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BOARD OF PHARMACY PUBLIC SESSION MEETING MINUTES SOMERSET CONFERENCE ROOM, 6th FLOOR January 29, 2014

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 Somerset Conference Room at 124 Halsey Street, Newark, New Jersey on January 29, 2014, at 9:10 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 9:19 AM
Marc Sturgill, PharmD	
Mahesh Shah, R.Ph.	Absent
Stephen Lieberman, R.Ph.	
Edward McGinley, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director
Rachel Glasgow	Regulatory Analyst
Matthew Wetzel	Government Representative
Linda Brodie	Board Staff
Jodi Krugman	Deputy Attorney General

IV. UPDATES BY EXECUTIVE DIRECTOR

Executive Director Rubinaccio reported for the month of December, \$ 44,250 in fines and penalties were collected. The following permits, licenses, and registrations were issued during the month of December:

- Technicians - 117
- Pharmacist - 35 (31 by examination/score transfer and 4 by reciprocity)
- Out-of-state pharmacies – 9
- In-state pharmacies - 5
- Pharmacists receiving immunization approval - 35
- Interns - 5

V. OLD BUSINESS

1) Public Orders Filed

- a. Jacobs Pharmacy - Order to Show Cause (12-9-13)
- b. Jacobs Pharmacy - Verified Complaint (12-9-13)
- c. Nicholas Parios, R.Ph. - Consent Order (12-11-13)
- d. Kavitha Paredy, R.Ph. - Consent Order to Reinstate (12-11-13)
- e. Dennis Kelly, P.T. - Final Order of Discipline (12-11-13)
- f. Helen Chavarriga, P. T. - Final Order of Discipline (12-11-13)
- g. Alfredo Balleras, R.Ph. - Amended Consent Order of Reinstatement (12-11-13)
- h. Kenneth Grossett, R.Ph. - Order Granting Unrestricted License (12-11-13)
- i. Robert A. Carlucci, R.Ph. - Consent Order of Surrender to be Deemed a Revocation (12-11-13)
- j. Jose Maltez, P.T. - Final Order of Discipline - (12-11-13)
- k. Liberty Drug & Surgical - Interim Consent Order (12-19-13)
- l. Robert Bucco, R.Ph. - Consent Order (12-23-13)

2) Bishoy Roshdi - Request for waiver of TOEFL Exam

From the November 13, 2013 Open Session minutes:
“(Tabled from 10-23-13 Agenda)

Mr. Roshdi indicates that he has a documented speech impediment which is preventing him from passing the speaking component of the TOEFL examination.

Edward McGinley moved, seconded by Thomas Bender, to table this request, and for the Board office to ask Mr. Rosdhi to provide evidence he is obtaining therapeutic intervention with the speech pathologist to indicate that he is trying to correct the speech impediment. Motion passed 7-0.”

Mr. Roshdi presented a report from his speech pathologist, Marian Ayad. Ms. Ayad indicated Mr. Roshdi (the ‘client’) received a speech-language evaluation

on September 12th, 2013. The findings of the evaluation revealed that Mr. Roshdi exhibits decreased intelligibility in conversational exchange due to an increased rate of speech and distortion of the /r/ phoneme. Based on this, speech therapy was recommended to remediate the aforementioned. To this date, Mr. Roshdi has attended seven therapy sessions. The client's rate of speech is being targeted as the primary therapy goal as it will have the maximum impact on Mr. Roshdi's overall intelligibility. Progress is noted as Mr. Roshdi is currently demonstrating increased discrimination of fast vs. slow speech rate in the speech of others. He is also able to inconsistently discriminate fast vs. slow rate in his own speech during structured tasks. However, verbal prompts are beneficial in improving the client's discrimination skills. Verbal prompts are also necessary at this time to assist the client in modifying his rate of speech during structured reading tasks of increased length and complexity. Based on the client's motivation and his progress thus far, prognosis is judged to be good.

Richard Palombo motioned, seconded by Stephen Lieberman, to allow Mr. Roshdi to take the TOEFL examination one more time. **Motion passed 6-0.**

3) Angelo Cifaldi, Esq - request to reinstate the license of his client Nick Stamatiadis, R.Ph.

Marc Sturgill moved, seconded by Stephen Lieberman, to deny this request. Mr. Stamatiadis may seek unrestricted reinstatement after July 12, 2014. The Board would like to see reports of negative urine screenings and updated reports from PAP. **Motion passed 6-0.**

VI. NEW BUSINESS

1) Express Scripts - New Facility

Phil Wickizer, senior legal counsel for Express Scripts, and Linda Doremus, Pharmacist in Charge for Express Scripts in Willingboro, New Jersey, presented an overview of a new facility which is being constructed to replace the original Express Scripts (previously "Medco") facility in Willingboro, New Jersey.

The facility will be open in 'value streams' phases due to the size of the operations. There will be no compounding, and no control substances dispensed at this site. The Value Streams consist of:

- * High volume filler
- * Unit of Use: labeled and passed through bar coding (ie. eye drops).
- * ICE : refrigerated products

Automation will be used for the first two value streams. This presentation was made to provide the Board the opportunity to ask any questions or raise any concerns they might have. Board President Bender indicated that the facility must be in a state of readiness to have the permit granted, and must also be inspected.

Waivers to exceed the Pharmacist / Pharmacy Technician ratio (as outlined in the regulations), as well as any existing Central Prescription Handling Agreements, will need to be resubmitted for approval.

The Board took this as an informational item.

2) **Giannotto's Specialty Pharmacy - Request for Institutional Permit**

Angelo Cifaldi sent a letter to the Board, on behalf of Giannotto's Pharmacy, requesting an Institutional Permit be issued to the pharmacy (in addition to their existing retail permit). Mr. Cifaldi wrote, in part:

"In the present instance, the Applicant plans to operate a "closed-door" pharmacy that will serve long-term care and assisted living facilities, such as nursing homes, pursuant to contracts with these institutions. The primary purpose of the pharmacy will be to prepare and dispense patient specific specialized medications to the residents of these facilities. The pharmacy will not be open to the public."

The Board noted that Giannotto's Pharmacy can service these clients under their current retail permit. This request does not meet the requirements of an Institutional permit. The pharmacy may be contracting with multiple health care systems, assisted living facilities may use a personal physician prescribing medication for a patient via a prescription, not a medication order, to be sent to the patient. The Board reviewed and decided that in their interpretation of subchapter 9 of N.J.A.C. 13:39 of the Pharmacy Regulations, this is not applicable to their business model.

The Board also commented that the dimensions of prescription department do not include specialty rooms 1 & 2. If Giannotto's wishes to pursue the increased workspace on second floor, they should submit a remodeling application which includes these areas as part of the pharmacy.

Edward McGinley moved, seconded by Marc Sturgill, to allow the application request to be withdrawn in lieu of having the Board deny it. **Motion passed 6-0.**

3) **Nilay Thakkar - Request for waiver of TOEFL Exam**

Mr. Thakkar has taken the TOEFL examination at least 21 times over the last 2 years, but has been unable to pass all required sections during the same examination period. He completed the FPGEE in April, 2011, and is asking the Board to waive the TOEFL requirement so that he can begin his internship.

Edward McGinley moved, seconded by Margherita Cardello, to deny this waiver request as Mr. Thakkar has not provided evidence of a medical hardship. **Motion passed 6-0.**

4) Michael Casner, R. Ph - Reciprocity Applicant working in industry

Mr. Casner is applying for licensure as a pharmacist in New Jersey by means of reciprocity from the state of Kansas. He has had a current license (renewed in June 2013) to practice pharmacy in Kansas, maintained in part by continued education. However, he has lived in New Jersey for the last fifteen years and has been involved with pharmaceutical manufacturing in New Jersey for thirteen years, and has been teaching chemistry full time at Rowan University for the last two years. He was interested in shadowing a pharmacist and/or fulfilling a pharmacy internship in order to become appropriately qualified to practice pharmacy in New Jersey.

Marc Sturgill moved, seconded by Margherita Cardello, to allow Mr. Casner to perform an internship of 1440 hours, as per New Jersey Board of Pharmacy regulations, under a guidance of a Board approved preceptor. The Board determined that his previous work experience does not meet the required 1500 hours of practice over past 2 years. **Motion passed 6-0.**

5) Angelo Cifaldi, Esq request to Modify Consent Order for client Calvin Osei, RPh

Mr. Cifaldi respectfully requested that the Board reinstate Mr. Osei's license on a probationary basis until May 4, 2014 because the length of Mr. Osei's suspension was predicated on the term of his probation. Mr. Osei completed his probationary term on December 17, 2013.

Stephen Lieberman moved, seconded by Thomas Bender, to deny this request. The Board noted that Mr. Osei is currently suspended until May 4, 2014. Even though his probation ended early, Mr. Osei's previous egregious behavior does not warrant this consideration. **Motion passed 6-0.**

6) CVS Technician Training Program - Assessment Questions Update

The CVS Training Team made minor changes to seven questions contained in their Pharmacy Technician Training program. The Board reviewed the changes.

The Board took this item as informational.

7) NABP MPJE Item Development Workshop -Being held March 20-21, 2014

The National Association of Boards of Pharmacy (NABP) will host the Multistate Pharmacy Jurisprudence Examination, (MPJE Item-Development Workshop on March 20-21, 2014, 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 writing led by NABP staff. Members from the MPJE Review Committee will be in attendance to assist item writers and to facilitate the meeting. The item-writing process is a collaborative effort, and NABP encourages all MPJE-participating states to attend this important event.

Richard Palombo moved, seconded by Marc Sturgill, to nominate President Bender to represent New Jersey at this meeting. **Motion passed 6-0.**

8) NABP 2014 Annual Meeting Delegate Selection

The NABP's 110th Annual Meeting will be held from May 17-20, 2014 in Phoenix, Arizona.

As per NABP bylaws, each active and associate member shall furnish credentials for the delegate and alternate delegates of the board to the Annual Meeting of this Association on a blank furnished by the Executive Director/Secretary and returned to the Association in accordance with policies set forth by the Executive Committee.

Edward McGinley moved, seconded by Marc Sturgill, to nominate Thomas Bender as the voting Delegate to represent New Jersey and the NABP Annual Meeting. **Motion passed 6-0.**

Marc Sturgill moved, seconded Thomas Bender, to nominate Richard Palombo as the Alternate Delegate. **Motion passed 6-0.**

9) Legislative Update - Rachel Glasgow provided the following overviews:

- **New Jersey Prescription Blank Regulations:** New security measures for prescription blanks will be published on February 18, 2014. The measures include print-based security features. Rachel will be able to disseminate more detailed information on this topic after February 18, 2014. This item will be included on the February Public Session Agenda as a discussion item.
- **Immunizations:** On January 21, 2014, Governor Christie signed into law S2567/A3251 permitting pharmacists to administer flu vaccine to children 7 years of age and older. The law requires pharmacists to obtain parental consent before administering the flu vaccine to patients under 18. In addition, for those patients who are between the ages of 7-11, a prescription is required. The Board of Pharmacy Regulations will need to be updated to reflect this change. The Board of Pharmacy and the Board of Medical Examiners will collaborate regarding the new rules.

The Board took this as informational.

VII. MITIGATION/HEARING REQUEST

1) **Young Sub Kim, RPIC - Toledo Pharmacy, Union City, NJ**

Edward McGinley moved, seconded by Richard Palombo to mitigate the \$1,000 fine and remove the citation for violation of N.J.A.C.13:45H-5.7, for the missing CDS inventory.

The request to mitigate the fine for violation of N.J.A.C.13:39-5.8(a)1 was denied because the Board determined the reference texts were too far out of date.

Marc Sturgill was recused because Mr. Kim was previously one of his students.
Motion passed 5-0.

2) **Mangeesh Joglebar, RPIC - Sav-On Pharmacy, Yardville, NJ**

Mr. Joglebar indicated that measures have been taken to correct the deficiencies noted during the inspection with the exception to the deficiency noted regarding the "use by" wording on the prescription label. It is unclear as to why the prescription label was found to be deficient. Mr. Joglebar is requesting a formal hearing to address this finding.

Edward McGinley moved, seconded by Richard Palombo, for DAG Krugman to contact Mr. Joglebar. If Mr. Joglebar rescinds his request for a hearing, and agrees to seek mitigation, the Board will remove the citation and fine for violation of N.J.A.C 13:39- 7.12(a)12 (use by date), and will send out an updated UPL.
Motion passed 6-0.

3) **Teresa A. Mars, RPIC - Bergen Point Pharmacy, Bayonne, NJ**

Pamela Mandel, esq, presented a mitigation request for Ms. Mars to the Board. Much of the request was based on change of ownership issues related to the sale of the business to Ms. Mars, and the incorrect name being placed on the change of ownership application for the pharmacist in charge. The Board reviewed all explanations presented and determined all actions had been corrected.

Thomas Bender moved, seconded by Edward McGinley, to deny all mitigation requests. **Motion passed 6-0.**

4) **Sreelatha Vattimilli, RPIC - Cresskill Pharmacy, Cresskill, NJ**

The pharmacy was cited for violations of N.J.A.C.13:39-5.8(a)1 and N.J.A.C.13:39-11-24 "Pharmacy library unsatisfactory; specifically, software vendor uses Clinical Data Services which is not on Board approved list for patient counseling.". Ms. Vattimilli claims there was a misunderstanding between the pharmacy staff and the Enforcement Bureau inspectors on the use of this software.

Edward McGinley moved, seconded by Stephen Lieberman, to deny this mitigation request. Motion passed 6-0.

5) Liliam Spieker, R.Ph. - Main Pharmacy, Vineland, NJ

Ms. Spieker is requesting mitigation of the \$600.00 fine for N.J.A.C.13:39-5.8(a)1 "Pharmacy library unsatisfactory (To be determined, see Exhibit #4)". At the time of the inspection, Ms. Spieker presented the same references used in the pharmacy library to be approved for our pharmacy licensure. One of these references is the exact software we have that conducts DURs etc. through Mckesson's Pharmaserv. She provided a copy of the citation of the database used.

Edward McGinley moved, seconded by Richard Palombo, to mitigate the fine and remove the citation for violation of N.J.A.C.13:39-5.8(a)1. **Motion passed 6-0.**

6) Aatif Al-Hout, RPIC - Medicine Shop Pharmacy, Saddle Brook, NJ

Mr. Al-Hout presented explanations to the Board for failing to complete the CDS inventory as required (N.J.A.C. 13:45H-5.5 & N.J.A.C. 13:45H-5.7), failing to ensure that a Pharmacy Technician had properly applied to the state for registration (N.J.A.C. 13:39-6.6.(b)), and having a reference library which was determined to be unacceptable by a Board inspector (N.J.A.C 13:39-5.8(a)(1)). The Board considered all information presented in making its determination.

Stephen Lieberman moved, seconded by Edward McGinley, to deny all mitigation requests. **Motion passed 6-0.**

7) Walter R. Quagliano, RPIC - Shop Rite Pharmacy, Somerville, NJ

Mr. Quagliano requested that the Board mitigate the \$1000 fine issued for violating N.J.A.C. 13:45H-5.5 & 5.7. He indicated that the pharmacy opened as a new pharmacy on Sept 22, 2011, and the inspection occurred 15 months later, which would be prior to their required biennial inventory date.

Edward McGinley moved, seconded by Richard Palombo, to mitigate the \$1000 fine, and remove the citation for violating N.J.A.C. 13:45H-5.5 & 5.7. **Motion passed 6-0.**

8) Vineet Patel, RPIC - St. Georges Family Pharmacy, Linden, NJ

Angelo Cifaldi, on behalf of Mr. Patel, presented a letter to the Board asking to mitigate and withdraw the fine for violations of N.J.A.C.13:39-5.6 - No hot water in prescription area sink. The sink did have water, but it took 15 minutes for that water to be considered 'hot', due to the infrastructure of the building.

Marc Sturgill moved, seconded by Stephen Lieberman, to remove this citation, as well as the second citation for violation of N.J.A.C.13:39-5.9 – Pharmacy

Balance/scales missing certificate of inspection. Edward McGinley and Thomas Bender were opposed. **Motion passed 4-2.**

VIII. INFORMATIONAL

- 1) **Bill Comment - S3003, Restricts coverage of opioid drugs under workers' Compensation.** *(Tabled from 10-23-13 Agenda)*

The Board took this item as informational.

- 2) **MedAvail MedCenter - Presentation to Board of Pharmacy**

Bob DuFour and Loreto Grimaldi of MedAvail provided an introductory overview of a pharmacist-centric medication dispensing system, that is currently deployed in non-pharmacy locations. It is currently in use in Toronto, Canada outside of hospital, has been utilized in Europe for a year now, and is used in Illinois in a large employer facility. They described the device as a Remote Automated Prescription System (“RAPS”), that is patient facing and pharmacist-centric. When they partner with an existing pharmacy, they may be back with the pharmacy applicant to ask the Board for permission to deploy the system in a retail location that does not have a pharmacy. This request may take the form of a waiver based pilot. They indicated they would sell or lease the machine to a licensed pharmacy (they are just the manufacturer of the system). They do not anticipate dispensing any CDS medication from this device at this time.

The Board took this item as informational.

IX. COMMITTEE REPORTS

Jacobs Pharmacy Interim Order

On September 12, 2013, Kofi Yeboah, owner of Jacob's Pharmacy came to the Board office to report the following: He bought the pharmacy several years ago. The prior owner recently died. On this date, the prior owner's wife, Akosua Serwah-Boadu, showed up with the Newark Police who told Mr. Yeboah that he could either hand over the keys and leave the pharmacy, or they would arrest him.

This started two months of back and forth with non-pharmacist owner Kofi Yeboah, with prior owner's wife, Akosua Serwah-Boadu, over the ownership of the pharmacy. Mr. Yeboah was locked out of store, the parties could not work together to allow pharmacy to operate. Drugs were removed from store, and patients were not receiving proper service.

A hearing was held on December 17, 2013 as a response to a verified complaint against the pharmacy. A committee of the Board, consisting of Edward McGinley and Margherita Cardello, presided over this hearing. The resulting decision was to offer Mr. Yeboah an order which outlines the steps he needed to follow to request to reopen the pharmacy.

Marc Sturgill moved, seconded by Thomas Bender, to accept the order as written in all respects. **Motion passed 6-0.**

Marc Sturgill moved, seconded by Margherita Cardello, to transfer the case to the Office of Administrative Law for follow up. **Motion passed 6-0.**

X. APPROVAL OF MINUTES

December 11, 2013 Public Session Minutes

Marc Sturgill moved, seconded by Stephen Lieberman, to approve the December 11, 2013 Public Session Minutes as amended. **Motion passed 6-0.**

Marc Sturgill moved, seconded by Margherita Cardello, to adjourn the Public session and move to Executive session at 11:09 a.m.. **Motion passed 6-0.**