried 7-0.**

- 3) **Antoinette Wallace, R.Ph.** – Request for Reinstatement

Edward McGinley moved, seconded by Mahesh Shah to schedule Ms. Wallace for an appearance before a committee or the full Board, as required by her consent order. **Motion carried 7-0.**

- 4) **Roma Patel** – Foreign graduate, request for educational/FPGEC waiver

Ms. Patel provided the Board with a narrative of her educational history, transcripts, and certificates earned. Upon review, Ms. Patel earned a Bachelor of Pharmacy at the University of Pune in India and a Master of Science in Pharmaceutical Chemistry from the New Jersey Institute of Technology.

Edward McGinley moved, seconded by Stephen Lieberman to deny Ms. Patel's request as the degrees obtained do not meet the minimum requirement for licensure as a pharmacist, pursuant to N.J.A.C. 13:39-2.1. **Motion carried 7-0.**

5) Unlimited Home Health Center Inc., San Antonio, Tx – Out-Of-State Pharmacy Applicant, Sterile Compounding

Edward McGinley moved, seconded by Richard Palombo to approve the application, contingent upon the receipt of an attestation that the policy and procedures manual submitted is in fact that of Unlimited Home Health Center Inc., noting the references to other pharmacies within the manual, and proof of a Class A-S pharmacy license from Texas. If the pharmacy is unable to provide the requested documentation, the matter is to be reagendaized for Board review. **Motion carried 7-0.**

6) Linda Helmbrect, R.Ph. – Collaborative Practice Pre-Approval Application

Stephen Lieberman moved, seconded by Linda Witzal to approve this application. **Motion carried 7-0.**

7) Ethan Nhan, R.Ph. – Collaborative Practice Pre-Approval Application

Chair direct: Request proof that the program meets one of the three criteria as defined in N.J.A.C. 13:39-13.3.

8) Punita Khara, R.Ph. – Collaborative Practice Pre-Approval Application

Linda Witzal moved, seconded by Mahesh Shah to approve this application. **Motion carried 7-0.**

9) Rachel Louis Rivera, R.Ph. – Collaborative Practice Pre-Approval Application

Edward McGinley moved, seconded by Mahesh Shah to approve this application. **Motion carried 7-0.**

10) Lindsey Tesseyman, R.Ph. – Collaborative Practice Pre-Approval Application

Linda Witzal moved, seconded by Stephen Lieberman to approve this application. **Motion carried 7-0.**

11) Dheeraj Khurana – Request to accept intern hours earned out-of-state

Edward McGinley moved, seconded by Stephen Lieberman to accept the 2,052 intern hours earned in New York, towards the 1,440 hour New Jersey internship requirement. **Motion carried 7-0.**

12) Continuing education audit clarification

Stephen Lieberman moved, seconded by Linda Witzal to require pharmacists who are delinquent in continuing education credits to make up the credits and submit proof of

the amount and type of credit (live, law) to the Board within sixty (60) days of the receipt of the letter or the last date of the mailing, whichever is first. Delinquent credits earned, fulfilling the 2015 renewal requirement, will not count towards the current biennial renewal. **Motion carried 7-0.**

VII. MITIGATION/HEARING REQUEST

1) **Aimee O'Donnell, RPIC** – Shop Rite Pharmacy, Belmar, NJ

Aimee O'Donnell, RPIC, responded on behalf of Shop Rite Pharmacy and requested mitigation of N.J.A.C. 13:45H-5-8.

Edward McGinley moved, seconded by Stephen Lieberman to remove N.J.A.C. 13:45H-5-8. **Motion carried 7-0.**

2) **Harold Blumenkrantz, R.Ph.** – Homestead Pharmacy, Long Branch, NJ

Harold Blumenkrantz, R.Ph., responded on behalf of Homestead Pharmacy and requested mitigation of N.J.A.C. 13:39-4.15(b)1.

Edward McGinley moved, seconded by Stephen Lieberman to mitigate N.J.A.C. 13:39-4.15(b)1 to a warning. **Motion carried 7-0.**

3) **Joseph Santisi, RPIC** – Kmart Pharmacy Department #4478, Trenton, NJ

Joseph Santisi, RPIC, responded on behalf of Kmart Pharmacy Department #4478 and requested a formal administrative hearing.

Chair Direct: DAG Jodi Krugman is to contact Frank J. Shamy, Esq., attorney for the pharmacy, regarding the request for a hearing.

4) **Maged Eldabh, RPIC** – Meds N More, Marlton, NJ

Maged Eldabh, RPIC, responded on behalf of Meds N More and requested mitigation of N.J.A.C. 13:45H-5.8, N.J.A.C. 13:39-7.12(a)3, and N.J.A.C. 13:39-7.12(a)12.

Edward McGinley moved, seconded by Stephen Lieberman to deny the request as all actions taken were corrective. **Motion carried 7-0.**

5) **Khoren Nalbandian, RPIC** – Junction Drugs, Fort Lee, NJ

Khoren Nalbandian, RPIC, responded on behalf of Junction Drugs and requested mitigation of N.J.A.C. 13:39-5.8(a)1.

Edward McGinley moved, seconded by Mahesh Shah to deny the request. **Motion carried 7-0.**

6) **Morton Barnett, RPIC** – Bear Apothecary, Lambertville, NJ

Morton Barnett, RPIC, responded on behalf of Bear Apothecary and requested mitigation of N.J.A.C. 13:39-4.15(b)1.

Stephen Lieberman moved, seconded by Mahesh Shah to mitigate N.J.A.C. 13:39-4.15(b)1 to a warning. **Motion carried 7-0.**

7) **Mark Harris, RPIC** – Hackettstown Community Hospital Pharmacy, Hackettstown, NJ

Mark Harris, RPIC, responded on behalf of Hackettstown Community Hospital Pharmacy and requested mitigation of N.J.A.C. 13:39-11.8.

Edward McGinley moved, seconded by Linda Witzal to remove N.J.A.C. 13:39-11.8. **Motion carried 6-0-1.** Mitch Sobel was recused.

8) **Shereef S. Mabrouk, RPIC** – CVS Pharmacy, Flemington, NJ

Shereef S. Mabrouk, RPIC, responded on behalf of CVS Pharmacy and requested mitigation of N.J.A.C. 13:45H-5.5 and N.J.A.C. 13:45H-5.7.

Richard Palombo moved, seconded by Stephen Lieberman to remove N.J.A.C. 13:45H-5.5 and N.J.A.C. 13:45H-5.7. **Motion carried 7-0.**

9) **Yakruti Patel, R.Ph.** – CVS Pharmacy Department #6872, Randolph, NJ

Yakruti Patel, R.Ph., responded on behalf of CVS Pharmacy Department #6872 and requested mitigation of N.J.A.C. 13:39-7.18, N.J.A.C. 13:39-5.3, and N.J.A.C. 13:39-6.15.

Linda Witzal moved, seconded by Richard Palombo to remove N.J.A.C. 13:39-6.15 based upon proofs provided and send back the certification page to have the correct box checked for a mitigation request. **Motion carried 7-0.**

10) **Farid B. Sannidhi, RPIC** – Community Health Pharmacy, Newark, NJ

Angelo Cifaldi, responded on behalf of Community Health Pharmacy and requested mitigation of N.J.A.C. 13:45H-5.7.

Mitch Sobel moved, seconded by Thomas Bender to deny the request based on insufficient documentation. **Motion carried 6-0-1.** Mahesh Shah was recused due to his affiliation with Mr. Cifaldi.

11) **Kellie McCloskey, RPIC** – Walgreens Pharmacy Department #6902, Millville, NJ

Kellie McCloskey, RPIC, responded on behalf of Walgreens Pharmacy Department #6902 and requested mitigation of N.J.A.C. 13:39-4.3, N.J.A.C. 13:39-4.14, N.J.A.C. 13:45H-5.7, and N.J.A.C. 13:45H-5.5.

Edward McGinley moved, seconded by Richard Palombo to remove N.J.A.C. 13:45H-5.7 and N.J.A.C. 13:45H-5.5. **Motion carried 5-1-1.** Stephen Lieberman was opposed. Thomas Bender was recused due to his affiliation with Walgreens.

12) Duane Rodgers, RPIC – Walgreens Pharmacy Department #7311, Bergenfield, NJ

Duane Rodgers, RPIC, responded on behalf of Walgreens Pharmacy Department #7311 and requested mitigation of N.J.A.C. 13:45H-5.7 and N.J.A.C. 13:45H-5.5.

Edward McGinley moved, seconded by Richard Palombo to remove N.J.A.C. 13:45H-5.5 and N.J.A.C. 13:45H-5.7. **Motion carried 6-0-1.** Thomas Bender was recused due to his affiliation with Walgreens

13) Lorice Awad, RPIC – Walgreens Pharmacy, Paterson, NJ

Lorice Awad, RPIC, responded on behalf of Walgreens Pharmacy and requested mitigation N.J.A.C. 13:39-6.15(e)2.

Stephen Lieberman moved, seconded by Mahesh Shah to remove N.J.A.C. 13:39-6.15(e)2. **Motion carried 6-0-1.** Thomas Bender was recused due to his affiliation with Walgreens

VIII. INFORMATIONAL

N/A

IX. COMMITTEE REPORTS

Edward McGinley advised the Board that the rules and regulations committee met on January 21, 2016 and discussed the language for the temperature monitoring regulations, modified the collaborative practice pre-approval application, drafted re-examination language, discussed updating environmental testing to require notification to the Board within 48 hours following abnormal results, developed a policy on handling outsourcing facilities, and discussed the initiation of a tri-regulator meeting with the Board of Medical Examiners, Board of Nursing, and Board of pharmacy to facilitate ongoing dialog.

The Board members have been asked to review the Board of Pharmacy regulations by the end of February 2016. The process of sunset review will begin on March 24, 2016.

X. APPROVAL OF MINUTES

Stephen Lieberman moved, seconded by Mahesh Shah to approve the December 16, 2016 Public Session Minutes as amended. **Motion passed 7-0.**

XI. ADJOURNMENT

Mahesh Shah moved, seconded by Stephen Lieberman, to move into the Executive Session for review of 5 Complaints, 8 Old Business Items, 12 New Business Items, the Secretary's Report and Recommendation on Inspection Reports from, and the approval of the Executive Session Minutes. **Motion passed 7-0.**

At 11:28 a.m., Stephen Lieberman moved, seconded by Edward McGinley, to adjourn the Public Session. **Motion passed 7-0.**