



**CHRIS CHRISTIE**  
Governor

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# **New Jersey Office of the Attorney General**

Division of Consumer Affairs  
Board of Pharmacy  
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## **BOARD OF PHARMACY PUBLIC SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7<sup>th</sup> FLOOR February 24, 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 February 24, 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 9:45 a.m.
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Linda Witzal, R.Ph.	
Mitch Sobel, R.Ph.	

### **OTHERS IN ATTENDANCE**

Anthony Rubinaccio, R.Ph.	Executive Director, Board of Pharmacy
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 January, \$0 was collected in fines and penalties. Payments were received, but not posted in time to be reflected in January's

statement. The following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 263
- Pharmacists licensed – 42 ( 28 by examination/score transfer and 14 by reciprocity)
- Out-of-State Pharmacies registered – 20
- In-State Pharmacies licensed – 4
- Pharmacists receiving immunization approval – 26
- Interns (foreign graduates) licensed – 1

Executive Director Anthony Rubinaccio informed the Board members that Matthew Wetzel, Executive Director of the Drug Control Unit has been promoted to the Assistant Deputy Director of the Division of Consumer Affairs. Jessica Kelley, Confidential Assistant to the Board of Pharmacy will now sit as Acting Executive Director of the Drug Control Unit.

A FAQ related to the Continuing Education audit is now available on the Board of Pharmacy website.

The Collaborative Practice Pre-Approval application is being streamlined and is now available to applicants on the website. The Division will also now offer a printed registration card for pharmacists approved to enter into collaborative practice agreements.

## V. OLD BUSINESS

### 1) Public Orders Filed

- a. Best Healthcare Services, Inc. – Interim Consent Order – (01/21/16)
- b. Jeffrey Simone, R.Ph. – Consent Order (01/21/16)
- c. Katherine Campanale– Consent Order of Voluntary Surrender of Registration (01/28/16)
- d. Paul Zamerowski, R.Ph. – Consent Order (01/29/16)
- e. Mark Cardis, R.Ph. – Order Granting Unrestricted License (01/29/16)
- f. Kimberly D. Rebar – Consent Order of Voluntary Surrender of Registration (02/09/16)

### 2) Walgreens – Request for the deployment of a patient accessible ADS in the emergency department of Robert Wood Johnson University Hospital

At the December 16, 2015 meeting, *Dan Luce, R.Ph., MBA, National Director of Pharmacy Affairs for Walgreens, provided the Board with an overview of an Automated Dispensing System (“ADS”) that they want to install in the emergency room at Robert Wood Johnson University hospital in Rahway, New Jersey as a pharmacy. Also in attendance were representatives from MedAvail Technologies and Robert Wood Johnson University Hospital. Mr. Luce supplied the following summary to the Board regarding this ADS:*

*“The Walgreens Prescription Center (WPC)” is a fully functional patient facing automated dispensing device which performs all of the major functions of a community pharmacy. The WPC features Face-to-face audio/visual interaction and counseling between a patient and the pharmacist before dispensing any medication. The Prescription Center is able to receive electronic prescriptions directly from the*

*prescriber as well as written prescriptions that are securely scanned and stored after submission by the patient. A Walgreen pharmacist located at a central pharmacy located in Orlando, Florida, will complete the prescription processing tasks, perform a full drug utilization review via our common electronic database, validate the prescription and medication dispensed, and provide patient consultation. The unit fills the prescription using multiple bar code scans and imaging of each surface of unit of use or pre counted drug containers. The unit does not require the presence of an on-site technician as the device is connected to the pharmacist and performs all drug selection, verification and labelling functions. After a medication is prepared it is verified by a pharmacist before being released to the patient.*

*Edward McGinley suggested that Walgreens review the New Jersey Board of Pharmacy Regulations, specifically subchapter 10 which addresses Automated Dispensing Systems. This ADS seems to fit better into this categorization rather than trying to make it fit the requirements of a 'pharmacy', and asking for many waivers to do so. Mr. Luce will review the regulatory requirements for ADS, and may request to come back to the Board to seek authorization to implement the WPC as an ADS in this setting.*

Edward McGinley moved, seconded by Mitch Sobel to authorize a committee to work with the DAGs and Walgreens to create a pilot program or recommend how the proposal might fit current regulatory framework and bring the matter back to the Board for approval. **Motion carried 7-0-1.** Thomas Bender was recused due to his affiliation with Walgreens.

Linda Witzal moved, seconded by Stephen Lieberman to approve a committee comprised of Mitch Sobel, Mahesh Shah, Rich Palombo and Edward McGinley. **Motion carried 7-0-1.** Thomas Bender was recused due to his affiliation with Walgreens

**3) All-Scripts Pharmacy Kissimmee, FL – Out-of-state applicant, misrepresentation on application**

At the December 18, 2015 meeting, the Board moved to allow the application to pend until Tamer Girgis, the owner of All-Scripts provided documentation showing full compliance with PAP. If compliance is proven, the Board will allow them to withdraw the application, with no reapplication for two years. If Mr. Girgis did not comply, the Board will deny the application, due to the pharmacist misrepresentation on the application.

The Board received and reviewed documentation indicating Mr. Girgis' compliance with PAP as well as a request for reconsideration from Angelo Cifaldi, Esq, stating that the inability to proceed with their application would result in financial hardship for the pharmacy.

The Board considers Tamer Girgis' failure to disclose prior discipline on the out-of-State pharmacy application as his second instance of misrepresentation known to this Board. Pursuant to N.J.S.A.45:1-21, the Board may refuse to issue a registration to an applicant upon proof that the applicant has engaged in the use or employment of

dishonesty, fraud, deception, misrepresentation, false promise, or false pretense. As an initial applicant, they should not currently be shipping into New Jersey; therefore, should not suffer any financial hardship if they are prohibited from re-applying for two (2) years.

Edward McGinley moved, seconded by Stephen Lieberman to allow the pharmacy to withdraw the application and reapply in two (2) years. **Motion carried 7-0-1.** Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

**4) American Custom Compounding Pharmacy, Dallas, TX** – Out-of-state applicant, sterile compounding, additional information

Following review at the May 6, 2015 meeting, the Board requested training documents, record of a current RPIC, clarification of hours of operation, an updated Texas permit and CDS registration, an updated application, and an explanation as to why the RPIC turnover rate is so high.

Upon review of the received documentation, there appears to be a conflict in the hours of operation, the affidavit submitted is from a prior RPIC, and the training documents are insufficient.

Linda Witzal moved, seconded by Richard Palombo to allow the application to remain in pending status until the requested information is provided and reviewed. The Board office is to remind the pharmacy that they should not ship into New Jersey at this time. **Motion carried 8-0.**

**5) Bhanwatie Latchman** – Active pharmacy technician, finalization of POD

The POD was sent to the correct address of record via certified and regular mail. The certified mail was returned unclaimed and the regular mail was not returned. No response was received.

Mahesh Shah moved, seconded by Stephen Lieberman to finalize the POD without modification by default. **Motion carried 7-0-1.** Thomas Bender was recused due to his affiliation with Walgreens.

**6) Rocky A. Patel** – Active pharmacy technician, finalization of POD

The POD was sent to the correct address of record via certified and regular mail. The certified mail was returned unclaimed and the regular mail was not returned. No response was received.

Stephen Lieberman moved, seconded by Margherita Cardello to finalize the POD without modification by default. **Motion carried 8-0.**

**7) Best Healthcare Services, Inc.** – Approval to ratify Interim Order

Edward McGinley moved, seconded by Thomas Bender to ratify the Interim Order, filed on February 23, 2016. **Motion carried 8-0.**

## VI. NEW BUSINESS

### 1) CVS- Pilot proposal for pharmacists and pharmacy technicians to work remotely

John Rocchio, Director of Pharmacy Regulatory Affairs for CVS appeared before the Board to seek approval for a pilot program enabling select pharmacists and pharmacy technicians to work in a remote setting, outside of the affiliated licensed pharmacy with the purpose of improving patient care and the prescription filling process.

The Board determined that CVS will need to present a more detailed proposal to address New Jersey specific laws, explaining the metrics, and provide detailed policies and procedures.

### 2) Resolution Regarding Board Action Between Meetings – Public Session

Upon review of the resolution, it was determined to add collaborative practice pre-approval applications for Executive Director review and approval. The language should also clarify that the Vice President of the Board shall act when the President is absent.

#### **RESOLUTION REGARDING BOARD ACTION BETWEEN MEETINGS PUBLIC SESSION**

*The Board of Pharmacy hereby moves to designate the Board President to function as Head of the Board of Pharmacy authorized to take action regarding certain events arising between Board meetings, where time is of the essence. Such actions would include:*

- 1. Issuing an Order to Show Cause upon the filing by the Attorney General of a Verified Complaint seeking emergent relief;*
- 2. Call a meeting of a committee of the Board to conduct an emergent Temporary Suspension hearing based upon such Complaint and issuing an Order to be ratified by the Board at its next meeting and having immediate effect, or call a meeting of the full Board to conduct an emergent Temporary Suspension hearing based upon such Complaint and issuing an Order having immediate effect.*
- 3. Determining settlement terms of a disciplinary case pending review and approval of the full board, including but not limited to, those cases where a final determination by the board must be made on short notice to effectuate global settlement with other civil or criminal authorities or where there is an immediate danger to the public health safety and welfare should a licensee remain in practice.*

*Each of the above actions is subject to review by the full Board at the next meeting at which such review can be scheduled. The full Board may then ratify, modify or vacate the emergent action taken by the President.*

*In the absence, unavailability or ineligibility of the President to address the matter, said authority is conferred upon the Vice President of the Board, acting as President*

*pro tempore, and then to remaining Board members in order of seniority.*

***The Board of Pharmacy hereby moves to authorize the Executive Director of the Board to approve routine applications that clearly meet the educational, exam and experience requirements for:***

- 1) *Pharmacist*
- 2) *Pharmacy technician*
- 3) *Pharmacy*
- 4) *Out-of-state pharmacy permits – where the pharmacy, owners and RPIC are in active good standing in their home state.*
- 5) *Centralized prescription handling service – where the pharmacies, owners and RPICs are in active good standing in their home state.*
- 6) *Collaborative practice pre-approval applications*

Rich Palombo moved, seconded by Linda Witzal to approve the resolution with the aforementioned additions. **Motion carried 8-0.**

**3) Gregory T. Bogart, R.Ph. – Collaborative Practice Pre-Approval Application**

Edward McGinley moved, seconded by Linda Witzal to approve this application. **Motion carried 8-0.**

**4) Adriana Nedea – Request to accept intern hours earned out-of-state**

Ms. Nedea completed 2,080 intern hours in New York, receiving outstanding reviews.

Stephen Lieberman moved, seconded by Mahesh Shah to accept the hours earned in New York, exceeding and fulfilling the 1,440 hour internship requirement in New Jersey. **Motion carried 8-0.**

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

The Board received 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.

Mitch Sobel moved, seconded by Linda Witzal to deny this request. Motion did not carry, 4-2-2. Edward McGinley and Richard Palombo were opposed. Margherita Cardello was recused due to her affiliation with Rite Aid and Mahesh Shah was

recused due to his affiliation with Mr. Cifaldi.

Thomas Bender moved, seconded by Stephen Lieberman to revisit this request upon receipt of a notarized affidavit explaining Mr. Amin's clinical training in detail.

**Motion carried 6-0-2.** Margherita Cardello was recused due to her affiliation with Rite Aid and Mahesh Shah was recused due to his affiliation with Mr. Cifaldi.

**6) Independent Healthcare Monitors – Information packet**

*“Our team at Independent Health Monitors (IHM), a division of Gates Healthcare Associates, has proven exceptional skill and knowledge in the areas of Sterile and Non-Sterile Compounding practices, Medication Error Prevention and Controlled Substances while serving as the direct monitoring program between State Board of Pharmacies and their Licensees.”*

Richard Palombo moved, seconded by Linda Witzal to approve as a Board approved monitor. **Motion carried 8-0.**

**7) Affiliate Monitors – Information packet**

*“Affiliated Monitors, Inc. (AMI) is a firm of dedicated monitoring and assessment experts with extensive knowledge in matters related to regulatory compliance. We serve regulatory authorities and many regulated businesses, including pharmacies, wholesalers, manufacturers, as well as pharmacists. AMI evaluates and monitors practices for compliance with federal, state, and local laws and regulations. We recommend improvements and share best practices to enhance public protection and remediate areas of concern. Monitoring allows the practitioner or business to achieve and demonstrate sustainable compliance.”*

Richard Palombo moved, seconded by Linda Witzal to approve as a Board approved monitor. **Motion carried 8-0.**

**8) Healthy Options, Inc. dba Postal Prescription Services – Self-reporting discipline**

Postal Prescription Services entered into Consent Orders with both Washington and Oregon Boards of Pharmacy after allegedly dispensing multiple patients a 90 day supply of Torrent brand telmisartan tablets in a prescription vial after removing the telmisartan from three 30 count manufacturer's containers, from approximately mid-August to early November 2014.

**Chair Direct:** The Board office is to determine if any New Jersey patients received the medication in question. If not, the Board accepts this as informational.

**9) Premier Pharmacy Services, Baldwin Park, CA – Out-of-state pharmacy application, sterile compounding**

Edward McGinley moved, seconded by Linda Witzal to verify that the California license is active as the verification provided expired on January 1, 2016. If the license is current, proceed with the application. **Motion carried 8-0.**

**10) Riddle Drugs #3, Oak Ridge, TN** – Out-of-state pharmacy application, sterile compounding

Mahesh Shah moved, seconded by Margherita Cardello to approve this application.  
**Motion carried 8-0.**

**VII. MITIGATION/HEARING REQUEST**

**1) Acme Pharmacy** – Acme Pharmacy Corporate Office

Following Board notification that Acme Pharmacy was offering a 10% discount on a future shopping orders after a patient purchased a flu shot form the pharmacy, violating N.J.S.A.45:14-65(26)(e), the Board issued a UPL seeking \$500 and a letter of corrective action.

Acme Pharmacy responded, indicating that they are attempting to remove barriers and encourage wellness. Additionally, they have a standing order with Dr. Frank Coppolino, a pulmonologist based out of Freehold, NJ.

Thomas Bender moved, seconded by Stephen Lieberman to deny the request. **Motion carried 8-0.**

**VIII. INFORMATIONAL**

**1) NABP MPJE Item Development Workshop notice**

The National Association of Boards of Pharmacy® (NABP®) will host the Multistate Pharmacy Jurisprudence Examination® (MPJE®) Item Development Workshop on March 15-16, 2016, at NABP Headquarters in Mount Prospect, IL. The two-day meeting will begin with an overview of the MPJE program, followed by an instructional session on item development led by NABP staff. The item development process is a collaborative effort and NABP encourages all MPJE participating states to attend this important workshop.

Thomas Bender is willing to participate remotely. Anyone interested in attending should let Anthony Rubinaccio know and he will coordinate attendance with NABP.

**IX. COMMITTEE REPORTS**

N/A

**X. APPROVAL OF MINUTES**

Mitch Sobel moved, seconded by Mahesh Sharhto approve the January 27, 2016 Public Session Minutes as amended. **Motion passed 8-0.**



## **XI. ADJOURNMENT**

Mitch Sobel moved, seconded by Mahesh Shah, to move into the Executive Session for review of 8 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 8-0.**

At 11:40 a.m., Mitch Sobel moved, seconded by Mahesh Shah, to adjourn the Public Session. **Motion passed 8-0.**