



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

ERIC T. KANEFSKY
Director

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

BOARD OF PHARMACY OPEN SESSION MEETING MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR August 28, 2013

I. CALL TO ORDER

The Open Session Meeting of the New Jersey Board of Pharmacy was called to order by the Board President Thomas Bender in the Monmouth Conference Room at 124 Halsey Street, Newark, New Jersey on August 28, 2013, at 9:05 a.m. All members were duly notified of the time and place and all pertinent materials were provided to the Board Members.

II. SUNSHINE LAW ANNOUNCEMENT

President Thomas Bender read a statement that the newspapers and appropriate elected officials have been notified of the meeting according to the requirements of the Open Public Meetings Act N.J.S.A. Chapter 231, P.L.1975, C.10:4-8

III. ROLL CALL

Thomas Bender, R.Ph.	President
Richard Palombo, R.Ph.	Vice President
Margherita Cardello, R.Ph.	Late Arrival 9:31 a.m.
Marc Sturgill, PharmD	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Edward McGinley, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director
Matthew Wetzel	Government Rep.
Megan Cordoma	Deputy Attorney General

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of July, \$ 40,166 in fines and penalties were collected. The following permits, licenses, and registrations were issued during the month of July:

- Technicians - 135
- Pharmacist - 80 (64 by examination/score transfer and 16 by reciprocity)
- Out-of-state pharmacies – 1
- In-state pharmacies - 2
- Pharmacists receiving immunization approval - 24
- Interns – 5

The Executive Director also reminded everyone that we will not have a Board meeting in September, however there will be two Board meetings in October.

V. OLD BUSINESS

1) **Public Orders Filed**

- a. Antoinette Wallace RPh – Consent Order filed (07-31-13)
- b. Joby George RPh – FOD filed (7-31-13)

2) **Jesse Munsick – Pharmacy Technician** – POD for finalization

Service was effective, there was no response received. Richard Palombo moved, seconded by Marc Sturgill, to finalize the order without modification by default.
Motion passed 6-0.

3) **Jennifer Miller – Pharmacy Technician** – POD to be finalized

Service was effective, there was no response received. Marc Sturgill moved, seconded by Mahesh Shah, to finalize the order without modification by default.
Motion passed 6-0.

4) **Twin City Specialty Pharmacy** – Waiver request of square footage requirement for second permit

The Board reviewed the information provided to support this waiver request.

Chair Direct: Provide Twin City Specialty Pharmacy with another opportunity demonstrate hardship. Also, afford them the opportunity to withdraw the application if they so desire.

5) **Crystal Ann Hanscom, R.Ph.** - Reinstatement

This item was added to the agenda, and was heard at the end of the Public agenda. At 12:15 PM, Edward McGinley motioned, seconded by Richard Palombo, to go into Executive Session for the advice of counsel. **Motion passed 7-0.**

At 12:22pm, Richard Palombo motioned, seconded by Margherita Cardello, to go back into Public Session. **Motion passed 7-0.**

Richard Palombo motioned, seconded by Marc Sturgill, to reinstate Ms. Hanscom's license without restriction. **Motion passed 7-0.**

VI. NEW BUSINESS

- 1) **Bassem W Agaybi – Pharmacist Applicant – NAPLEX Testing** additional attempt requested

Mr. Agaybi contacted the National Association of Boards of Pharmacy requesting authorization to take the NAPLEX. He had failed the examination on eight (8) prior attempts and had contacted NABP for additional testing with primary licensure in NJ. The Board reviewed his testing scores below:

2/26/2013	53
9/28/2012	55
11/03/2011	63
11/22/2010	55
4/26/2010	42
12/14/2009	65
12/05/2008	44
5/23/2008	18

Stephen Lieberman moved, seconded by Edward McGinley, to deny Mr. Agaybi's request, based on the number of attempts, and the period of time over which the attempts were made to pass the examination. The Board was concerned with the consistency of the low scores and the lack of improvement. **Motion passed 7-0.**

Richard Palombo moved, seconded by Margherita Cardello, to refer this to the Rules & Regulations Committee to discuss formalizing the Board's position that the Board should not extend the number of times an applicant may take the exam. **Motion passed 7-0.**

- 2) **Weatherford Compounding Pharmacy – Out of state sterile compounding pharmacy** - new application with questionable inspection report

Edward McGinley moved, seconded by Mahesh Shah, to deny this pharmacy's application for the following reasons: the pharmacy is not open 6 days a week as

required by Statute, the Beyond Use Date labeling violation citation (on the inspection report) is concerning since application indicates they perform sterile compounding, the hoods show no evidence of being inspected, the presence of a sink in the ante area. There were also numerous citations for sterile compounding violations. There was also a discrepancy over who was the actual Pharmacist in charge, when reviewing the application versus what appeared on the Texas license. **Motion approved 7-0.**

3) **Cathy Chin** – Client questions regarding Automated Dispensing Devices.

The Board had received many question regarding the proper policy and procedures regarding the use of Automated Dispensing Devices in Long Term Care facilities. Edward McGinley moved, seconded by Richard Palombo, for the Board to create a Committee to address the questions and issues raised. The committee will consist of Richard Palombo and Thomas Bender, assisted by Matthew Wetzel, Megan Cordoma, and various stakeholders.

Motion passed 7-0.

4) **Kenneth Grossett Jr., R.Ph.** – Request for an unrestricted license

Mr. Grossett requested an unrestricted license of the Board. He provided the Board with Urine Screening results, statements of participation in PAP, a completed pharmacist reinstatement application.

Chair Direct: The Board office is to issue a Demand for Statement under Oath of Mr. Grossett requesting details of his employment history.

5) **Monica Amo, R.Ph.** – Reciprocity applicant, review of work experience

The Board reviewed Ms. Amo's reciprocity application, and her previous work experience. Based on her current length of service acting as the pharmacist in charge at CVS Caremark in Allentown, Pennsylvania, Edward McGinley moved, seconded by Richard Palombo, that the requisite number of hours for reciprocity (1500) had been met, and that the application should be approved.

Motion passed 7-0.

6) **Dora Rebelo, R.Ph.** – Reinstatement Request – NAPLEX waiver

Ms. Rebelo took the NAPLEX as well as the MPJE exams and became a New Jersey licensed pharmacist in March 1992. She worked for two years from 1992-1994 as a licensed pharmacist for Walgreens in North Arlington, NJ. During this time, she also took the NAPLEX again and became licensed in the state of Florida. In January 1995, she permanently moved to Orlando, during the past 19 years, she worked for Publix as a registered Pharmacy Manager. She did not renew her NJ pharmacist license because she never received her renewal notices. Ms. Rebelo is looking to relocate to New Jersey for personal reasons, and requested to have her New Jersey pharmacist license reinstated.

Marc Sturgill moved, seconded by Stephen Lieberman, to ask Ms. Rebelo to withdraw her request for reinstatement of her New Jersey license, and to advise her to apply for reciprocity based on her licensure by examination in Florida. If all the application requirements are met, the Board will approve her reciprocity application. Ms. Rebelo will also be instructed to maintain FL license

7) **Tammanna Chopra RPh – Reinstatement Request**

Ms. Chopra wrote to the Board of pharmacy requesting the reinstatement of her pharmacy license in the state of New Jersey. She claims to have completed all requirements of her Consent Order, and complied with all rules and regulations required by PAP. As of December 23, 2010 she ceased practicing pharmacy and has been continuously monitored for the last two and one half years by PAP, and has fulfilled every obligation. She is requesting the Board to grant her permission to reenter the practice of pharmacy again as she feels she is now capable of executing the functions of a licensee in a manner consistent with the public's health, safety and welfare.

Edward McGinley moved, seconded by Marc Sturgill, that she review the continuing education credits submitted as they appear to be missing one (1) law credit. She should also be scheduled for an Investigative Inquiry.

Motion passed 7-0.

8) **Tara Wiltrout – Genoa Healthcare – Request for approval to open pharmacies less than 40 hours per week.**

Tara Wiltrout is a pharmacist and National Sales Manager with Genoa Healthcare. She is requesting the Board's consideration to allow a part-time pharmacy within the State of New Jersey. Genoa Healthcare is a mental health specialty pharmacy provider, and they are working to develop a partnership with South Jersey Behavioral Health Resources (SJBHR), an organization that serves clients living with severe and persistent mental illness (SPMI) with offices in both Camden and Stratford. She states that Genoa cannot feasibly justify opening a full-time pharmacy at each location. Instead, they believe that they would be able to serve the most clients and make the largest clinical impact if they could operate a part-time pharmacy at each clinic location.

Edward McGinley moved, seconded by Richard Palombo, for Ms. Wiltrout to address the following questions:

- Address steering issue, will patients have freedom of choice as to where to have their prescriptions filled ?
- Insurance issues; do the clients have policies that mandate the use of mail order that will preclude patients from using this location ?
- How will pharmacists be available for patient consultation and DUR issues with limited hours ?
- Who will have access to the pharmacy when it is closed?
- What is the patients' ability to contact the pharmacist after hours?

- How are refills addressed ?
- Are, or will there be, any patients on Clozapine therapy (which requires additional monitoring)?

The answers to these questions will assist the Board in determining if they should give possible consideration for specialized permit under N.J.A.C 13:39- 4.16 Specialize Permits. **Motion passed 7-0.**

- 9) **John Magalla – Home Solutions Infusion Therapy** – Request for approval of Pharmacy Technician Training program.

Mr. Magalla provided documentation regarding their patient care representatives and intake specialists responsibilities and their training. They are trained and then evaluated at 90 days and annually thereafter. He is asking the Board to let him know if the training Home Solutions provides is sufficient to allow them to exceed the 2-1 pharmacist to technician ratio.

Margherita Cardello moved, seconded by Richard Palombo, to deny the request until the Standard Operating Procedures are updated to meet the minimum criteria and content as outlined in the Pharmacy Technician Training Program Content worksheet. Once it has been updated, Mr. Magalla may resubmit it for the Board's review/approval. **Motion passed 7-0.**

- 10) **PARE Exam- Item Development Workshop** – November 7-8, 2013

The National Association of Boards of Pharmacy (NABP) will host a Pharmacist Assessment for Remediation Evaluation (PARE) Item-Development Workshop on November 7-8, 2013, at NABP Headquarters in Mount Prospect, IL. The two-day meeting will begin with an overview of the PARE examination, followed by an instructional session on item writing led by NABP staff. NABP encourages participation from members and staff from boards of pharmacy who have knowledge and experience in one or more of the following three content domains.

- Medication Safety and the Practice of Pharmacy (Area 1- 50% of questions)
- Professional Ethics/Pharmacist Judgment (Area 2 - 25% of questions)
- Clinical Pharmacy Practice (Area 3 - 25% of questions)

Chair Direct: Marc Sturgill will attend this workshop to represent New Jersey.

- 11) **Pipeline Rx** – Request for approval of Central Prescription Handling Agreement and remote processing.

Pipeline Rx is based in Illinois, and is registered with New Jersey as an out-of-state pharmacy. Chris Ciolko attended the meeting to answer any questions the Board may have had regarding a Central Prescription Handling Agreement that Pipeline had submitted with the Memorial Hospital of Salem County in New Jersey. The Board confirmed that all Pharmacists are employed by Pipeline, and that they are licensed in Illinois.

Richard Palombo moved, seconded by Stephen Lieberman, to approve this Central Prescription Handling Agreement contingent upon Pipeline Rx supplying the Board with a roster of the employee pharmacists licensed in Illinois and employed by Pipeline Rx that will be participating in this specific agreement. **Motion passed 7-0.**

12) **Village Fertility** – Request for modification of Consent Order

Village Pharmacy entered into a Consent Order with New Jersey on March 8, 2013, preventing them from shipping any medication to patients in New Jersey, based on action taken by their home state of Massachusetts due to a contamination issue related to sterile products.

David Brass, the Quality Assurance Manager for Village Fertility, indicated that Massachusetts had authorized Village Fertility to begin compounding low risk sterile products. They are asking for a modification of the New Jersey Consent Order to allow them to resume shipping these low risk sterile compounded products to patients in New Jersey.

Edward McGinley moved, seconded by Richard Palombo for DAG Cordoma to offer a Consent Order allowing resumption of shipping low risk sterile compounded products into New Jersey based on the approval of Massachusetts Board; the order will be limited to the list of medications provided to date. **Motion passed 7-0.**

13) **Gordon Magee, Drs. Foster & Smith** – Concern Regarding Restricted Distribution and Revenue Sharing between Veterinarians and Pharmacies.

Mr. Magee provided the Board with material that was sent to one of this group's Veterinarians. It was a solicitation from Wag. com to get Veterinarians into the Vet Source program. Mr. Magee is concerned with the Vet Source model of sharing prescription revenue in some form, with veterinarians.

Edward McGinley moved, seconded by Richard Palombo, to accept this as informational, and had no comment at this time. **Motion passed 7-0.**

VII. MITIGATION/HEARING REQUEST

1) **Carla Goldberg, RPh, Pharmacy Manager** – Walgreens, Lodi, NJ

Ms. Goldberg requested that the fine for violation of N.J.A.C.13:39-4.3 be mitigated. The Board of Pharmacy permit for the store which could not be located at the time of the inspection was at the store and of course was active and in good standing. A copy was also resubmitted with her mitigation request and

she asked the Board to mitigate the fine associated since the permit was active at the time of the inspection.

Stephen Lieberman moved, seconded by Mahesh Shah, to deny the mitigation request. Thomas Bender was recused due to his affiliation with Walgreens. **The motion tied 3-3 and did not pass.**

The Board entertained additional discussion of this mitigation request, and on the second attempt, Stephen Lieberman moved, seconded by Mahesh Shah, to deny the mitigation request. Thomas Bender was recused due to his affiliation with Walgreens. **This time the motion passed 4-2.**

2) Marian Mikaile, RPIC – Brunswick Square Pharmacy, East Brunswick, NJ

Ms. Mikaile submitted a request to waive the Penalty of \$10,000.00 for not having the CDS registration Active for a period of time. She indicated that she had only been in business for a short period of time, and now fully understands that she must keep all licenses active at all the time and that is her responsibility to renew all the licenses in the appropriate time before its expiration date.

Back in October, 2012, she indicated that she was trying to renew the CDS License online, and thought that it was renewed (as that was the first time she had used the renewal online service). She later determined that the CDS license was expired and realized a mistake had been made.

Thomas Bender moved, seconded by Edward McGinley, to deny this mitigation request. **Motion passed 7-0.**

3) Deborah Hurley – on behalf of RiteAid # 1360, Washington Township, NJ

Deborah Hurley contacted the Board to request mitigation of fines assessed to Rite Aid #1360 as a result of the inspection deficiencies noted on 10/25/12. The PDM met with the PIC a few days after the inspection to review all of the deficiencies as well as to issue a written corrective action notice. The staff pharmacist was also counseled as a result of the inspection deficiencies and issued a written corrective action notice.

In late December the PDM conducted his own unannounced inspection at RA 1360 and found that many of the same violations existed. Both the PIC & staff pharmacist were issued final written corrective action notices -- both of these pharmacists were terminated a few weeks later.

The PDM replaced the pharmacist staff, corrected all of the inspection deficiencies as well as performed a white glove inspection himself to assure that the new pharmacist staff in place was continuing to operate the pharmacy violation free.

Ms. Hurley wanted the Board to be aware as to the corrective action taken by Rite Aid to bring this store into 100% compliance.

In light of the actions that Rite Aid proactively undertook prior to the receipt of the July 19th fine notice, she requests that the Board consider lowering the amount of the fine. She is not contesting the fact that these violations did exist but rather are asking for instance if the 73 vials that were misbranded (original fill date crossed out) could be assessed at \$25 per rather than \$50. This would bring the total amount of the penalty from \$4,400 to \$2,575.

Margherita Cardello was recused due to her affiliation with Rite Aid. Based on the explanation provided to the Board, Edward McGinley moved, seconded by Stephen Lieberman, to mitigate the fine as requested. **Motion passed 6-0.**

VIII. INFORMATIONAL

1) **Changes to AbbVie's Vicodin formulation**

The Board took this item as informational.

2) **Commercial availability of 'INDOCIN'**

The Board took this item as informational.

3) **Joseph Gani, RPh – Enforcement Bureau – Request for review of proposal for monitoring refrigerator temperatures.**

Mr. Gani is an Inspector with the Enforcement Bureau, He wrote to the Board, regarding a concern he had noticed as described below.

"With the expanding role of immunizing pharmacists in both the retail chain and independent pharmacy settings, I see the need to include refrigerator and freezer thermometers as mandatory equipment in those pharmacies that stock and administer vaccines. At present, the "New (retail) Pharmacy" application requires that the refrigerator be operational (N.J.A.C. 13:39-5.8(a)12) Item (A) page #6. The current guidelines require that refrigerated vaccines as well as other medications to include insulin, certain eye drops, suppositories, and birth control devices to be stored at a temperature range between 35 degrees (F) - 46 degrees (F), and frozen vaccines to be stored at a temperature range between 5 degrees (F) and -30 degrees (F) or colder. To ensure the integrity of these specific vaccines and refrigerated medications with respect to public safety, I feel that we as Enforcement Bureau inspectors for the Board of Pharmacy should assume the responsibility to check that the subject pharmacies have functional thermometers and that the refrigerators are operational within the required temperature range at the time on inspection."

Edward McGinley moved, seconded by Richard Palombo, to refer Mr. Gani's suggestion to the Rules and Regulations Committee for review and consideration. **Motion passed 7-0.**

IX. COMMITTEE REPORTS

Edward McGinley reported the following items from the Rules and Regulations Committee which was held on 8/15, 2013:

- Pharmacy Technician Regulation changes were adopted on 8/5/13.
- The Container draft regulations are currently in review by the Division of Law.
- One of the main agenda items for the September 26, 2013 Rules and Regulation Committee meeting is to draft guidance for pharmacists on what items may be added and/or changed on Schedule II prescriptions

X. APPROVAL OF MINUTES

July 24, 2013 Public Session Minutes

Stephen Lieberman moved, seconded by Edward McGinley, to approve the July 24, 2013 Public Session Minutes as amended. **Motion passed 7-0.**

At 12:15 p.m., Richard Palombo moved, seconded by Stephen Lieberman, to go into Executive Session. **Motion passed 7-0.**

At 12:22 p.m., Richard Palombo moved, seconded by Margherita Cardello, to go back into Open Session. **Motion passed 7-0.**

The Board received a request from NABP to review the Multistate Pharmacy Jurisprudence Examination (MPJE) question pool to verify the accuracy and relevancy of questions that may be asked to candidates taking the New Jersey MPJE examination.

The people who will be reviewing the questions between 9/3/13 – 9/13/13 are: Marc Sturgill, Edward McGinley, Richard Palombo, Thomas Bender and Margherita Cardello.

At 12:27 p.m., Richard Palombo moved, seconded by Margherita Cardello, to go back into Executive Session. **Motion passed 7-0.**