



**CHRIS CHRISTIE**  
Governor

**KIM GUADAGNO**  
Lt. Governor

# New Jersey Office of the Attorney General

Division of Consumer Affairs  
Board of Pharmacy  
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## **BOARD OF PHARMACY PUBLIC SESSION MINUTES SOMERSET CONFERENCE ROOM, 6th FLOOR April 22, 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, Somerset Conference Room, 6<sup>th</sup> floor, on April 22, 2015 at 9:00 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.	
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Calliope Alexander	
Carol Jacobson, Esq.	
Linda Witzal, R.Ph.	
Mitch Sobel, R.Ph.	

### **OTHERS IN ATTENDANCE**

Anthony Rubinaccio, R.Ph.	Executive Director, Board of Pharmacy
Matthew Wetzel	Executive Director, Drug Control Unit
Megan Cordoma	Deputy Attorney General
Jessica Kelley	Board Staff

#### IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of March, \$25,875 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month of March:

- Pharmacy Technicians registered – 277
- Pharmacists licensed – 34 (26 by examination/score transfer and 8 by reciprocity)
- Out-of-State Pharmacies registered – 3
- In-State Pharmacies licensed – 7
- Pharmacists receiving immunization approval – 36
- Interns (foreign graduates) licensed - 5

The Executive Director of the Board of Pharmacy advised the Board that Michael Westenberger, Supervising Investigator in the Enforcement Bureau, will be retiring May 1, 2015 after many years of service to the citizens in New Jersey. Mr. Westenberger has served the Board of Pharmacy for the past 5 years. He has been instrumental in assisting this Board directly, on a near daily basis, to ensure the safety of the public by orchestrating inspections for the 2200+ pharmacies in NJ. He was instrumental in coordinating efforts with NABP surveyors, to inspect every one of our 180 sterile compounding pharmacies after the NECC tragedy in Massachusetts. He was always available to assist with any emergent situation that arose at the Board, whether it was a sterile compounding issue, investigating a consumer complaint, or providing assistance during Hurricane Sandy. In working with him, the Board office has come to respect him as a man of integrity. He produced an unparalleled quality work product and the Board could count on support for assistance without question. The Board could not have achieved many of our accomplishments over the last few years without his diligent work ethic. Mr. Rubinaacio stated, “I know I speak for the Board when I say that we will miss Micky, and wish him all the best in his future endeavors.”

#### V. OLD BUSINESS

##### 1) **Jeffrey Strougo, R.Ph.** – Request for modification of consent order

The Board received and reviewed Mr. Strougo’s request for an unrestricted license. By Consent Order dated May 6, 2014, Mr. Strougo’s license was reinstated with restriction following a period of suspension based on his diversion of CDS for personal use. Pursuant to the Order, the period of probation ended automatically on February 13, 2015. Mr. Strougo is in full compliance with the requirements of his Consent Order and has been released by PAP after a three year rule out period.

Edward McGinley moved, seconded by Stephen Lieberman, that the Consent Order, by its own terms, grants Mr. Strougo an unrestricted license as of February 13, 2015. **Motion passed 8-1. Thomas Bender was opposed. Margherita Cardello is recused as Mr. Strougo previously worked for her.**

2) **DocLane's Veterinary Pharmacy, Lexington, KY- Out-of-State Pharmacy Applicant – Sterile Compounding**

On July 23, 2014, the Board reviewed DocLane's Veterinary Pharmacy application and moved to request an updated inspection report from Kentucky or allow DocLane's Veterinary Pharmacy to withdrawal their application. The pharmacy submitted an updated inspection report dated February 12, 2015.

Edward McGinley moved, seconded by Margherita Cardello, to approve the out-of-state pharmacy application. **Motion passed 10-0.**

**VI. NEW BUSINESS**

1) **Bill A4271, FYI**

*This bill requires health insurers (health, hospital and medical service corporations; commercial individual and group health insurers; health maintenance organizations; health benefits plans issued pursuant to the New Jersey Individual Health Coverage and Small Employer Health Benefits Programs; the State Health Benefits Program; and the School Employees' Health Benefits Program) to provide health benefits coverage for prescribed abuse-deterrent opioid analgesic drugs, subject to the following requirements:*

- (1) If the health insurer provides prescription drug benefits through use of a formulary, abuse-deterrent opioid analgesic drugs shall be on the most preferred tier of the formulary;*
- (2) Cost-sharing for abuse-deterrent opioid analgesic drugs shall not exceed the lowest cost-sharing level applied to other prescription drugs; and*
- (3) Any prior authorization requirements or other utilization review measures for opioid analgesic drugs shall not require first use of non-abuse-deterrent opioid analgesic drugs in order to access opioid analgesic drugs with abuse-deterrent properties.*

*Opioid analgesic drugs are drugs prescribed to treat moderate to severe pain or other conditions. Abuse-deterrent opioid analgesic drugs are drugs approved by the U.S. Food and Drug Administration with abuse-deterrence labeling claims that indicate the drug is expected to result in a meaningful reduction in abuse.*

The Board accepted the Bill as informational.

2) **Bill S2779, FYI**

*This bill requires each licensed residential or outpatient substance abuse treatment facility in the State to provide the county health department of the county in which the facility is located with certain information about the availability of services at the facility, on an estimated average basis.*

*Under the provisions of the bill, the county health department is to display and maintain the information on its Internet website, and share the information with the Department of Human Services (DHS), which would also display and maintain the information on its website arranged by county.*

*The displayed information would provide: the total capacity of a licensed residential or outpatient substance abuse treatment facility to provide inpatient or outpatient services; the number of expected openings available, on an estimated daily basis, for a person seeking services from the facility on an inpatient or outpatient basis; and the average waiting time for an opening for a person to receive services from the facility on an inpatient or outpatient basis.*

*Each facility is required to update the information provided at least annually, and may update information more frequently at its discretion.*

*The displayed information would include the address and telephone number for each facility, as well as the availability of services, by county, from a licensed residential or outpatient substance abuse treatment facility, in order to provide access to information that would facilitate referrals of persons to services and transfers from facilities when necessary.*

The Board accepted the Bill as informational.

**3) Ravi Lattupally, Pharmacist Applicant – Request to take NAPLEX 8<sup>th</sup> time**

The Board received and reviewed Mr. Lattupally's request to take the NAPLEX an 8<sup>th</sup> time. Upon review of all documentation provided, Mr. Lattupally was granted a waiver to take the exam a 6<sup>th</sup> time in 2013. He did not indicate that he has taken the review courses suggested by the Board and provided no other explanation for his scores other than a lack of knowledge and study.

Edward McGinley moved, seconded by Stephen Lieberman, to deny the request to take the NAPLEX an 8<sup>th</sup> time. **Motion passed 10-0.**

**4) Baseem Agaybi, Pharmacist Applicant – Request to take NAPLEX 9<sup>th</sup> time**

The Board received and reviewed Mr. Agaybi's request to take the NAPLEX a 9<sup>th</sup> time. Mr. Agaybi took the NAPLEX 8 times between 2008 and 2013, achieving scores between 18 and 65. Mr. Agaybi has registered to take a three day NAPLEX review course.

Stephen Lieberman moved, seconded by Mitch Sobel, to deny the request to take the NAPLEX a 9<sup>th</sup> time as it has been 26 months since the last attempt and the remedial step should have been taken years ago. **Motion passed 9-0. Mahesh Shah is recused due to a previous association with Mr. Agaybi's attorney, Angelo Cifaldi.**

- 5) **Jersey Shore Pharmacy, Tinton Falls, NJ and Galloway, NJ** – Request for waiver of N.J.A.C. 13:39-6.3 and N.J.A.C. 13:39-7.12(a)12

The Board received and reviewed Jersey Shore Pharmacy's waiver requests for the option to not wear name badges as they are a closed door pharmacy, and to use "see package date" in lieu of "use by" on labels.

Mitch Sobel moved, seconded by Richard Palombo, to deny both waiver requests. **Motion passed 10-0.**

- 6) **Barnabas Health, Monmouth Medical Center** – Request for waiver of N.J.A.C. 13:39-7.18

The Board received and reviewed the waiver request, allowing the medical center to provide samples of Abilify Maintena, a long acting injection for schizophrenia, to inpatients prior to discharge in an effort to continue the patient's therapy, which may be hindered by impaired cognitive function or economic hardship.

Edward McGinley moved, seconded by Margherita Cardello to approve the waiver with the caveats that the waiver applies only to the Abilify Maintena sample product, the product will remain segregated, policy and procedure and a copy of the Board's approval letter must be readily available to inspectors at the time of the inspection, and the waiver will be terminated once they stop receiving the product for free. Barnabas Health, Monmouth Medical Center is to report to the Board any issues they encounter and any changes to the representation in their waiver request letter. **Motion passed 10-0.**

- 7) **George Yost, R.PH** – Request for modification of consent order

The Board received and reviewed Mr. Yost's request for an unrestricted license. By Consent Order dated November 4, 2009, Mr. Yost's license was suspended following his diversion of CDS and a lapse in his licensure. Pursuant to the Order, the period of probation has ended. Mr. Yost unconditionally passed ProBE, passed MPJE, and is in full compliance with the requirements of his Consent Order.

Mahesh Shah moved, seconded by Stephen Lieberman that the Consent Order, by its own terms, grants Mr. Yost an unrestricted license. **Motion to support 9-1. Thomas Bender is opposed.**

- 8) **Christopher Kim, R.Ph.** – Request for CE credit for attending medical school

The Board received and reviewed Mr. Kim's request for CE credit for academic course work while attending medical school. Mr. Kim provided a comprehensive overview of the pharmacy components in his medical school classes.

Margherita Cardello moved, seconded by Linda Witzal, to approve ten (10) credits for this biennial renewal cycle with the stipulation that he still needs to obtain the remaining credits, including three (3) law credits. **Motion passed 10-0.**

- 9) **Life Worth Living Foundation Inc., Orlando, FL** – Out-of-state Pharmacy Applicant, Sterile Compounding

The Board received and reviewed the out-of-state pharmacy application. The pharmacy submitted answers to complete the previously incomplete survey questions and addressed the deficiencies found in the last inspection on 08/20/2014. Richard Palombo moved, seconded by Mahesh Shah, to approve the out-of-state pharmacy application as presented. **Motion passed 10-0.**

- 10) **Encino Pharmacy, Encino, CA** – Out-of-state Pharmacy Applicant, Sterile Compounding

Edward McGinley moved, seconded by Linda Witzal, to approve this out-of-state pharmacy application as presented. **Motion passed 9-0. Mahesh Shah was out of the room.**

- 11) **Cardinal Health 414, LLC, Indianapolis, IN** – Out-of-state Pharmacy Applicant, Sterile Compounding

Linda Witzal moved, seconded by Thomas Bender, to approve the out-of-state pharmacy application as presented. **Motion passed 9-0. Mahesh Shah was out of the room.**

- 12) **FDA Memorandum of Understanding (MOU)**– Distributions of Compounded Human Drug Products Between the States and the FDA

The FDA published a draft MOU addressing distributions of compounded human use drug products with requirements which raise potential questions if NJ were to sign the MOU.

- *Any report about compounded products for human use shipped out of NJ MUST be investigated to determine the root cause of the problem. Although we would, of course, investigate NJ-based pharmacy contamination, the MOU would make it mandatory even if none of the product was utilized in NJ and regardless of our resources and priorities.*
- *Reports of complaints about NJ based compounding pharmacies MUST be reported to the FDA within 72 hours, although no procedure or standards are proposed.*
- *Ongoing monitoring of pharmacies would be mandatory to determine the amount of product shipped out of state, relative to the total amount of compounded product, as would reporting to the FDA whenever the ratio*

*exceeded 30%. These requirements would place a new regulatory and monitoring burden on NJ. The requirement lacks specificity regarding the defining the number of units to determine volume; the mechanism to determine the ratio during an inspection or through submissions from the compounding pharmacy; whether veterinary products are included or the requirements only pertain to compounded drugs for human use; the course of action when the pharmacy exceeds the 30% limit; and any distinctions on monitoring physician (as opposed to pharmacy/pharmacist prepared) compounding.*

Director Rubinaccio and DAG Jodi Krugman provided the Board with a summary of the MOU. Board members are instructed to email comments individually to Director Rubinaccio and DAG Krugman. The Board will review the memorandum updated with Board member comments and provide it to the FDA.

**13) NJ Prescription Monitoring Program Pilot Integration Program – Matthew Wetzel**

On behalf of the Drug Control Unit and the NJ Prescription Monitoring Program (NJPMP), Matthew Wetzel sought funding from the Board of Pharmacy for a pilot program that the NJPMP and the Division is developing. The NJPMP is developing a pilot program to integrate the NJPMP into both an electronic health records (EHR) system and a pharmacy software system so that practitioners and pharmacists can access the NJPMP seamlessly. The integration would eliminate the need for the practitioner/pharmacist to separately login to the NJPMP outside of the EHR/software system in order to perform a patient lookup. The NJPMP is seeking funding to offset the cost of the connection that will need to be established between the EHR/pharmacy software and the PMPGateway, which is the portal that will be used for the EHR/pharmacy software to access the NJPMP. The estimated cost of the pilot is between \$20,000 and \$30,000 for both the EHR and pharmacy software connections. The NJPMP would help develop a connection with two (2) EHR systems and two (2) pharmacy software systems which are widely used by independent pharmacies.

Edward McGinley moved, seconded by Mahesh Shah to approach the Board of Medical Examiners to bear half of the expenditure requested and request DAG Cordoma to research if this is legally feasible. The Board will revisit this item at next month's Board meeting. **Motion passed 10-0.**

**14) Pharmacy Technician Certification and Education Standards Proposal – Mitch Sobel**

Mr. Sobel presented the Board with a proposal to standardize pharmacy technician education and certification in the state of New Jersey to establish performance standards and a minimum competency. The initial proposal suggests acceptable certifications such as PTCB and NHA and a grace period of approximately two (2) years for current pharmacy technicians to become certified

prior to the next registration deadline.

A discussion followed the presentation which included commentary, questions, and support from the public and Board members.

Mitch Sobel moved, seconded by Carol Jacobson to refer the proposal to the Rules and Regulations committee for consideration. **Motion passed 10-0.**

**15) Redchip of Nevada, Irvine, CA - Out-of-state Pharmacy Applicant, California Inspection**

The Board received and reviewed Redchip of Nevada's out-of-state pharmacy application. The pharmacy works specifically with pre-authorization of hemophilia medications.

Edward McGinley moved, seconded by Stephen Lieberman, to grant the out-of-state permit once we receive an affidavit regarding open hours/availability by phone, access to pharmacist who has access to patient records at least 6 days a week, 40 hours a week, and the promise to limit their activities as outlined in their application. Should their scope of practice change in any way, they must seek prior approval from the Board. **Motion passed 10-0.**

**16) Roma Tandon, R.Ph. – Request waiver for N.J.A.C. 13:39-2A(c), which requires the FPGEE exam for foreign graduates.**

Ms. Tandon appeared before the Board to request the waiver in person and address any questions the Board may have. Ms. Tandon has been licensed and working as a registered pharmacist in the state of New York for many years. At the time of her initial licensure as a pharmacist in New York, she was not required to take the FPGEE. She successfully passed the TOEFL examination and completed all other requirements to become a licensed pharmacist in New York.

Ms. Tandon is currently working one (1) or two (2) days a week due to physical repercussions of a long commute from New Jersey to New York.

Richard Palombo moved, seconded by Mahesh Shah, to approve the waiver request based on Mr. Tandon's academic record, work history, experience, promise of employment, and presence at the Board meeting. **Motion passed 10-0.**

## **VII. MITIGATION/HEARING REQUEST**

**1) Tri M. Le, RPIC – Walgreens Pharmacy, Stirling, NJ**

Following an inspection revealing a violation related to misbranded medications found in the active drug inventory stock, a UPL was issued seeking a fine for this, and

a letter of corrective action.

Tri M. Le, RPIC provided an explanation for the violations and requested that the Board mitigate the fine.

Stephen Lieberman moved, seconded by Linda Witzal, to mitigate N.J.A.C. 13:39-7.18 to two (2) of the five (5) misbranded medications. **Motion passed 9-0. Thomas Bender was recused due to his affiliation with Walgreens.**

2) **Steven Stuhltrager, RPIC** – Rite Aid Pharmacy, Mantua, NJ

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

Steven Stuhltrager, RPIC provided an explanation of the automated telephone system, addressing the violation and requested that the Board mitigate the fine.

Stephen Lieberman moved, seconded by Richard Palombo, to mitigate the fine as the explanation provided was sufficient and to revisit this issue at sunset to amend regulations to accommodate new technology. **Motion passed 9-0. Margherita Cardello was recused to due to her affiliation with Rite Aid.**

3) **John Abraham, RPIC** – Rite Aid Pharmacy, Somerset, NJ

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

John Abraham, RPIC provided an explanation of Rite Aid's inventory process, explaining it could have been reprinted with the date, addressing the violation and requested that the Board mitigate the fine.

**Chair Direct:** The Board office is to request that Mr. Abraham submit a dated copy of CDS inventory. **Margherita Cardello was recused to due to her affiliation with Rite Aid.**

4) **Amy Sneddon, RPIC** – Rite Aid Pharmacy, Hackettstown, NJ

Following an inspection revealing a violation related to the certification of the ScriptPro system by the Office of Weights and Measures, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Deborah Hurley of Rite Aid provided an explanation that the ScriptPro system was marked as "condemned" on the Weight and Measures initial inspection report following observed counting errors, the devise was fixed, but was certified by Weights and Measures three (3) days following the Board of Pharmacy inspection.

Ms. Sneddon requested that the Board mitigate the fine.

Edward McGinley moved, seconded by Linda Witzal, to deny the mitigation request of N.J.A.C. 13:39-5.9. **Motion passed 9-0. Margherita Cardello was recused to due to her affiliation with Rite Aid.**

5) **Barbara Ann Hoagland, RPIC** – Shop Rite Pharmacy, Toms River, NJ

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

Barbara Ann Hoagland, RPIC provided an explanation, addressing the violation and requested that the Board mitigate the fine. The explanation that the keys are locked in a safe in the front office raised further questions from the Board members regarding non-pharmacy personnel access to the office and safe.

Stephen Lieberman moved, seconded by Edward McGinley, to deny the mitigation request of N.J.A.C. 13:39-4.15(b)1. **Motion passed 10-0.**

6) **Albert Imperiale, Jr., RPIC** – CVS Pharmacy, Jackson, NJ

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

Albert Imperiale, Jr., RPIC provided an explanation that the pharmacy technicians are PTCB Certified and while failing to produce policies and procedures for the inspector, the training manual, which has been signed off by all pharmacists and pharmacy technicians, is available on the intranet. Mr. Imperiale, Jr. requested that the Board mitigate the fine.

Edward McGinley moved, seconded by Mitch Sobel, to mitigate N.J.A.C.13:39-6.15(d) to a warning. **Motion passed 10-0.**

7) **Leanne Kalsch, RPIC** – CVS Pharmacy, Barnegat, NJ

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

Leanne Kalsch, RPIC explained that the inventory problems were caused by a computer glitch and requested that the Board mitigate the fine.

Linda Witzal moved, seconded by Stephen Lieberman, to deny the mitigation request of N.J.A.C.13:39-7.12(a)11 because the documentation didn't identify who conducted the inventory and it was not signed. **Motion passed 10-0.**

8) **Heena Dhiren Patel, RPIC** – CVS Pharmacy, Denville, NJ

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

Heena Dhiren Patel, RPIC provided an explanation that while proper documentation wasn't provided, all pharmacy technicians present during the inspection have completed the approved CVS in-house Pharmacy Technician Training Program, addressing the violation. Ms. Patel requested that the Board mitigate the fine.

Item tabled as Ken Taraska of CVS offered to produce appropriate documentation within two weeks for Board review.

9) **Ghada Elzibak, RPIC** – Park Avenue Pharmacy, Paterson, NJ

Following an inspection revealing a violation related to the computer system generating pharmacist initials, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Ghada Elzibak, RPIC provided an explanation that the computer forces pharmacists to log-in each time using their own personal identification and requested that the Board mitigate the fine.

Stephen Lieberman moved, seconded by Linda Witzal, to deny the mitigation request for N.J.A.C.13:39-7.6(b). **Motion passed 10-0.**

10) **Nady Azer, RPIC** – Quick Stop Pharmacy, Newark, NJ

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

Angelo Cifaldi, Esq. provided an explanation on behalf of Quick Stop Pharmacy that due to the infrastructure of the building, it takes approximately 15 minutes to obtain hot water, requesting that the Board mitigate the fine.

Richard Palombo moved, seconded by Mitch Sobel, to remove the citation. **Motion passed 7-2. Stephen Lieberman and Carol Jacobson were opposed. Mahesh Shah was recused to a previous affiliation with Mr. Cifaldi.**

**VIII. INFORMATIONAL**

N/A

## IX. COMMITTEE REPORTS

Board President, Thomas Bender reported that Linda Witzal was unable to attend the MPJE workshop as her flight was cancelled due to inclement weather. NABP has authorized New Jersey to participate remotely. Mr. Bender reported that MPJE tests on 47 competencies. New Jersey was short on eight (8) of the competencies by a question or two, but the questions we have in our pipeline more than make up for the areas where we are short. Three (3) of the areas where New Jersey was short are due to the silence of our regulations on repackaging OTC, mandatory reporting and enrollment of impairment, and delivery. Given the statistical feedback from NABP, approximately 50% of questions in the pipeline are accepted. Overall, our scored pool and pre-test pool questions are in good shape.

## X. APPROVAL OF MINUTES

Margherita Cardello moved, seconded by Mahesh Shah to approve the March 25, 2015 Public Session Minutes as amended. **Motion passed 10-0.**

## XI. ADJOURNMENT

Margherita Cardello moved, seconded by Mitch Sobel, to move into the Executive Session for review of 10 Complaints, 2 Old Business Items, 15 New Business Items, the Secretary's Report and Recommendation on Inspection Reports from, and the approval of the Executive Session Minutes. **Motion passed 10-0.**

At 12:53 p.m., Margherita Cardello moved, seconded by Mitch Sobel, to adjourn the Public Session. **Motion passed 10-0.**