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BOARD OF PHARMACY OPEN SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7TH FLOOR December 10, 2014

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 December 10, 2014 at 9:01 a.m. All members were duly notified of the time, place and all pertinent materials were provided to 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, PL 1975/C.10:4-8.

III. ROLL CALL

Thomas F.X. Bender, R.Ph.	President
Richard Palombo, R.Ph.	
Margherita Cardello, R.Ph.	Late arrival 9:19 a.m.
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Calliope Alexander	Late arrival 9:12 a.m.
Carol Jacobson, Esq.	Late arrival 9:17 a.m.
Linda Witzal, R.Ph.	
Mitch Sobel, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director
Matthew Wetzel	Board Staff
Megan Cordoma	Deputy Attorney General

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of November, \$18,825 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month of October:

- Technicians registered - 266
- Pharmacists licensed - 52 (39 by examination and 13 by reciprocity)
- Out-of-State Pharmacies registered –35
- In-State Pharmacies licensed – 5
- Pharmacists receiving immunization approval – 44
- Interns (foreign graduates) licensed – 9

V. OLD BUSINESS

1) Public Orders Filed

- a) Vladimir Kleyman ,R. Ph. - Order to Show Cause 10/20/14
Prescription R Us Pharmacy
- b) Vladimir Kleyman, R.Ph. - Administrative Complaint 10/20/14
Prescriptions R Us Pharmacy
- c) Ellen Finnegan, Ph arm Tech - POD 10/21/14
- d) Shanne Fraguada, Pharm Tech - POD 10/21/14
- e) Tara Tomaselo, Pharm Tech - POD 10/22/14
- f) Vladimir Kleyman, R. Ph. - Interim Consent Order 10/29/14
Prescription R Us Pharmacy
- g) Eric Gonzalez, Pharm Tech - POD 10/30/14
- h) Rieters Pharmacy - Consent Order 10/31/14
- i) Mark Forgang, R.Ph. - Revocation 10/31/14
- j) Jalika Dorsey Huggins, Pharm Tech - FOD 11/12/14
- k) John Hussey, Pharm Tech - FOD 11/12/14
- l) Stephen Matthews, Pharm Tech - FOD 11/13/14
- m) Candice Gianettino, Pharm Tech - FOD 11/12/14
- n) Brianne Canto, Ph arm Tech - FOD 11/12/14
- o) Candyce Craig, Pharm Tech - FOD 11/12/14
- p) Jordan Gonzalez, R. Ph. - Revocation 11/12/14
- q) Kevin Tusso, R. Ph. - FOD 11/14/14

VI. NEW BUSINESS

1) Assembly Bill #3561 - Requires Professional Boards to Provide for Online Processing of Application for licensure or renewal

This bill stipulates that each professional or occupational board designated in section 2 of P.L.1978, c.73 (C.45:1-1S) shall provide on its Internet website a secure process to allow applicants to complete online any application documents including any fee

payments, required to obtain an initial license, certificate of registration, or certification, or renewal of an existing license, certificate of registration, or certification, as the case may be, and to submit electronically all necessary documentation for review and approval of the board.

Richard Palombo moved, seconded by Mahesh Shah, to support this Bill. **Motion passed 7-0.**

2) Cara Paluchovic – Pharmacy Technician – POD to be finalized

This item was tabled to await confirmation of delivery.

3) Pravin K. Patel, R. Ph. - Request for Reinstatement

On May 12, 2010, Mr. Patel entered into a consent for improperly dispensing controlled substances on numerous occasions between January 2006 and December 2008 at Family Pharmacy, located in Lindenwold, New Jersey during a period in which he was the sole owner and permit holder for Family Pharmacy. His pharmacist license was revoked for a period of 5 years. He has met the terms of his consent order, and is seeking reinstatement of his pharmacist license.

Edward McGinley moved, seconded by Stephen Lieberman, to schedule Mr. Patel for an Investigative Inquiry, as per his consent order. Everything he submitted appears to be in order. **Motion passed 7-0.**

4) Lina Ludwikowski Zangari – RPh – Request for restrictions to be removed

On September 21, 2012, Ms. Ludwikowski Zangari entered into a consent order for obtaining CDS medications by fraud, and for dispensing non-CDS prescription items without a legitimate prescription. Her license to practice pharmacy in New Jersey was suspended for 2 years, with the first three months serving as an active suspension, and the remainder as probation. Ms. Ludwikowski Zangari requested that the Board remove the remaining restrictions on her license at this point in time. She completed the ProBE course, but only passed it conditionally. The terms of her consent order require that she pass it ‘unconditionally and without reservation’.

Richard Palombo moved, seconded by Edward McGinley, to authorize the Board office to remove the restrictions after she provides documentation indicating that she has completed the course unconditionally, as outlined in her consent order. Ms. Ludwikowski Zangari may complete either the ProBE or Prime course to satisfy this requirement. **Motion passed 10-0.**

5) Pine Pharmaceutical LLC, Tonawanda, NY - Out- of- State pharmacy performing sterile compounding

Chair Direct: The Board office is to ask this applicant if they are receiving any patient specific orders at this time. If they are, they would need to register with New Jersey as a non-resident pharmacy. If they are not, they are not required to register with the New Jersey Board of Pharmacy. This item is to be re-agendized after a response is received.

6) Lakehurst Rx pharmacy – Waiver request for counter space.

As a result of an inspection of the pharmacy, a deficiency was noted for not having sufficient continuous counter space in the pharmacy. The owner asked for a waiver, as they have installed a center island which provided a large amount of workable counter space around the surface which was much wider than is required by the regulations.

Stephen Lieberman moved, seconded by Edward McGinley, that the counter meets the requirements and intent of the regulations, so the waiver request is granted. **Motion passed 10-0.**

7) Assembly Bill A622 - Concerns the sale of dextromethorphan to minors and supplementing Title 2A of the New Jersey Statutes.

Stephen Lieberman moved, seconded by Mitch Sobel, to oppose this Bill for the following reasons: it inhibits access to medications effective for common colds (without a prescription) to patients, drives up the cost of health care, there are concerns about how the retail community will monitor the sale of these medications (California has a model that provides for the scanning of identification at time of purchase). Also, there was no education component outlined in the Bill, and no limit or restriction on purchases. **Motion passed 10-0.**

8) S2370 / A709 - Requires pharmacies and prescribers to notify patients about how to ensure proper and safe disposal of unused prescription drugs.

This Bill has already passed Senate and Assembly health committees, and will require pharmacists and prescribers to notify patients how to ensure safe disposal of unused prescription medications. The ‘notice’ is to be prepared by the Division of Consumer Affairs, and is to be disseminated by the prescriber when dispensing medication to patients in the office. Pharmacies will also be required to disseminate this notice.

Carol Jacobson moved, seconded by Margherita Cardello, to oppose the Bill only insofar as the pharmacist and prescribers already have a professional obligation to educate consumers on how to safely dispose of CDS, and requiring a written notice to be disseminated with all CDS dispensed by pharmacies and physicians is an unnecessary economic burden, and is an ineffective step, to accomplish the goal of educating the public on this important public health issue. **Motion passed 10-0.**

VII. MITIGATION REQUEST

1. Lawrence Summers, RPIC - Rite Aid Pharmacy, Logan, NJ

Following an inspection revealing violations related to information from the pharmacist on duty indicating that the pharmacy department has dedicated telephone lines within their phone tree system, but extensions of the pharmacy dedicated line can be picked up outside of the department by non-pharmacy department personnel, a UPL was issued seeking a fine for this, and a letter of corrective action.

Deborah Hurley, administrator of government affairs for Rite Aid, provided an explanation for the violation and requested that the Board mitigate the fines.

Edward McGinley moved, seconded by Mahesh Shah, to table mitigation requests #1, #2 & #5 (as they all have similar violations). The Board office is to request that Rite Aid investigate the phone system in these locations to determine if a call, waiting for the pharmacy, can be picked up using a phone located outside of the pharmacy. Rite Aid is to talk directly with the people who indicate that this is indeed happening. **Motion passed 9-0.** Margherita Cardello was recused due to her affiliation with Rite Aid.

2. Lisa Eckert, RPIC - Rite Aid Pharmacy, North Cape, NJ

Same response as for Mitigation Request #1 above (for violation of N.J.A.C. 13:39-13:4.15(c)3.)

3. Dinesh Chaudhari, RPIC - Express Pharmacy, Ewing, NJ

Following an inspection revealing a violation related to insufficient reference texts, the RPIC not working 35 hours a week as required by the regulations, and a worker performing pharmacy technician duties without properly submitting an application to do so in a timely manner, a UPL was issued seeking a fine for these, and other violations, and a letter of corrective action.

Dinesh Chaudhari, RPIC of the pharmacy, provided an explanation for the violations and requested that the Board mitigate the fines.

Stephen Lieberman moved, seconded by Richard Palombo, to mitigate the fines and remove citations for violations of N.J.A.C.13:39-5.8(a)1 (*online version of facts and comparisons*), N.J.A.C.13:39-6.2(f) (*RPIC not working minimum of 35 hours weekly*), but to deny the mitigation request for violation of N.J.A.C.13:39-6.6(b)&(c) (*pharmacy technician not following proper process for registration*). **Motion passed 10-0.**

4. Lauren Farco, RPIC - Walgreens Pharmacy, Short Hills, NJ

Following an inspection revealing a violation related to lack of display of the store hours and name of the current RPIC, a UPL was issued seeking a fine for these violations, and a letter of corrective action.

Bincy Alexander, manager of the pharmacy, provided an explanation for the violations and requested that the Board mitigate the fine.

Richard Palombo moved, seconded by Edward McGinley, to remove the citation and fine of \$1,000 related to the violation of N.J.A.C.13:39-5.3(b)&(c). The Board office will issue an updated permit without charge. **Motion passed 9-0.** Thomas Bender was recused due to his affiliation with Walgreens.

5. Robert Bodine, RPIC - Rite Aid Pharmacy, Bayville, NJ

Same response as for Mitigation Request #1 above (for violation of N.J.A.C. 13:39-13:4.15(c)(3)).

6. Brian Pinto, RPIC - Tiffany Natural Pharmacy, Westfield, NJ

Following an inspection revealing numerous violations relating to outdated medications, return to stock medication issues, CDS biennial inventory not being properly met, and other violations, a UPL was issued seeking a fine for these, and a letter of corrective action.

Brian Pinto, RPIC for the pharmacy, provided explanations for the violations and requested that the Board mitigate the fines.

Margherita Cardello moved, seconded by Richard Palombo, to deny all mitigations, with the exception of the mitigation request for violation of N.J.A.C.13:39-6.7(b)&(c) (*Pharmacy technician did not have registration on display, nor her wallet-sized registration.*). **Motion passed 10-0.**

VIII. INFORMATIONAL

1) NABP Inspection BluePrint Meeting: Enforcement Bureau Inspector Qi and Director Rubinaccio will be attending a meeting at NABP headquarters in Illinois in mid-January. The purpose of the meeting is to develop a common template which all states can utilize to capture information on inspection reports of interest to all member states. This will help states to make better decisions regarding the registration of non-resident pharmacies.

2) NABP PARE exam review: Linda Witzal attended a meeting at NABP headquarters with academia and other state's Board members. The purpose was to identify standards for rating pharmacists who are re-entering the practice of pharmacy. The PARE examination questions consist of the following ratios: 50% is on medication safety, 25%

on ethics, and 25 % is clinical in nature. In order to pass the PARE examination, one must achieve an overall score of at least 80 as well as a minimum score of 75 in each of the three content areas. Currently, many people taking the examination are not achieving a passing grade. It was also noted that not a lot of states are utilizing PARE at this time, and that the test is psychometrically sound. The group performed evaluations to determine if the examination contains appropriate questions. The results of workshop will be reported out later by NABP.

3) NABP Board Member forum: Calliope Alexander attended this meeting at NABP headquarters. She was able to participate in panel discussions, state Board presentations, reviewed FDA regulations and discuss issues with other state's Board members. Ms. Alexander found the meeting to be very stimulating and informative.

IX. COMMITTEE REPORTS

N/A

X. APPROVAL OF MINUTES

Margherita Cardello moved, seconded by Edward McGinley, to approve the November 12, 2014 Open Session minutes as amended. **Motion passed 10-0.**

XI. ADJOURNMENT

At 11:09 a.m. Stephen Lieberman moved, seconded by Margherita Cardello, to adjourn the Public Session and move into the Executive Session for review of 5 Old Business Items, 23 New Business Items, the Secretary's Report and Recommendation on Retail and Institutional Permits, the Secretary's Report and Recommendation on Inspection Reports, and the approval of the November 12, 2014 Executive Session Minutes. **Motion passed 10-0.**