



CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102



JOHN J. HOFFMAN
Acting Attorney General

STEVE C. LEE
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

BOARD OF PHARMACY OPEN SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7TH FLOOR November 12, 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 November 12, 2014 at 9:04 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 9:30 a.m.
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Calliope Alexander	Late arrival 9:09 a.m.
Carol Jacobson, Esq.	
Linda Witzal, R.Ph.	Excused Absence
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 October, \$15,050 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month of October:

- Technicians registered - 299
- Pharmacists licensed - 95 (83 by examination and 12 by reciprocity)
- Out-of-State Pharmacies registered –43
- In-State Pharmacies licensed – 7
- Pharmacists receiving immunization approval – 94
- Interns (foreign graduates) licensed – 6

Director Rubinaccio announced that Board President Bender will be honored as “Pharmacist of the Year” by the New Jersey Retail Merchants Association at a dinner on December 4, 2014 at the Trenton Masonic Temple in Trenton, New Jersey. The Board wished President Bender congratulations on this accomplishment.

V. OLD BUSINESS

1) Public Orders Filed

- a) Noha Amar, Pharmacy Technician - POD 10/21/14
- b) Harold Ross, Pharmacy Technician - POD 10/21/14

VI. NEW BUSINESS

1) AnazaoHealth Corporation, Las Vegas, NV - Out -of- State Pharmacy Performing Sterile Compounding

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

2) Care Solutions, Inc., Nashville, TN - Out -of- State Pharmacy Performing Sterile Compounding

Edward McGinley moved, seconded by Thomas Bender, to hold the application pending information that this pharmacy has met the Tennessee obligation for becoming compliant with USP <797>, and that the license is free and clear of all restrictions. The NJ Board is also to request a copy of the ‘modifier’ as well, to demonstrate authorization to perform sterile compounding. **Motion passed 9-0.**

3) Carol Hunt, Pharmacy Technician - POD to be Finalized

On February 5, 2013, Ms. Hunt was arrested for the theft of CDS from CVS Pharmacy in Moorestown, New Jersey. She pleaded guilty and received 2 years probation. Service of the POD was effectuated, but no response was received.

Stephen Lieberman moved, seconded by Carol Jacobson, to finalize the POD as written. **Motion passed 8-0.**

4) Stephen Matthews, Pharmacy Technician - POD to be Finalized

On August 27, 2013, Mr. Matthews was arrested for the theft of CDS from CVS Pharmacy in Little Silver, New Jersey. Service of the POD was effectuated, but no response was received.

Mahesh Shah moved, seconded by Mitch Sobel, to finalize the POD as written. **Motion passed 8-0.**

5) Sanjay Patel, R.Ph. - Request for Reinstatement through PAPNJ

At 11:00 a.m., Edward McGinley moved, seconded by Stephen Lieberman to move to Executive Session for advice of counsel. **Motion passed 9-0.**

At 11:36 a.m. Stephen Lieberman moved, seconded by Mahesh Shah, to go back to Open Session. **Motion passed 9-0.**

Edward McGinley moved, seconded by Mitch Sobel, to deny the request for reinstatement from PAP on behalf of Mr. Patel. Mr. Patel's New York license is not unrestricted. His 2008 New Jersey consent order requires that his New York license be unrestricted before he can apply for reinstatement in New Jersey, so this request is denied. **Motion passed 9-0.**

6) Board of Pharmacy 2015 Meeting Dates

All meetings will be held in the Monmouth Conference Room, 7th floor, 124 Halsey Street, Newark, NJ 07102, with the exception of the November meeting, which will be held in the Essex Conference Room, 7th floor at the same address. The meetings will begin at 9:00 a.m.

- January 28
- February 25
- March 25
- April 22
- May 27
- June 24
- July 22

- August 26
- ~~September 23~~ **September 30**
- October 28
- ~~November 11~~ **November 18**
- December 9

Richard Palombo moved, seconded by Mitch Sobel, to accept the meeting dates above as amended. **Motion passed 9-0.**

7) Virtua Voorhees Health – Inspection results of IV Robots

Pharmacy inspector Tony Qi provided overview: 3rd phase of remodeling-introducing 2 robotic stations in clean room. Can only compound non-hazardous in ISO 5 environment positive pressure (cleaning like cleaning a hood). 35-50 non-patient specific doses per hour. Efficiency and patient safety. Internal Sterility: Bacterial and Fungal 500 tests completed, 200 underway. No contamination noted to date. Products will be ramped up to include 20 products, with Oxytocin being produced initially. Pharmacist's verification is performed at the beginning of the process: required items are laid out, scanned, then the pharmacy technician stages the items, the pharmacist checks them, then original stager loads the robot. Each dose is labeled by the IV Robot machine. The pharmacist scans the final product & signs off. Recommendations are to have the policies and procedures include date and time in & out. The P&P should also elaborate on how to handle a contamination; - activity ceases, then what happens as a root cause and follow up to get it functional again. Include user training after an incident- what is process to re-educate users, etc.

This IV robot is installed in 27 sites in the United States, with a total of 60-70 units in total. The closest two sites are Brigham and Women's Hospital in Boston, Duke University Hospital in North Carolina. These are first generation IV robots.

Anticipated live date is in the December 1st or January 1st timeframe. They will perform daily sterility testing, and Greg Bauer (Director of Pharmacy Services of Virtua Voorhees) will notify the Board if this will change. Inspectors Qi and Geisler suggested that the following items be addressed; label issues, incorporate didactic component into training, incorporate robot into media fill testing for users, touch screen is outside the ISO 5 area, hands should be sprayed with IPA 70% sterile alcohol after touching touch screen. Virtua is to notify the Board within 48 hours of any confirmed contamination, and the Policy and Procedures should also be updated to include addressing the shipping between sites (as part of central fill agreement). Mr. Bauer explained that the IV robot has an ultraviolet (UV) sanitizing system, which takes 8 hours to run to complete the cycle properly. He indicated that he may like to utilize this UV method for a shorter period of time. Mr. Bauer must supply documentation to the Board from the manufacturer of the IV robot indicating that running the UV cycle for a shorter period of time under specific conditions has the equivalent effect as utilizing the 8 hour cycle. The Board will review

this information prior to giving approval for the shorter cycle to be utilized.

Edward McGinley moved, seconded by Mitch Sobel, to approve the implementation of this system at this site, pending review of the updated Policies and Procedures manual by inspectors Qi and Geisler. The inspectors will advise Director Rubinaccio with their findings after their review has been completed, and Director Rubinaccio will inform Board President Bender of their determination. **Motion passed 9-0.**

8) Certified Medication Aides: Mitch Sobel led a discussion of this topic.

In accordance with N.J.A.C. 13:37-6.2, only a registered professional nurse may delegate the medication administration task. Licensed practical nurses are not authorized to delegate this task to Certified Medication Aides (CMAs). Delegation of the medication administration task to a CMA may occur in Assisted Living Residences and Comprehensive Personal Care Homes, or only as part of an Assisted Living Program. These facilities are licensed by the New Jersey Department of Health (NJDOH).

Facility Trainers/Instructors are responsible for selecting qualified Certified Nurse Aides (CNAs), Certified Homemaker/Home Health Aides (CHHHAs), and/or Certified Personal Care Assistants (PCAs) for the responsibility of administering medications, under the circumstances when a registered professional nurse delegates this task.

The Board took this item as informational.

VII. MITIGATION REQUEST

1. Rukaiya Rizvi, RPIC - Medical Home Pharmacy, Trenton, NJ

Following an inspection revealing violations related to counter space outside of the prescription department being utilized for prescription filling activities, a UPL was issued seeking a fine for this, and other violations, and a letter of corrective action.

Omer Ugur, owner of the pharmacy, provided an explanation for the violations and requested that the Board mitigate the fines.

Edward McGinley moved, seconded by Carol Jacobson, to deny the request to mitigate the citation for violation of N.J.A.C 13:39-4.15(c)(1). **Motion passed 8-1.** Thomas Bender was opposed.

2. Peter Pogany, RPIC - Rapp's Pharmacy, Plainfield, NJ

Following an inspection revealing a violation related to the CDS biennial inventory missing schedule III-IV medications, and an issue with hot water not being available in the pharmacy, a UPL was issued seeking a fine for this, and other violations, and a letter of corrective action.

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

Edward McGinley moved, seconded by Richard Palombo, to deny the mitigation request as not enough evidence was provided to support the request. The CDS inventory was missing drugs in schedules III-V. **Motion passed 8-0.** Stephen Lieberman was recused as he went to school with the licensee.

3. Ehmee Galchalian, RPIC - Walgreens Pharmacy, West Caldwell, NJ

Following an inspection revealing a violation related to misbranded medication being found in active drug stock, a UPL was issued seeking a fine for this, and other violations, and a letter of corrective action.

Douglas Watson, RPIC of the pharmacy, provided an explanation for the violation and requested that the Board mitigate the fines.

Margherita Cardello moved, seconded by Stephen Lieberman, to remove the citation and fine of \$1,000 related to the misbranded portion of UPL. The Board also requested that the labeling for return to stock items be clarified in the quarterly State newsletter. **Motion passed 8-0.** Thomas Bender was recused due to his affiliation with Walgreens.

4. Malwina Sarnas, RPIC - Walgreens Pharmacy, Belleville, NJ

Following an inspection revealing a violation related to misbranded medication being found in active drug stock, a UPL was issued seeking a fine for this, and a letter of corrective action.

Malwina Sarnas, RPIC of the pharmacy, provided an explanation for the violation and requested that the Board mitigate the fine.

Margherita Cardello moved, seconded by Stephen Lieberman, to remove the citation and fine of \$1,000 related to the misbranded portion of UPL. The Board also requested that the labeling for return to stock items be clarified in the quarterly State newsletter. **Motion passed 8-0.** Thomas Bender was recused due to his affiliation with Walgreens.

5. Sandhya Nuthalapati, RPIC - Rite Aid Pharmacy, Northfield, NJ

Following an inspection revealing a violation related to the DEA certificate on display at the pharmacy being expired, a UPL was issued seeking a fine for this, and a letter of corrective action.

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

Thomas Bender moved, seconded by Stephen Lieberman, to reduce the fine to a warning, and for the Board office to advise the licensee to always have the original on file. The Board office is to create a quarterly State newsletter item to clarify this topic; explaining

that all original and renewal license and permit documents must be available on site. **Motion passed 8-0.** Margherita Cardello was recused due to her affiliation with Rite Aid.

6. Shivam Parikh, RPIC - Rite Aid Pharmacy, Wildwood, NJ

Following an inspection revealing a violation related to no system in place to notify the patient of the offer to counsel when the patient or caregiver is not physically present, a UPL was issued seeking a fine for this, and a letter of corrective action.

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

Edward McGinley moved, seconded by Stephen Lieberman, to mitigate the fine to a warning. Only one component, the hours, was missing from the documentation provided by Rite Aid. **Motion passed 8-0.** Margherita Cardello was recused due to her affiliation with Rite Aid.

VIII. INFORMATIONAL

Lori Clark and Elise Barry of NJPhA informed the Board that the Senate Bill S2378, (which would amend the "Overdose Prevention Act." P.L2013.c.46. in order to extend the act's immunity provisions to certain professionals and professional entities that administer or dispense opioid antidotes), has passed committee. They expressed concern that the Bill which the Board reviewed at a previous meeting, was not the most current. They offered to pass along any of the Board's feedback regarding this Bill. President Bender reiterated that the Board's comments included the following:

"The Board support S2378 and if it is not already defined, the Board recommends the extension of the immunity provisions to cover pharmacists, who in an emergency overdose situation, have the expertise and training to play an active role to help a person in distress. No additional training or education would be needed for a pharmacist."

IX. COMMITTEE REPORTS

N/A

X. APPROVAL OF MINUTES

Richard Palombo moved, seconded by Margherita Cardello, to approve the October 29, 2014, Open Session Minutes as amended. **Motion passed 9-0.**

XI. ADJOURNMENT

At 11:00 a.m. Margherita Cardello moved, seconded by Edward McGinley, to adjourn the Public Session and move into the Executive Session for review of 2 Complaints, 3 Old Business Items, 39 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 October 29, 2014 Executive Session Minutes. **Motion passed 9-0.**