



New Jersey Office of the Attorney General

Division of Consumer Affairs

Board of Pharmacy

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BOARD OF PHARMACY OPEN SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7TH FLOOR August 27, 2014

I. CALL TO ORDER

The Open Session of the New Jersey Board of Pharmacy was called to order by the Board President, Mr. Thomas F.X. Bender, at 124 Halsey Street, Monmouth Conference Room, 7th floor, on August 27, 2014 at 8:50 a.m. All members were duly notified of the time, place and all pertinent materials were provided to members.

II. SUNSHINE LAW ANNOUNCEMENT

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

III. ROLL CALL

Thomas F.X. Bender, R.Ph.	President
Richard Palombo, R.Ph.	Vice President
Margherita Cardello, R.Ph.	Late arrival 9:30 a.m.
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Calliope Alexander	
Carol Jacobson, Esq.	
Linda Witzal, R.Ph.	
Mitch Sobel, R.Ph.	Excused absence

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director
Linda Brodie	Board Staff
Megan Cordoma	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of July, \$23,100 was collected in fines and

penalties. The following permits, licenses, and registrations were issued during the month of July:

- Technicians registered - 144
- Pharmacists Licensed - 50 (35 by examination and 15 by reciprocity)
- Out-of- State Pharmacies registered –4
- In State Pharmacies licensed –5
- Pharmacists receiving immunization approval – 71
- Interns (foreign graduates) licensed – 3

V. OLD BUSINESS

1) Orders Filed

- a) Vince Deluca, R.Ph. - Consent Order of Reinstatement of License (7/10/14)
- b) Pharmacy Creations - Second Interim Consent Order (7/21/14)
- c) Ahmed Aly, R.Ph. - Provisional Order of Discipline (7/23/14)
- d) Oliver Alvarez, Pharmacy Technician - Provisional Order of Discipline (7/23/14)
- e) Peter Riccio, R.Ph. - Notice of Hearing (7/29/14)
- f) Peter Riccio, R.Ph. - Administrative Action Complaint (7/29/14)
- g) Tammanna Chopra, R.Ph. - Consent Order (7/28/14)
- h) Mandells Clinical Pharmacy -Interim Consent Order (8/4/14)

2) Candice Gianettino, Pharmacy Technician - POD to be finalized

On or about November 7, 2012, Respondent provided a handwritten, voluntary, signed, sworn statement to Gina Callahan, MAPM, admitting that she stole CDS from her employer, Walmart Pharmacy. A POD was issued on May 9, 2014 seeking a minimum 5 year suspension.

Stephen Lieberman moved, seconded by Mahesh Shah, to finalize the POD by default without modification. The Board determined that service was adequate, and no response was received. **Motion passed 8-0.**

3) Stephen Matthews, Pharmacy Technician - POD to be finalized

This item was tabled; the Board office is to remail the POD with a complete set of exhibits attached.

4) John Hussey, Pharmacy Technician - POD to be finalized

On or about July 22, 2013, Mr. Hussey provided a handwritten, voluntary, signed, sworn statement to Tim Russell, Regional Loss Prevention Manager, admitting that he stole medications from his employer, CVS pharmacy, for his own use. A POD was issued on June 3, 2014 seeking a minimum 5 year suspension.

Stephen Lieberman moved, seconded by Mahesh Shah, to finalize the POD by default without modification. The Board determined that service was adequate, and no response was received. **Motion passed 8-0.**

5) Candyce Craig, Pharmacy Technician - POD to be finalized

On or about August 23, 2013, Ms. Craig provided a handwritten, voluntary, signed, sworn statement to Scott McMullen, District Loss Prevention Manager of the Walgreen Company, admitting that she had stolen medications for personal use from her employer. A POD was issued on May 28, 2014 seeking a minimum 5 year suspension.

Stephen Lieberman moved, seconded by Mahesh Shah, to finalize the POD by default without modification. The Board determined that service was adequate, and no response was received. **Motion passed 8-0.**

6) Jalika Dorsey, Pharmacy Technician - POD to be finalized

On or about August 23, 2013, Ms. Dorsey provided a handwritten, voluntary, signed, sworn statement to Alexandra Rutch, District Loss Prevention Manager of the Walgreen Company, admitting that she stole medication from her employer, Walgreens, and sold it to pay her bills. A POD was issued on May 28, 2014 seeking a minimum 5 year suspension.

Stephen Lieberman moved, seconded by Mahesh Shah, to finalize the POD by default without modification. The Board determined that service was adequate, and no response was received. **Motion passed 8-0.**

VI. NEW BUSINESS

1) Clarification of N.J.A.C. 13:39-4.21- Requirements for pharmacists to Administer Influenza Vaccine to patients over the age of 7

Rachel Glasgow provided an overview of the clarification below that was added to N.J.A.C. 13:39-4.21(d):

(d) A pharmacist shall not administer an influenza vaccine to a patient who is younger than seven years of age.

Carol Jacobson moved, seconded by Linda Witzal, to approve this minor clarifying change. **Motion passed 8-0.**

2) **Karen Scoullos, Pharm.D. - Collaborative Practice Pre-Approval Application**

Edward McGinley moved, seconded by Linda Witzal, to approve this application as the criteria for approval has been met. **Motion passed 9-0.**

3) **Laura Balsamini, Pharm. D. - Collaborative Practice Pre-Approval Application**

Richard Palombo moved, seconded by Stephen Lieberman, to approve this application as the criteria for approval has been met. **Motion passed 9-0.**

4) **Megan Maroney, R.Ph. - Collaborative Practice Pre-Approval Application**

Edward McGinley moved, seconded by Mahesh Shah, to approve this application as the criteria for approval has been met. **Motion passed 9-0.**

5) **Otsuka American Pharmaceutical, Inc. - Inquiring regarding Drug Manufactures giving out Samples in Hospitals and to patients upon discharge**

Rich Aiena & Ray Zarzar attended to represent Otsuka, and answered questions the Board had regarding this request. The request is to administer sample medication to schizophrenic patients without charge, to help ensure compliance with treatment.

The Board understands the benefits of administering medications to this particular patient population, however, New Jersey's regulations prohibit pharmacies from storing or dispensing samples of medications to patients. The Board instructed Mr. Aiena and Mr. Zarzar to review N.J.A.C.13:39-1.6 (waiver rule), and to present a waiver request for each individual pharmacy where they would like to implement this program. The Board will review each request individually.

6) **Analysis of Drug Quality and Security Act ("DQSA")– Impact of creation of 503B Outsourcing Facilities on New Jersey's current laws and regulations**

It is unclear what impact, if any, the new DQSA law will have on New Jersey's laws and regulations pertaining to the practice of pharmacy. This matter will be referred to the Rules and Regulations Committee, who will analyze the impact and present it's finding to the full Board at a future date.

I. MITIGATION REQUEST

1. **Jacqueline White, RPIC - University Medical Center of Princeton at Plainsboro, Plainsboro, NJ**

Following an inspection revealing lack of display of a Pharmacy Technician's license, a UPL was issued seeking a fine for this violation. Ms. White offered this

explanation for the Board to consider:

“Pharmacy Technician Jhonnalyn T. Lu did not have her biennial renewal displayed in the pharmacy because she also works at a commercial retail pharmacy that had the original copy on display there. Mrs. Lu brought a copy of that renewed license, which I held in my office and presented to the inspectors. A few weeks prior to our inspection, Mrs. Lu was told that she could not have a copy displayed and needed to apply for an original copy for the hospital. At the time of inspection Mrs. Lu had not received the original copy requested online and since her license was expiring in August 2014, I told Mrs. Lu to apply for her license renewal which she has received and is on display at the University Medical Center of Princeton at Plainsboro.”

Edward McGinley moved, seconded by Mahesh Shah, to remove the \$50 Fine & the citation. **Motion passed 8-1.** Thomas Bender was opposed.

2. Krunal Kararadia, R.Ph. - Rite Aid Pharmacy, Clementon, NJ

Following an inspection revealing the following violations: “Name of present day RPIC not posted”, and “For those instances when the patient or caregiver is not physically present, there was no system to notify the patient of the offer to counsel; specifically Rx #0782763, #0784920 and #0784956”, a UPL was issued seeking a fine for these violations and a letter of corrective action. Deborah Hurley, Government affairs administrator for Rite Aid provided this explanation for the Board to consider:

“The purpose of this letter is to respond to the deficiency notice issued to Rite Aid Pharmacy #236 due to the \$1,000 penalty assessed for no system to notify the patient of the offer to counsel when the patient or caregiver is not physically present.

In such instances, the attached form is completed and inserted into the prescription bag. In fact, this form is provided to all patients that receive a prescription delivered at their home.

Rite Aid utilizes this form in every state in which we do business and up until the inspection at Rite Aid #236 on 11/24/13 as well as a small handful of other stores (inspections performed by the same individual), we have never been cited for failure to provide the patient as to the offer to counsel when the patient or caregiver is not physically present.

For your files, I have attached the Certification form completed by Krunal Kararadia who is the current PIC at Rite Aid 236 in Clementon.

We would respectfully request that the \$1,000 penalty cited above be withdrawn by the Board.”

Edward McGinley moved, seconded by Thomas Bender, to mitigate this citation for violation of N.J.A.C. 13:39-7.21(d) to a warning, as only one criteria was

missing regarding patients being able to contact the pharmacy for counseling. Margherita Cardello was recused due to her affiliation with Rite Aid. **Motion passed 8-0.**

3. Emmanuela Audige, RPIC - Walgreens Pharmacy, Bloomfield, NJ

Following an inspection revealing the following violations: “outdated medications found in active drug stock”, “The hours that the pharmacy department is open were not posted in plain view at the entrance to the pharmacy department.”, and “The telephone number of the RPIC was not available in the office of the manager of the establishment”, a UPL was issued seeking a fine for these violations and a letter of corrective action.

Emmanuela Audige, RPIC, provided this explanation for the Board to consider:

“Please allow this letter to serve as a request for partial mitigation for the citation from my inspection on 2/1/2013. The (12) items cited as outdated for over 1 year were actually quarantined compounding ingredients not in active stock. They were kept in a box separate from the active drug stock waiting to be returned to an appropriate vendor.

Kindly consider my request for mitigation of the \$600.”

Edward McGinley moved, seconded by Margherita Cardello, to mitigate the \$600 fine and remove the citation. Thomas Bender was recused due to his affiliation with Walgreens. Stephen Lieberman was opposed. **Motion passed 7-1.**

4. Vincent Paparo, RPIC - Rite Aid Pharmacy, West Deptford, NJ

Following an inspection revealing the following violation: “For those instances when the patient or caregiver is not physically present, there was no system to notify the patient of the offer to counsel; specifically Rx #67469, #67442 and #67486.”, a UPL was issued seeking a fine for this violations and a letter of corrective action.

Deborah Hurley, Government affairs administrator for Rite Aid provided this explanation for the Board to consider:

“The purpose of this letter is to respond to the deficiency notice issued to Rite Aid Pharmacy #4094 due to the \$1,000 penalty assessed for no system to notify the patient of the offer to counsel when the patient or caregiver is not physically present.

In such instances, the attached form is completed and inserted into the prescription bag. In fact, this form is provided to all patients that receive a prescription delivered at their home.

Rite Aid utilizes this form in every state in which we do business and up until the inspection at Rite Aid #4094 on 1/16/13 as well as a small handful of other stores (inspections performed by the same individual), we have never been cited for failure to provide the patient as to the offer to counsel when the patient or caregiver is not physically present. For your files, I have attached the Certification form completed by PIC Vincent Paparo.

We would respectfully request that the \$1,000 penalty cited above be withdrawn by the Board."

Richard Palombo moved, seconded by Stephen Lieberman, to mitigate this citation for violation of N.J.A.C. 13:39-7.21(d) to a warning, as only one criteria was missing regarding patients being able to contact the pharmacy for counseling. Margherita Cardello was recused due to her affiliation with Rite Aid. **Motion passed 8-0.**

5. Anna Malinskaya, RPIC - Rite Aid Pharmacy, Voorhees, NJ

Following an inspection revealing the following violation: "For those instances when the patient or caregiver is not physically present, there was no system to notify the patient of the offer to counsel", a UPL was issued seeking a fine for this violations and a letter of corrective action.

Deborah Hurley, Government affairs administrator for Rite Aid provided this explanation for the Board to consider:

"The purpose of this letter is to respond to the deficiency notice issued to Rite Aid Pharmacy #1596 due to the \$1,000 penalty assessed for no system to notify the patient of the offer to counsel when the patient or caregiver is not physically present.

In such instances, the attached form is completed and inserted into the prescription bag. In fact, this form is provided to all patients that receive a prescription delivered at their home.

Rite Aid utilizes this form in every state in which we do business and up until the inspection at Rite Aid #1596 on 12/18/12 as well as a small handful of other stores (inspections performed by the same individual), we have never been cited for failure to provide the patient as to the offer to counsel when the patient or caregiver is not physically present. For your files, I have attached the Certification form completed by PIC Anna Malinskaya.

We would respectfully request that the \$1,000 penalty cited above be withdrawn by the Board ."

Stephen Lieberman moved, seconded by Richard Palombo, to mitigate this citation for violation of N.J.A.C. 13:39-7.21(d) to a warning, as only one criteria was missing regarding patients being able to contact the pharmacy for counseling. Margherita Cardello was recused due to her affiliation with Rite Aid. **Motion passed 8-0.**

6. Pathik Brahmhatt, R. Ph. - CVS Pharmacy, Denville, NJ

Following an inspection revealing the following violations: “exceeding the 2:1 Pharmacy Technician/Pharmacist ratio. No documentation available supporting PTCB certification or passing CVS’ in house training program”, “outdated medications in active prescription stock”, and “incorrect prescribers name recorded in the computerized mpatient profile system, a UPL was issued seeking a fine for this violations and a letter of corrective action.

Pathik Brahmhatt, RPIC, provided this explanation for the Board to consider:

“In response to the inspection that occurred on February 22, 2013, I respectfully request to mitigate the fines associated with N.J.A.C.13:39-6.15(d)(e)(f).

Please accept this letter of Corrective action in response to the inspection report referenced above. The following actions have been taken in order to address each citation, outlined below.

N.J.A.C. 13:39-6.15(d)(e)(f): The pharmacy received a citation because at the time of inspection, there were three pharmacy technicians present and on duty and only one pharmacist present and on duty, thus exceeding the 2:1 pharmacy technician/pharmacist ratio. Additionally, there was no documentation available to attest that each of the technicians had either taken or passed the PTCB National Examination or successfully completed the Board of Pharmacy approved CVS in-house Pharmacy Technician Training Program. The following corrective actions have been taken:

- Documentation is available to show that all three pharmacy technicians working on February 22, 2013 had successfully completed the Board of Pharmacy approved CVS in house Pharmacy Technician Training Program. (See attached.) Documentation is retained in the 2014 Records Box .*

...”

Chair Direct: Board Counsel will reach out to this pharmacist to discuss the Hearing process.

7. Gerald Coice, R.Ph. - Valley Pharmacy, Clifton, NJ

Following an inspection revealing the following violation: “Photocopies of two pharmacist’s licenses were posted on display”, a UPL was issued seeking a fine for this violations and a letter of corrective action.

Gerald Cioce, RPIC, provided this explanation for the Board to consider:

“This letter is in response to the fines assessed against Valley Pharmacy in Clifton, New Jersey for the failure to post the original pharmacist license of Anthony Cioce in the pharmacy and the alleged failure of Gerald Cioce to post his original pharmacist license in the pharmacy.

Anthony Cioce is a relief pharmacist for Valley Pharmacy (as opposed to staff pharmacist at the pharmacy) and accordingly may choose to work at other pharmacies from time to time. Moreover, Mr. A. Cioce was not working at the pharmacy on the day the fine was assessed. Therefore it would not be appropriate or reasonable for his original pharmacist license to be posted at Valley Pharmacy as he would need his original pharmacist license to post at other pharmacies where he may choose to work. Instead Mr. A. Cioce's original pharmacist license would only be posted at Valley Pharmacy when he is the pharmacist on duty there. Accordingly, the fine assessed against Valley Pharmacy for the failure of Mr. A. Cioce to post his original pharmacist license at the pharmacy is neither accurate nor reasonable and I respectfully request that such fine be removed and any violation associated therewith be cleared.

Gerald Cioce is the pharmacist in charge at Valley Pharmacy. On the date the Board of Pharmacy inspected Valley Pharmacy Mr. G. Cioce had planned to visit the Department of Motor Vehicles to replace his lost driver's license. In order to facilitate the replacement of his lost driver's license, Mr. G. Cioce intended to bring his original pharmacist license as evidence of his identity. Mr. G. Cioce explained this to the Board of Pharmacy inspector and, with the permission of the inspector, Mr. G. Cioce left during the inspection with his original pharmacist license to seek to replace his driver's license. Mr. G. Cioce offered to show his original pharmacist license before leaving but was advised by the inspector that he did not need to do so as part of the inspection. Therefore Mr. G. Cioce left the inspector, however a staff pharmacist remained at the pharmacy with a copy of Mr. G. Cioce's pharmacist license. Nevertheless, a fine was assessed against Valley Pharmacy for the alleged failure of Mr. G. Cioce to have his original pharmacist license posted at the pharmacy. Accordingly, such fine is neither accurate nor reasonable and I respectfully request that such fine be removed and any violation associated therewith be cleared.”

Thomas Bender moved, seconded by Edward McGinley, to mitigate the fine to a warning. **Motion passed 9-0.**

II. INFORMATIONAL

1. **October Board Meeting - Director Anthony Rubinaccio will not be able to attend**

Director Rubinaccio will be chairing a task force offsite for NABP on this date. The Board suggested that the meeting be moved to October 29th, and that the proper notifications be made to properly inform all interested parties of the rescheduling of this meeting.

2. Rachel Glasgow noted that the **Container Integrity rules** received no comments, and will be on a future Board agenda for review.

3. **NJPB:** Rachel Glasgow updated the Board that the time that medical professionals may utilize the old prescription blanks has been extended until September 19, 2014. Written prescriptions must utilize the new prescription blanks beginning September 20, 2014.

XI. COMMITTEE REPORTS

N/A

X. APPROVAL OF MINUTES

July 23, 2014

Richard Palombo moved, seconded by Mahesh Shah, to approve the July 23, 2014 Open Session minutes as amended. **Motion passed 9-0.**

XI. ADJOURNMENT

At 10:42 a.m. Richard Palombo moved, seconded by Stephen Lieberman, to adjourn the Public Session and move into the Executive Session for review of 4 Complaints, 1 Old Business Item, 12 New Business Items, the Secretary's Report and Recommendation on Retail and Institutional Permits, the Secretary's Report and Recommendation on Inspection Reports, and the approval of the July 23, 2014 Executive Session Minutes.