



**CHRIS CHRISTIE**  
Governor

**KIM GUADAGNO**  
Lt. Governor

# New Jersey Office of the Attorney General

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## **BOARD OF PHARMACY PUBLIC SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7<sup>th</sup> FLOOR April 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, 7<sup>th</sup> floor, on April 27, 2016 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.	Arrived 9:42 a.m.
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Linda Witzal, R.Ph.	
Mitch Sobel, R.Ph.	Excused Absence

### **OTHERS IN ATTENDANCE**

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

### **IV. UPDATES BY EXECUTIVE DIRECTOR**

The Executive Director reported for the month of March, \$24,777 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the

month:

- Pharmacy Technicians registered – 265
- Pharmacists licensed – 48 ( 31 by examination/score transfer and 17 by reciprocity)
- Out-of-State Pharmacies registered – 15
- In-State Pharmacies licensed – 11
- Pharmacists receiving immunization approval – 23
- Interns (foreign graduates) licensed – 6

The Executive Direct reported the following numbers for the 2016 pharmacist continuing education credit audit:

- Pharmacist Advised – 2,067
- Responses received, but not yet reviewed – 550
- Reviewed and closed files – 968
- Deficient files, pending UPL – 116
- Requires additional review – 19
- Deceased pharmacists – 2
- Waiver requests – 3
- Inactivation requests – 4
- Responses not yet received - 405

## V. OLD BUSINESS

### 1) Public Orders Filed

- a. Alexis Vega, Provisional Order of Discipline, filed 03/24/16
- b. Marshaya Scurry, Provisional Order of Discipline, filed 03/24/16
- c. LAN Pharmacy, Final Consent Order of Voluntary Surrender of Registration, 03/30/16
- d. A1 Pharmacy, Final Consent Order of Voluntary Surrender of Registration, 03/30/16
- e. Jahnna Gainer, Provisional Order of Discipline, filed 03/30/16
- f. Shawna Terry, Consent Order of Voluntary Surrender of Registration, filed 04/04/16
- g. Stephen Freedman, R.Ph., Interim Consent Order of Voluntary Surrender of License, filed 04/06/16
- h. Cheyenne Maldonado, Provisional Order of Discipline, filed 04/11/16

### 2) CVS - Pilot proposal for pharmacists and pharmacist technicians - supplemental information

John Roccio and Al Carter appeared before the Board on behalf of CVS.

Richard Palombo moved, seconded by Linda Witzal, to approve the CVS pilot for pharmacists and pharmacy technicians to work from home. **Motion carried 6-0.**

### 3) NAPLEX & MPJE Discussion – Retaking exams after third failure

The Board reviewed an amendment to N.J.A.C.13:39-2.2, which states that after three

failed attempts at either the NAPLEX or MPJE, for each subsequent attempt at reexamination, the application shall not be eligible to retake the examination for licensure until one year from the last exam date. Additionally, the Board shall consider a failing score to include a 'no score' and 'not passing'.

Edward McGinley moved, seconded by Richard Palombo that the proposal will now start with an internal approval process. **Motion passed 6-0.**

**4) AlexiaCare Health Solutions** – Current VPP Report for existing Out of State Sterile Compounding Pharmacy

Item moved to executive session.

**5) Pinkalkumar Amin** – Applicant for Initial Licensure, Request for partial waiver of N.J.A.C. 13:39-2.1(b)(4) – additional information

The Board reviewed this request at the February 24, 2016 meeting following a letter from Angelo Cifaldi, Esq., requesting a waiver of the 1,440 hour internship for Mr. Amin, as he was a licensed pharmacist in India and worked as a clinician in industry between 2004 and 2006. Since 2012, Mr. Amin has worked as a pharmacy technician and in 2014, he completed his thesis at Alpha Stats, Inc. The Board moved to revisit this request upon receipt of a notarized affidavit explaining Mr. Amin's clinical training in detail.

Mr. Amin provided the Board with an affidavit detailing his clinical training, which included 600 hours of clinical work in a hospital and approximately 800 hours in clinical research for his thesis.

Richard Palombo moved, seconded by Linda Witzal, to grant a waiver for 440 hours based on Mr. Amin's clinical experience and research. Mr. Amin will have to complete a 1,000 hour internship. **Motion carried 5-0-1.** Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

**6) Marshaya Scurry** – response to POD

Item removed from the agenda.

**7) Tetra RX, Cherry Hill, NJ** - delayed mitigation request

David Metzger, RPIC, responded on behalf of Tetra RX, requesting a refund of the \$1,000 fine paid for N.J.A.C.13:39-4.15(b)1, while submitting proofs that cellular back-up to their security system was installed and being monitored on the date of the inspection.

Edward McGinley moved, seconded by Mahesh Shah, to remove N.J.A.C.13:39-4.15(b)1 and refund the pharmacy \$1,000. **Motion carried 6-0.**

**8) Kyle Colalillo** - request for unrestricted license

The Board received and reviewed a request from Angelo Cifaldi, Esq., on behalf of Kyle Colalillo to remove the restrictions place on Mr. Colalillo's license. Mr. Colalillo's license was reinstated by Consent order filed on 11/09/11. Mr. Colalillo is six years in recovery, in stable status, and has been complaint with NJPAP. Edward McGinley moved, seconded by Stephen Lieberman, to remove the restrictions from Mr. Colalillo's license, effective upon approval of the minutes, before the Order of Unrestricted License if filed. **Motion carried 5-0-1.** Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

**9) CE audit POD for review – DAG Megan Cordoma**

DAG Megan Cordoma reviewed the Provisional Order of Discipline (POD) to be used in the continuing education credit audit.

Mahesh Shah moved, seconded by Edward McGinley, to approve the CE audit POD, which will be self-finalizing and automatically suspend the license if the licensee does not respond within 60 days, and to include an explanatory cover letter. **Motion carried 7-0.**

**10) Innoveix Pharmaceuticals, Inc, Addison, TX – Out-of-state pharmacy, sterile compounding**

The Board reviewed this application at the July 22, 2015, and by way of a chair direct, requested testing logs for the PIC and other sterile compounding personnel, documentation for beyond use dates of six (6) months for Gonadotropin, and the strength of and compounding logs for Sildenafil.

Brett Riddle, current RPIC of Innoveix Pharmaceuticals, submitted the requested documentation.

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

**11) Citizens Waiver**

Since the review of this request at the March 23, 2016 meeting, new information has been made available to the Board that was not available at the March meeting. The additional information will be reviewed during executive session.

Edward McGinley moved, seconded by Linda Witzal to pend this waiver request until the Board has an opportunity to review the new information. **Motion carried 7-0.**

**VI. NEW BUSINESS**

**1) Bill A3519**

*This bill requires the Division of Consumer Affairs in the Department of Law and Public Safety to establish a process by which a patient may request that the patient's prescription monitoring information include an indication that the patient should not*

*be prescribed opioid drugs or other controlled substances with a significant potential for abuse or addiction. The indication would not be included in the patient's prescription monitoring information except at the patient's request. The Division would establish a process for removing the indication that a patient should not be prescribed opioid drugs or other controlled substances with a significant potential for abuse or addiction, at the patient's request. The Division would also establish a method, for persons who indicate that they should not be prescribed opioid drugs or other controlled substances with a significant potential for abuse or addiction, to communicate this preference, in the event that the person is incapacitated or otherwise unable to communicate this preference prior to or while receiving health care services. The Division would develop an education and outreach program for health care providers concerning this process.*

Stephen Lieberman moved, seconded by Richard Palombo, to support the intent of this bill with concern that implementation within the PMP program may be a challenge, and it is unclear if/when does the doctor/pharmacist become liable.

**Motion carried 7-0.**

## **2) Bill A3554**

*This bill amends section 8 of P.L.1977, c.240 (C.24:6E-7) to require a physician or other authorized prescriber, prior to transmitting an oral prescription or writing a prescription, to inform a consumer: that when filling the prescription, unless the physician or prescriber explicitly states that there will be no substitution or indicates that substitution is permissible and requests notification of the substitution in accordance with the provisions of the law, a different brand name or non-brand name drug product would be dispensed by a pharmacist; and about the circumstances under which, when a substitution is indicated, the consumer is allowed to request that the drug product prescribed by the physician be dispensed.*

Edward McGinley moved, seconded by Stephen Lieberman to oppose this as it is onerous for prescribers and perhaps misplaced. The state funded plans require mandatory substitution. Benefit managers and PBMs design plan parameter that require substitution, therapeutic interchange, step therapy, and other cost-saving tactics. Physicians want to treat patients, not be prescription benefit gurus. **Motion carried 7-0.**

## **3) Bill S2035**

*This bill provides that a practitioner may not issue an initial prescription for an opioid drug in a quantity exceeding a seven-day supply. Subsequent prescriptions for the drug may be issued in any quantity that complies with applicable State and federal laws, provided that the prescription is not deemed to be an initial prescription, the practitioner determines the prescription is necessary and appropriate to the patient's treatment needs, and the practitioner determines that issuance of the subsequent prescription does not present an undue risk of abuse, addiction, or diversion.*

Thomas Bender moved, seconded by Mahesh Shah, to support this bill. **Motion**

carried 7-0.

4) **Matthew Garretson** - Pharmacy technician, finalization of POD

The POD filed on 12/18/15 was successfully delivered at Mr. Garretson's address of record with the Board. The Board has not received a response.

Edward McGinley moved, seconded by Linda Witzal to finalize POD by default. **Motion carried 6-0-1.** Thomas Bender was recused due to his affiliation with Walgreens.

5) **Charmaine Bean** – Pharmacy technician applicant with criminal history

Moved to executive session.

6) **Ralph Ypil** - requesting NAPLEX testing accommodation

Richard Palombo moved, seconded by Mahesh Shah to allow the requested accommodations. NABP vets these requests well and the Board relies on their judgement. **Motion carried 6-1.** Stephen Lieberman was opposed.

7) **Nicole Asper, R.Ph.** – Pharmacist reinstatement application

The Board received a letter from Angelo Cifaldi, Esq. on behalf of Nicole Asper, requesting the reinstatement of her pharmacist license.

Richard Palombo moved, seconded by Edward McGinley, to schedule Ms. Asper for an investigative inquiry. **Motion carried 5-0-2.** Thomas Bender was recused due to his affiliation with Walgreens and Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

8) **Ben Aalampour** - Request for Reinstatement

The Board received and reviewed a request from Mr. Aalampour to reinstate his pharmacist license. Mr. Aalampour has not practiced pharmacy since 2011 and did not renew his license in 2013. Mr. Aalampour needs to meet the requirements of N.J.S.A.45:1-7.4, at which point, the Board can review the request, pursuant to N.J.S.A.45:1-7.4(e).

**Chair Direct:** Mr. Aalampour should submit all necessary documents and the item will be reagendaized.

9) **Jessica Kim** - Request for waiver of intern hours

The Board received and reviewed Ms. Kim's request to waive the intern hours requirement of her application. Ms. Kim passed both the MPJE and NAPLEX in October of 2015, sending the scores to California. At the time, she believed she would permanently reside in California and was unaware that score transfers must be requested within 90 days. She is requesting the waiver since passing the NAPLEX

was fulfilled, just not transferred.

Thomas Bender moved, seconded by Margherita Cardello, to advise NABP that our regulations allow a five (5) year window and to please transfer her NAPLEX score to New Jersey. If NABP has a reason for the 90 day window, the Board kindly requests that it's forwarded to the Board office. Ms. Kim will need to take the NJ MPJE.

**Motion carried 7-0.**

**10) North Carolina State University – Request for waiver to ship prescriptions into New Jersey**

The Board received and reviewed a letter from the NC State University College of Veterinary Medicine requesting permission to ship prescription medications and food to their clients in New Jersey without becoming a licensed non-resident pharmacy in New Jersey. They cited that it is not financially feasible for them to become licensed in each of the 50 states as they are a non-profit pharmacy business.

N.J.A.C.13:39-1.3(a)4 imposes a \$175 fee for non-resident pharmacies.

Richard Palombo moved, seconded by Mahesh Shah to deny this request. **Motion carried 7-0.**

**11) Pawel Lasocha - Request to accept intern hours earned out-of-state**

Edward McGinley moved, seconded by Stephen Lieberman, to accept the 2,080 hours earned in New York towards the New Jersey internship requirements.

**Motion carried 7-0.**

**12) Ragy Salama Tantawy - Request to accept intern hours earned out-of-state**

Edward McGinley moved, seconded by Stephen Lieberman to deny the request. The internship was completed three years ago and does not meet the requirements for an internship as defined in N.J.A.C.13:39-2.1(d)4. Mr. Tantawy did not supply where he went to school or where he graduated. **Motion carried 7-0.**

**13) Carla Maxemous- Reciprocity applicant requesting guidance**

Ms. Maxemous contacted Executive Director Rubinaccio requesting guidance on how to apply for licensure as a pharmacist in New Jersey. Ms. Maxemous graduated from Albany College of Pharmacy in 2014, took the NAPLEX in 2014, worked in Canada as a pharmacist for over 1,500 hours, and became licensed by examination in Florida in March 2016.

Thomas Bender moved, seconded by Mahesh Shah, to transfer the Florida NAPLEX scores to New Jersey and allow Ms. Maxemous to become licensed as a pharmacist via score transfer. **Motion carried 7-0.**

**14) Anne Neely - Collaborative Practice Pre-Approval Application**

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

**15) Terri Marxen - Collaborative Practice Pre-Approval Application**

Stephen Lieberman moved, seconded by Margherita Cardello, to approve this collaborative practice application. **Motion carried 6-1.** Edward McGinley was opposed.

**16) NJPhA - Collaborative Practice continuing education clarification request**

The Board received communication from NJPhA, requesting clarification on the number of additional hours of continuing education credits needed, specifically for comorbid conditions.

Regulatory Analyst, Rachel Glaskow advised the Board by providing a response to a comment from the February 4, 2013 New Jersey Register which stated:

*Comment: The Society noted that the repropose rule requires pharmacist to complete 10 hours of training biennially in the "area covered", but notes that "area covered" is not a defined term. The Society urged the Board to more specifically define "area covered" to include the specific disease state or conditions covered by any collaborative practice agreement. They believe it is essential to train pharmacists on specific disease states and conditions being addressed by the collaborating pharmacist.*

*Response: The Boards agree that the "area covered" refers to the specific disease state or conditions covered by the collaborative practice agreement, and will change the phrase "area covered" to "disease state(s) or condition(s) covered". The Boards agree that the pharmacist should complete continuing education related to the disease states or conditions covered by the collaborative practice agreements, and wish to clarify that the rules would require a pharmacist who is a party to collaborative practice agreement(s) to take 10 continuing education credits in each condition or disease state covered by the collaborative practice agreement(s), unless the conditions are co-existing, interrelated conditions, such as diabetes and hypertension. The Boards will change the rules based upon adoption to make this clear. The Boards believe requiring a total of 10 continuing education credits will be sufficient because continuing education courses offering a thorough review of a condition or disease state that is often interrelated with other conditions or diseased states should include a discussion of the associated conditions or diseased states.*

**17) Enclara Health, West Deptford -Temporary closing request**

Walter Valentine, R.Ph, appeared before the Board on behalf of Enclara Health and requested approval a temporary closure the pharmacy for 60 days, to possibly reopen the pharmacy at a different site. This request would allow the pharmacy permit to remain active and the CDS registration associated with the pharmacy permit would remain active.

Edward McGinley moved, seconded by Richard Palombo, to deny this request for a temporary retention of the license without the pharmacy being open. **Motion carried 7-0.**

**18) Andover Apothecary – Applying to recommence sterile compounding**

At the February 4, 2016 Board meeting, the Board received and reviewed an inspection report of Andover Apothecary and their request to resume sterile compounding.

Edward McGinley moved, seconded by Margherita Cardello, to approve the request to recommence sterile compounding, based on the inspector's report. **Motion carried 6-0.** Stephen Lieberman was out of the room.

**19) MCS Enterprise Inc, dba Medicine Shoppe Xubec - Out of State Pharmacy application with discipline**

The former RPIC, who is the current owner of the pharmacy entered into a consent order with the State of Florida Board of Pharmacy on February 25, 2013 after a pharmacy technician stole approximately 96,338 Oxycodone pills from the pharmacy.

Edward McGinley moved, seconded by Richard Palombo, to allow MCS Enterprise Inc, to withdraw their application within 30 days, or it will be denied, based upon operation of the pharmacy that allowed substantial diversion under the same management. **Motion carried 7-0.**

**20) CAP Pharmacy, LLC - Existing Out of State Pharmacy - response to NJ Sterile Compounding questionnaire and NABP Inspection report**

Edward McGinley moved, seconded by Thomas Bender, to approve this application pending satisfactory response to the environmental and clean room deficiencies in the NABP inspection report. **Motion carried 7-0.**

**21) Hamid Rahimtoola, R.Ph. - Request for reinstatement**

Mr. Rahimtoola was licensed as a pharmacist in New Jersey and administratively suspended for non-renewal in 1997. He has been living in Europe since 1994 and has worked as a retail pharmacy manager in the Netherlands from 1997-2013. He is currently working as a hospital pharmacy manager.

Thomas Bender moved, seconded by Stephen Lieberman, that by virtue of the fact that he has not worked in the United States in over 20 years, to be comfortable that he is competent to practice and to protect the citizens of New Jersey, he will need to take the NAPLEX and MPJE. Motion did not carry 2-5.

Mahesh Shah moved to proceed with the PARE exam, followed by a remediation plan, MPJE, and a 200 hour internship. Motion withdrawn.

Mahesh Shah moved, seconded by Edward McGinley, to authorize the DAG to offer a consent order allowing reinstatement following successful completion of the NAPLEX and MPJE or the PARE exam with a remediation plan to the satisfaction of the Board and the MPJE, both with a required 200 hour internship. The Board's determination is based on the impressive credentials and demonstrated clinical proficiency in the Netherlands. **Motion carried 7-0.**

## VII. MITIGATION/HEARING REQUEST

### 1) David Lee, Director of Pharmacy - Shop Rite Pharmacy, Rio Grande, NJ

David Lee, director of Pharmacy, responded on behalf of Shop Rite Pharmacy and requested mitigation of N.J.A.C. 13:39-4.15(b)1.

Edward McGinley moved, seconded by Margherita Cardello to review previous, similar mitigation requests to determine if the Board provided Shop Rite a period of time to rectify this problem in all of their stores. **Motion carried 6-0-1.** Thomas Bender was recused.

### 2) David Lee, Director of Pharmacy - Shop Rite Pharmacy, Abescon, NJ

David Lee, Director of Pharmacy, responded on behalf of Shop Rite Pharmacy and requested mitigation of N.J.A.C. 13:39-4.15(b)1.

Edward McGinley moved, seconded by Margherita Cardello to review previous, similar mitigation requests to determine if the Board provided Shop Rite a period of time to rectify this problem in all of their stores. **Motion carried 6-0-1.** Thomas Bender was recused.

### 3) Gerald Cioce, RPIC – Valley Pharmacy, Clifton, NJ

Gerald Cioce, RPIC, responded on behalf of Valley Pharmacy and requested mitigation of N.J.A.C. 13:45H-7.5(a), N.J.A.C.13:45H-7.8(a), N.J.A.C.13:39-6.2(f)7.

Stephen Lieberman moved, seconded by Margherita Cardello to deny this request. **Motion carried 7-0.**

### 4) Gurdine Soma, RPIC – Soma Pharmacy, Howell, NJ

Gurdine Soma, RPIC, responded on behalf of Soma Pharmacy and requested mitigation of N.J.A.C.13:39-6.2(f).

Edward McGinley moved, seconded by Margherita Cardello to remove N.J.A.C.13:39-6.2(f). **Motion carried 7-0.**

### 5) Denise Martino, RPIC - CVS Pharmacy, Old Tappan, NJ

Denise Martino, RPIC, responded on behalf of CVS Pharmacy and requested mitigation of N.J.A.C. 13:39-6.13(a)(b) and N.J.A.C.13:39-4.18.

Edward McGinley moved, seconded by Stephen Lieberman to remove N.J.A.C. 13:39-6.13(a)(b) and N.J.A.C.13:39-4.18 because they have a valid registration.  
**Motion carried 7-0.**

**6) Theresa Battista, RPIC** – Liss Medical Arts Pharmacy, Summit, NJ

Theresa Battista, RPIC, responded on behalf of Liss Medical Arts Pharmacy and requested a formal administrative hearing.

**Chair Direct:** DAG Cordoma is to contact Ms. Battista to explain the process and transfer to prosecution if necessary.

**7) Gleb Chemerisov, RPIC** - Empire Specialty Pharmacy, West New York, NJ

Gleb Chemerisov, RPIC, responded on behalf of Empire Specialty Pharmacy and requested mitigation of N.J.A.C.13:39-5.6, N.J.A.C.13:39-7.19(b)9, and N.J.A.C.13:39-7.10(h).

Edward McGinley moved, seconded by Stephen Lieberman to deny mitigation of N.J.A.C.13:39-5.6 and N.J.A.C.13:39-7.19(b)9, and remove N.J.A.C.13:39-7.10(h).  
**Motion carried 7-0.**

**8) Miriam Gergis, RPIC** – CVS, Hillsborough, NJ

Miriam Gergis, RPIC, responded on behalf of CVS and requested mitigation of N.J.A.C.13:39-4.18 and associated \$200 fine, following the Board's review of a complaint claiming a HIPPA violation. Ms. DiStefano claims the citation is a catch all regulation and they have not been provided a specific citation to have been found in violation.

**Chair Direct:** The Board office is to reach out to Ms. Gergis to identify the individuals involved in the intake processing, DUR filling and the verification and sale of the prescription.

## VIII. INFORMATIONAL

**1) Comment from Ritesh Shah, Chairman NJ Rx PAC** - regarding the proposed Walgreens pilot program

The Board received and discussed a letter from Ritesh Shah, detailing concerns with the proposed Walgreens pilot program. Mr. Shah also appeared in person to discuss his letter with Board. DAG Cordoma and the Board assured the public that all comments submitted will be taken under consideration by the committee who is developing the parameters for the pilot.

**2) Containment Technologies Group** – allegation of false and misleading training

The Board accepted as informational.

**IX. COMMITTEE REPORTS**

N/A

**X. APPROVAL OF MINUTES**

Edward McGinley moved, seconded by Margherita Cardello to approve the March 23, 2016 Public Session Minutes as amended. **Motion passed 7-0.**

**XI. ADJOURNMENT**

Stephen Lieberman moved, seconded by Margherita Cardello, to move into the Executive Session for review of 11 Complaints, 2 Old Business Items, 21 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 1:00 p.m., Stephen Lieberman moved, seconded by Margherita Cardello, to adjourn the Public Session. **Motion passed 7-0.**