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BOARD OF PHARMACY PUBLIC SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR June 24, 2015

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 June 24, 2015 at 9:03 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.	Excused Absence
Margherita Cardello, R.Ph.	
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	Excused Absence
Calliope Alexander	
Linda Witzal, R.Ph.	Excused Absence
Mitch Sobel, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director
Matthew Wetzel	CDS Executive Director
Megan Cordoma	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst
Jessica Kelley	Board Staff

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of May, \$13,275 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 309
- Pharmacists licensed – 21 (12 by examination/score transfer and 9 by reciprocity)
- Out-of-State Pharmacies registered – 8
- In-State Pharmacies licensed – 8
- Pharmacists receiving immunization approval – 42
- Interns (foreign graduates) licensed – 3

V. OLD BUSINESS

1) **Absolute Pharmacy** – Out-of-State Pharmacy Applicant, new inspection report

The Board previously reviewed this out-of-state application at the February 25, 2015 meeting and determined to request the NABP VPP report prior to further consideration of the application. The pharmacy has since withdrawn its 503b registration from the FDA on 5/26/15 as a business decision. The pharmacy submitted an April 1, 2015 state inspection report for Board review.

Edward McGinley moved, seconded by Mitch Sobel, to approve the out-of-state pharmacy application. **Motion passed 5-0.**

2) **Public Orders Filed**

- a. Tara M. Tomasello, Pharmacy Technician – FOD – Suspension of Registration (5/27/15)
- b. Shanne M. Fraguada, Pharmacy Technician – FOD – Suspension of Registration (5/27/15)
- c. Cara Paluchovic, Pharmacy Technician – FOD – Suspension of Registration (5/27/15)
- d. Ellen A. Finnegan, Pharmacy Technician – FOD – Suspension of Registration (5/27/15)
- e. Eric M. Gonzalez, Pharmacy Technician – POD – Administrative Action Seeking Suspension of Registration (5/27/15)
- f. Melanie Olson, R.Ph. – Consent Order – Suspension of License (5/27/15)
- g. Jeffrey Strougo, R.Ph. – Order Granting Unrestricted License (5/27/15)
- h. George Yost, R.Ph. – Order Granting Unrestricted License (5/27/15)

VI. NEW BUSINESS

1) Request for Approval of Student Shadow – Walgreens, Sicklerville, NJ

Ji Lee, RPIC at Walgreens in Sicklerville, NJ has requested approval from the Board for a one day, one time only, individual high school student shadow.

Margherita Cardello moved, seconded by Mitch Sobel, to approve the request with a letter of advice that the RPIC is responsible for the student. The student should not be left unattended and is there solely to observe. The RPIC is to be aware of HIPAA concerns and make sure they are compliant with the law. **Motion passed 5-0.** Thomas Bender was recused due to his affiliation with Walgreens.

2) Kiran Chaudhary – Foreign graduate, requesting educational credit towards a Bachelor of Science with a minimum five-year course of study

Ms. Chaudhary completed a four (4) year pharmacy program in India in 2013 and took ten (10) additional classes throughout the year following her graduation. She submitted her transcripts, curriculum vitae, and correspondence with NABP to the Board for review in consideration of her request.

Edward McGinley moved, seconded by Cali Alexander, to deny this request. Ms. Chaudhary needs to obtain the FPGE Certification and participate in an internship, pursuant to N.J.A.C. 13:39-2.1(b). **Motion passed 6-0.**

3) Immunization Certificate of Achievement – APhA 3 year expiration, regulations silent

Recent APhA certificates note that they are “*current for 3 years from the date of issue.*”

Edward McGinley moved, seconded by Mitch Sobel, that for the purposes of providing immunizations in New Jersey, the Board recognizes that taking the initial certification, coupled with BLS protocol and continuing CE requirements pursuant to N.J.A.C. 13:39-3(a)1 in each biennial renewal period is sufficient. **Motion passed 6-0.**

4) Barbara Pesciotta, R.Ph. – Request for Reinstatement

Ms. Pesciotta's is under a Consent Order filed January 25, 2006 for practicing pharmacy under a surrendered license and obtaining CDS through the use of stolen and forged prescription blanks. Her license is surrendered and deemed a revocation with prejudice to any reapplication.

The Board reviewed all documentation provided and Ms. Pesciotta's history in its

consideration.

Margherita Cardello moved, seconded by Mitch Sobel, to deny this request for reinstatement. **Motion passed 6-0.**

5) Cynthia Sullivan, R.Ph. – Request for Reinstatement

The Board received and reviewed Ms. Sullivan's request for reinstatement. The terms of her Consent Order require an appearance before the Board.

Chair Direct: Schedule Ms. Sullivan for an Investigative Inquiry.

6) Agevital Pharmacy, LLC, Sarasota, FL – Out-of-State Pharmacy Applicant

Tabled pending receipt of additional information to complete the application review.

7) Noble Health Services, Inc., Syracuse, NY – Out-of-State Pharmacy Applicant, Sterile Compounding

Thomas Bender moved, seconded by Mahesh Shah, to allow the pharmacy to withdraw the application until they have an NABP VPP inspection performed in a dynamic environment and provide an updated answer to question #15 of the sterile compounding questionnaire. **Motion passed 5-0.** Edward McGinley was recused as the parent company is part of Chain Drug Consortium, with which he had a previous affiliation.

8) Great Lake Distribution Center, LLC, d/b/a Diplomat Specialty Pharmacy, Flint, MI – Out-of-State Pharmacy Applicant, Sterile Compounding

Edward McGinley moved, seconded by Margherita Cardello, to approve the out-of-state application. **Motion passed 5-0.** Mitch Sobel was out of the room.

9) Sterile Compounding Pharmacy, LLC., Largo, FL – Out-of-State Pharmacy Applicant, Sterile Compounding

Chair Direct: The pharmacy is to provide updated licenses and clarify if they intend to be an outsourcing facility and if they going to ship into New Jersey under their outsourcing facility registration or their pharmacy license.

10) Northmark Pharmacy, Blue Ash, OH – Out-of-State Pharmacy Applicant, Sterile Compounding

Edward McGinley moved, seconded by Cali Alexander, to request an inspection

third report, within the last two years, from the Ohio State Board of Pharmacy or a party such as a VPP inspection by NABP. The pharmacy is to explain what they plan to ship to New Jersey and explain how they will get medication to New Jersey for same day administration. **Motion passed 5-0.** Mitch Sobel was out of the room.

11) Board Elections – President and Vice President

Tabled until next meeting for when all Board members are present.

VII. MITIGATION/HEARING REQUEST

1) Mitigation Request – Roy C. Putrino, RPIC- Basic Home Infusion Pharmacy, Wayne, NJ

Following an inspection revealing violations related sterility and stability of compounded products as well as beyond-use dates, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Roy C. Putrino, RPIC appeared before the Board to answer questions and provide explanation of how they test for the sterility and stability of compounded products in house.

Cali Alexander moved, seconded by Mitch Sobel, to remove the citation for violation of N.J.A.C. 13:39-11.24(a)5 and N.J.A.C. 13:39-11.19(c). The pharmacy is to obtain a technician for the HPLC machine, and seek a third party lab to substantiate sterility and stability findings within 60 days of this notice, for a period of 90 days, and must submit monthly report to the Board detailing the testing done during that period. **Motion passed 6-0.**

2) Mitigation Request – Anthony Lawrence, RPIC- Walgreens Pharmacy, Bernardsville, NJ, Manville, NJ

Following an inspection revealing a violation related to misbranded medications, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Anthony Lawrence, RPIC provided an explanation that the supervisor of the pharmacy said that four (4) of the five (5) vials cited contained the required information.

Margherita Cardello moved, seconded by Mahesh Shah, to deny the mitigation request. **Motion passed 5-0. Thomas Bender was recused due to his affiliation with Walgreens.**

3) Mitigation Request – Dina Eisa, RPIC, Walgreens Pharmacy, Franklin Park, NJ

Following an inspection revealing a violation related to a pharmacy technician registration, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Dina Eisa, RPIC provided an explanation that the February 7, 2014 inspection occurred within the first 6 months of Kyrollos Moawad's employment as a technician.

Margherita Cardello moved, seconded by Mahesh Shah, to remove the citation for violation of N.J.A.C. 13:39-6.16(b)(c)(d). **Motion passed 5-0. Thomas Bender was recused due to his affiliation with Walgreens.**

4) Mitigation Request – Lauri Susienka, R.Ph., Walgreens Pharmacy, Bridgewater, NJ

Following an inspection revealing a violation related to CDS inventory, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Lauri Susienka, R.Ph., provided an explanation on behalf of Walgreens, while unable to readily retrieve a copy of its 2013 biennial inventory for the inspector, the pharmacy has attached it for the Board's review.

Mahesh Shah moved, seconded by Margherita Cardello, to remove the citation for violation of N.J.A.C.13:45H-5.5(d). **Motion passed 5-0. Thomas Bender was recused due to his affiliation with Walgreens.**

5) Mitigation Request – Hetal Kansagra, RPIC, Walgreens Pharmacy, Deptford, NJ

Following an inspection revealing a violation related to over-filled medications in the active drug stock and policy & procedures manual for an ADS, a UPL was issued seeking a fine for this and a letter of corrective action.

Hetal Kansagra, RPIC provided an explanation that the overfilled medications have been removed from active drug stock and staff members have been retrained. Although the policy & procedures manual could not be produced at the time of the inspection, Ms. Kansagra has provided it to the Board and made it available to staff.

Margherita Cardello moved, seconded by Mahesh Shah, to remove the citation for violation of N.J.A.C.13:39-10.4(c) because the device in question is a counting device, not an automatic dispensing device. **Motion passed 5-0. Thomas Bender was recused due to his affiliation with Walgreens.**

6) **Mitigation Request – Brittany Wissel, RPIC, Walgreens Pharmacy, Toms River, NJ**

Following an inspection revealing a violation related to the DEA Certificate, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Brittany Wissel, RPIC provided an explanation that the DEA certificate display in the pharmacy has been corrected to display an active certificate.

Margherita Cardello moved, seconded by Mitch Sobel, to remove \$350 from the UPL. **Motion passed 5-0. Thomas Bender was recused due to his affiliation with Walgreens.**

VIII. INFORMATIONAL

1) **Independent Healthcare Monitors – Introduction**

The Board reviewed a letter received from Independent Healthcare Monitors describing themselves to be a monitoring company available to assist licensees in complying with compliance reporting to the Boards.

The Board accepted this as informational.

2) **NABP- MPJE Standard Setting Meeting Notice, August 19, 2015**

Board members are encouraged to participate in an upcoming standard setting meeting for the Multistate Pharmacy Jurisprudence Examination (MPJE).

3) **NABP – Committees and Task Force Volunteer Request**

NABP is seeking volunteers from its active member Boards of pharmacy to serve on the 2015-2016 committees and task forces.

4) **NC Dental Board/ Antitrust issue**

DAG Megan Cordoma advised the Board of a recent North Carolina court decision that the Dentistry Board does not have state anti-trust immunity. DAG Cordoma explained how the New Jersey State Boards were created and function differently from those in North Carolina as members are appointed by the Governor, rather than elected by pharmacists. New Jersey State Boards function under the supervisory umbrella of the Division of Consumer Affairs.

IX. COMMITTEE REPORTS

N/A

X. APPROVAL OF MINUTES

Margherita Cardello moved, seconded by Mahesh Shah to approve the May 27, 2015 Public Session Minutes as amended. **Motion passed 6-0.**

XI. ADJOURNMENT

Margherita Cardello moved, seconded by Mitch Sobel, to move into the Executive Session for review of 12 Complaints, 5 Old Business Items, 20 New Business Items, the Secretary's Report and Recommendation on Inspection Reports from, and the approval of the Executive Session Minutes. **Motion passed 6-0.**

At 11:25 p.m., Margherita Cardello moved, seconded by Mitch Sobel, to adjourn the Public Session. **Motion passed 6-0.**