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BOARD OF PHARMACY PUBLIC SESSION MEETING MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR April 23, 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 Monmouth Conference Room at 124 Halsey Street, Newark, New Jersey on April 23, 2014, 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, and C.10:4-8

III. ROLL CALL

Thomas Bender, R.Ph.	President
Richard Palombo, R.Ph.	Excused Absence
Margherita Cardello, R.Ph.	Late Arrival 10:45 a.m.
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Edward McGinley, R.Ph.	
Calliope Alexander	Government Representative
Carol Jacobson, Esq.	
Mitch Sobel, R.Ph.	
Linda Witzal, R.Ph.	

OTHERS IN ATTENDANCE

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

IV. UPDATES BY EXECUTIVE DIRECTOR

Director Rubinaccio reported for the month of March \$ 13,450 in fines and penalties were collected. The following permits, licenses, and registrations were issued during the month of March:

- Technicians - 287
- Pharmacist - 26 (17 by examination/score transfer and 9 by reciprocity)
- Out-of-state pharmacies – 10
- In-state pharmacies - 6
- Pharmacists receiving immunization approval - 36
- Interns – 2 (foreign graduates)

V. OLD BUSINESS

1) Public Orders Filed

- a) Plainfield Drugs Corp. - Provisional Order of Discipline (3/13/14)
- b) Main Street Family Pharmacy - Consent Order of Voluntary Surrender (3/14/14)
- c) Michael Cuttruff, Pharmacy Technician Applicant - Final Order of Discipline (3/14/14)
- d) Pascal Osei, R.Ph. - Consent Order of Reinstatement of License (3/20/14)
- e) Michael Jaffe, R.Ph. - Order Granting Unrestricted License (4/9/14)

2) Mark Cardis, R.Ph. - Request Modification of Consent Order

Mr. Cardis wrote to the Board requesting an unrestricted license, (specifically removing #6) from his Consent Order, filed in July of 2011. Mr. Cardis cited five years of documented recovery time with PAP NJ, and included recommendations from Mr. Clark Boyd III (his father-in-law), and PAPNJ.

From February 26, 2014 minutes:

*“Stephen Lieberman moved, seconded by Thomas Bender, to deny this request. Mahesh Shah, Marc Sturgill and Richard Palombo opposed. Margherita Cardello was recused due to her affiliation with Rite Aid. **Motion 2-3 did not carry. This item is tabled until a quorum can be reached.***

From March 26, 2014 minutes:

*“**Chair Direct:** Reagendaize for next month to allow new Board members to review for the next meeting (include all background documentation). Also include documentation relating to adherence to PAP NJ recommendations.”*

Tom Bender moved, seconded by Stephen Lieberman, to deny Mr. Cardis' request to vacate or modify his Consent Order. **Motion passed 8-0.**

VI. **NEW BUSINESS**

1) **Plainfield Drugs Corp - Provisional Order of Discipline for Finalization**

Edward McGinley moved, seconded by Thomas Bender to finalize the POD by default upon proof of service. **Motion passed 8-0.**

2) **Amir Tadros, R.Ph. - Requesting unrestricted license**

Mr. Tadros plead guilty to Medicaid fraud in 2010. The Court suspended his license to practice pharmacy, and his Consent Order reiterated that as well. He was suspended on 6/30/2010, and was debarred from participating in Medicaid and Medicare until 2015. His court ordered probation has been satisfied early, so he is petitioning the Board to remove the restrictions from his license.

Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

Edward McGinley moved, seconded by Thomas Bender, to deny request pursuant to Consent Order his minimum time to be out is up in 2015. **Motion passed 7-1.**

3) **Garvi Solanki - Requesting waiver of Foreign Pharmacy Graduates Entrance Examination FPGEE**

Ms. Solanki indicated that she was a pharmacy graduate from England who has not been able to finish her internship and not able to obtain a pharmacist license because she got married last year and moved to New Jersey. As per FPGEC application bulletin, she was denied to sit for FPGEE due to lack of licensure.

She reached out to NABP, who indicated that the FPGEC is unable to waive the requirement regarding licensure and/or registration to practice pharmacy as indicated in the *Application Bulletin*. In order to qualify for the program she must hold licensure and/or registration to practice pharmacy in a foreign country or jurisdiction.

Ms. Solanski asked the Board to waive the FPGEE requirement so that she can begin an internship in New Jersey.

Stephen Lieberman moved, seconded by Linda Witzal to deny Ms. Solanki's request. The Board determined that it does not have the expertise or tools to approve her school as being ACPE equivalent or acceptable, and as such, cannot waive the FPGEC requirement. The Board referred Ms. Solanki to remedies as outlined in N.J.A.C. 13:39- 2.6 & 2.7(c) for guidance. **Motion passed 8-0.**

4) **Shruthi Ravi - Requesting waiver of Foreign Pharmacy Graduates Entrance Examination FPGEE**

Mr. Ravi is pursuing his Pharm D internship in JSS College of Pharmacy, Mysore, India. He will be completing the course in June 2014. He writes that:

“I have secured 1st rank overall for all years and would be graduating this year in June. I have also obtained Post Graduate certificate course in Advanced pharmacology from National Institute of Health, USA and Post Graduate diploma in Clinical Research from KCS Pharma, Punjab, India. I have also attended Advanced Pharmacy Practice Modules.

I have been posted in various specialty and medicine clinics and hospital wards since 5th year Pharm D. The various units worked are Psychiatry, Neurology, Cardiology, General Medicine, Surgery and Pulmonology. I have had exposure to different hospital setups in Mysore as well as in Melbourne and Adelaide. I was selected for a student exchange program to Latrobe University, Bendigo, Australia for 1 semester. Hence had an opportunity to attend rounds in different hospitals in Melbourne and Adelaide.”

He is requesting that the Board provide him with an exemption from taking the Foreign Pharmacy Graduates Entrance Examination FPGEE.

Edward McGinley moved, seconded by Stephen Lieberman to deny Mr. Ravi’s request. The Board determined that it does not have the expertise or tools to approve his school as being ACPE equivalent or acceptable, and as such, cannot waive the FPGEC requirement. The Board referred Mr. Ravi to remedies as outlined in N.J.A.C. 13:39-2.7(c) for guidance. The Board also noted that no hardships to support this request were identified. **Motion passed 8-0.**

5) Martin Jeiven, R.Ph. - Requesting Reactivation; he has not worked as a Pharmacist for more than 2 years

Mr. Jeiven is requesting reactivation of his license, has not been active since 1991.

“My name is Martin L. Jeiven, and I graduated from Rutgers University in 1967 (5 year program) with a BPharm degree from the Rutgers University College of Pharmacy and a BS degree from Rutgers University. I also have an MS degree from the Rutgers University in physiology/zoology, obtained in 1971. I did my internship at Morris Drugs in Elizabeth, NJ and Muhlenberg Hospital in Plainfield, NJ, and completed all requirements for registration. In the 1970s and 1980s, my career focused exclusively on industrial pharmacy (Ciba-Geigy and Ortho Pharmaceutical Corporation), with a short period (3 months) as a registered pharmacist at Cranford Pharmacy, Cranford NJ, before starting my own consulting company (Jeiven Pharmaceutical Consulting, Inc., Vvwww.ieiven.com) in 1989. Since that time, I’ve started two other companies, AdiraMedica LLC (www.adiramedica.com) and NutraReg LLC (www.Dutrareg.com). Information about the companies is included with this memo.

I would like to reinstate my license. I have no intention to practice either community or institutional pharmacy in New Jersey or any other state. The reason for the reinstatement is that clients of AdiraMedica LLC (a global sourcing company for comparator drugs, ancillary supplies and rescue medications required for clinical trials) are requesting that there be a registered pharmacist overseeing the activities

of the company. My title at AdiraMedica LLC is Chairman, and while my President and CEO is a pharmacist (from India), there is no one on our organizational chart who is a registered pharmacist.”

Edward McGinley moved, seconded by Carol Jacobson, to direct Mr. Jeiven to follow N.J.A.C 13:39-3.8, which outlines the process he is required to follow to have his license reactivated. This will include successfully passing both the MPJE & NAPLEX examinations; completing 75 continuing education units; internship and back fees. The Board determined because of the lapse of time since his license went into an inactive status, and because his work experience was not traditionally related to the practice of pharmacy. Mr. Jeiven also is instructed not to use the term “Registered Pharmacist (“R.Ph.”)” until he has satisfied all requirements and his license is reinstated. **Motion passed 8-0.**

6) Draft of New Law 13:39-4.21A - Requirements for Pharmacist to Administer Influenza Vaccine to Patients Under 18 Years of Age

Rachel Glasgow provided a synopsis of the new immunization law. The New Jersey Board of Pharmacy recognizes the importance of pharmacists being able to provide influenza vaccinations to patients 7 years of age and older. The Board of Pharmacy has determined that the law is self-executing, pending agreement of the same by the Board of Medical Examiners (BME). The Board of Pharmacy, in consultation with the BME, is proposing regulations to implement the law. A draft of the proposed new pharmacy regulations includes the following points:

- (a) A licensed pharmacist must be authorized to administer vaccines and related emergency medications pursuant to and comply with the requirements of N.J.A.C. 13:39-4.21.
- (b) For a patient who is under 18 years of age, a pharmacist must obtain the written consent of the patient's parent or legal guardian.
- (c) For a patient who is under 12 years of age (and at least seven years of age), a pharmacist may administer the influenza vaccine only pursuant to a prescription by a licensed physician.

This regulation is being jointly promulgated between the Board of Pharmacy and the Board of Medical Examiners (BME), regulatory process is pending approval of the BME.

Edward McGinley moved, seconded by Thomas Bender, to recognize the law as self-executing and move to approve the draft regulation and move forward in regulatory process, pending BME approval. **Motion passed 8-0.**

VII. MITIGATION/HEARING REQUEST

1) Jitesh Padh, RPIC - Highstown Pharmacy, Highstown, New Jersey

Mr. Padh is requesting a reduction of his \$500 fine for violation of N.J.A.C.13:39-5.8(a)12, and 16 CFR 1700.14.15:

“In regards to the violation listed on Attachment A (“Schedule III-V medication dispensed in non-safety closure without consumer having requested same; specifically Rx C 130875”), the medication in Rx# C 130875 was sitting in the will-call bin at the time of the incident and was never dispensed to the patient in reality with the wrong cap. Admittedly, a mistake was made in the store, but the error was corrected while the medication was still in our possession. By the time the patient came to pick up his medication, the medicine was ready with the correct cap. Therefore, I believe that it is extremely cumbersome, especially in today's bad economy, to have been dealt such a harsh fine by The Board for a mistake that in all honesty never affected the safety of the patient.”

Mahesh Shah moved, seconded by Stephen Lieberman, to reduce the fine to \$200 because it was a single incident. **Motion 5-3 did not carry. Linda Witzal, Carol Jacobson, and Thomas Bender opposed.**

Edward McGinley moved, seconded by Thomas Bender, to deny the mitigation request. **Motion passed 6-2. Stephen Lieberman and Mahesh Shah opposed.**

2) Dharmesh Parikh, RPIC - Wharton Pharmacy, Wharton, New Jersey

Mr. Parikh is requesting a reduction of his \$800 fine for violation of N.J.A.C.13:39-5.8(a)1 (“No Current reference text(s) in the required categories were present in the pharmacy. Specifically, the Drug Facts & Comparisons hard copy present was last updated in August 2007. Updates until May 2008 were present in their original unopened mailing envelopes, but they were never incorporated into the hard copy binder style book”.):

“..At my pharmacy I am using on-line service from Epocrates, Daily med prescribing information data base for the drug information and medication insert for the drug information. So far I found that's more accurate and faster since it's available on-line. If for some reason, if I need more information drug manufactures representative are knowledgeable and they provide information for their own drugs.

After the inspection I did order Hardcover Drug Facts and Comparisons and that cost me \$248.59 for the book. Hardcover books give information on drugs of the previous year and any current drug information we have to rely on on-line information from other source or to get information directly from the manufacturer. Small pharmacy like our it is very expensive for the book for every year and which most of the pharmacy is not going to use it. State Board of Pharmacy should allow to small pharmacy to have alternative way to have information for their business. I perfectly understand as per pharmacy regulation you need to have current reference book. In my opinion Epocrates and Daily med Prescribing information are current and helpful for small business owner. ...”

At 12:25 p.m. Edward McGinley moved, seconded by Thomas Bender, to have

this item moved to Executive Session for advice of counsel.
Motion passed 8-0.

At 12:40 p.m. Stephen Lieberman moved, seconded by Carol Jacobson to move back to the open session. **Motion passed 9-0.**

Mitch Sobel moved, second by Mahesh Shah to table mitigation request so that all issues relative to the inspection report can be considered at the same time as part of an amended UPL. **Motion passed 9-0.**

3) Robert Schneiderman, RPIC - Pink's Pharmacy, Mount Freedom, New Jersey

Mr. Schneiderman wrote the following requesting a reduction of his \$600 fine for violation of N.J.A.C.13:39-S.8(a)1 (“No current Board of Pharmacy approved reference text(s) in the required categories of Comprehensive Pharmaceutical Reference Text, Drug Interactions and Drug Product Composition, were present in the pharmacy. Specifically, the hard copy Drug Facts & Comparisons present was last updated in October 2001.

Mr. Schneiderman stated that the pharmacy utilizes Elsevier Clinical Pharmacology on-line as a reference resource.

Edward McGinley moved, seconded by Thomas Bender, to table this request until the pharmacist can demonstrate proof of access to Elsevier on-line at time of inspection. **Motion passed 8-0.**

4) Focus Express Mail Pharmacy/Shipping into New Jersey prior to being registered. Requesting Leniency Regarding Fine (moved from item 4e-5 on Exec agenda)

From January 29, 2014 Executive Minutes:

“Referral to the Board of Pharmacy from the office of Insurance Fraud Prosecutor, Division of Criminal Justice. In the years of 2007 through 2011 Focus Express Mail Pharmacy was shipping into New Jersey without being registered.

*Stephen Lieberman moved, seconded by Richard Palmobo to send a UPL for \$40,000 citing them for violation of statute NJ.S.A. 45: 14-73. **Motion passed 5-0.”***

Mr. Shpigel R.Ph., CEO of Focus Express, mitigation request states:

“In 2011, during a dispute with a New Jersey insurance company, we were told, by them, that we were in violation of the New Jersey State Board of Pharmacy Law because we did not have an out of state pharmacy registration. Unaware that New Jersey had this requirement, we immediately contacted the New Jersey State Board of Pharmacy to confirm this information and put the wheels in motion to get that license. When we

called the state, we asked the representative when the law was enacted and we were told "November of 2007 and every pharmacy on the Medicare/Medicaid list was notified". We said that "we do not fill those types of prescriptions, so was there another way that we could have found out?". They said that it was on the state board's website. Enclosed is a copy of the letter confirming our licensure in 2011.

Focus is a small "Ma and Pa" retail/mail order pharmacy operation with only eight full time employees. We have always been compliant with all laws and regulations and have never been cited nor fined for any reason, The fine that is -mentioned of \$40,000.00 would be a severe hardship for us. I understand that "ignorance of the law excuses no one" but I hope that the Board can see from my explanation that we had no intent to "put one over on them". After many years of dispensing medications and supplies to patients in New Jersey when there was no out of state licensing requirement, we simply were unaware of the change made in 2007."

Stephen Lieberman moved, seconded by Mahesh Shah, to deny the mitigation request. **Motion passed 8-0.**

5. Acme/Sav-On Pharmacy- Mitigation request to complaint #7932 (moved from item 4E(6) on Exe. Agenda)

Ms Bobbie Riley, VP of Pharmacy Compliance, requested the Board to consider her explanation regarding the pharmacy being charged with a violation of N.J.A.C. 13:39-4.18(b) for not having the proper systems in place and N.J.A.C. 13:39-7.20 for inadequate DUR. *"We respectfully disagree with the Board's findings in this regard and request that the Board consider the following factors with respect to any sanctions imposed against the permit holder. She presented a chronology of the events related to this complaint, outlined the pharmacies policies and procedures, system alerts in place, and other factors to indicate that the permit holder had then, and still has now, policies, procedures, and systems in place to adequately establish company expectations that pharmacists comply with their profession at duty to request allergy and other critical information from patients prior to processing or dispensing any prescription, consider all such information along with other alerts or warnings flagged by the pharmacy system in performing a comprehensive DUR screening, and appropriately provide patient counseling on all new prescriptions. As such, he respectfully request that the Board dismiss its findings, and the related penalty imposed, against Acme/Sav-on Pharmacy."*

Edward McGinley moved, seconded by Thomas Bender, to remove the fine and from permit holder because there was a process in place, NSAID allergy was not reported until after the event. The Board notes the pharmacist used First Data bank as a reference. **Motion passed 9-0.**

VIII. INFORMATIONAL

1) **Pharmacy Library Reference Texts**

- a. Pharmacy Library Reference Text List Currently Being Used
- b. Marc Sturgill's Updated Pharmacy Library Reference Texts
- c. Enforcement Bureau Revised Pharmacy Library for Reference Texts

Chair Direct: The Board office will compile a comprehensive list of all included references to be distributed at the next board meeting.

2) **Thomas Medwick, Emeritus Professor Rutgers University – Compounding Pharmacy Regulation**

Dr. Medwick supplied the Board with a copy of an article entitled “Pharmaceutical Compounding or Pharmaceutical Manufacturing?” from the International Journal of Pharmaceutical Compounding, March/April 2014 issue.

The Board took this item as informational.

3) **Mark Conradi - Candidate for NABP Executive Committee for District III**

The Board took this item as informational.

4) **Jay Campbell- Candidate for NABP Executive Committee for District III**

The Board took this item as informational.

5) **Phil Burgess - Candidate for NABP Executive Committee for District IV**

The Board took this item as informational.

6) **Pharmacy Technician Letter**

It has come to the attention of the Board of Pharmacy that a number of Pharmacy Technicians may not be abiding by the regulations related to obtaining and maintaining an active registration as a Pharmacy Technician in the State of New Jersey. Effective immediately, Pharmacy Technicians who do not hold a valid registration, and who fall into one of the three groups outlined in the attached memo, have until May 15, 2014 to come into full compliance with the requirements of N.J.A.C. 13:39-6.6 "Pharmacy technician registration and pharmacy technician applicants". All Pharmacists-in-Charge and those individuals performing the duties of Pharmacy Technicians are encouraged to review this information in its entirety at the Board's website. The information will also be distributed via the PMP and email to chain stores, NJPhA, GSPO and IPA.

The Board accepts this item as informational.

7) **Naloxone Guidance Letter – Overdose Prevention Act.**

Rachel Glasgow provided an overview. The Board of Medical Examiners has waived some regulations allowing physicians to waive regulations to write prescriptions. The Board of Pharmacy is working on regulations, and is providing this Guidance document to assist pharmacists in complying with the new law until the time that regulations are promulgated.

GUIDANCE FOR PHARMACISTS DISPENSING NALOXONE

On May 2, 2013, Governor Christie signed into law the Overdose Prevention Act (P.L. 2013, c. 46, N.J.S.A. 254:6J-1 et seq.) One of the purposes of the law is to reduce the number of opioid overdose deaths by making Naloxone, an opioid antidote, more widely available and accessible. The statute allows health care professionals to prescribe or dispense Naloxone, or similarly acting drugs, not only to patients who may be in danger of overdosing, but also to first responders, family members, caregivers, or peers who are not at risk for an opioid overdose but who, “in the judgment of a physician, may be in a position to assist another individual during an overdose.”

The Board will draft regulations to implement this new law. Until those regulations are published, the Board is issuing this guidance for licensees who are presented with a prescription for Naloxone or another similar-acting drug.

When presented with a prescription for Naloxone, you should:

- 1. Ask if the prescription is for use by the person whose name is on the prescription.*
- 2. Document on the prescription that the question was asked along with the answer.*
- 3. If the prescription is for the end user, then fill as any usual prescription, including the offer of counseling.*
- 4. If the prescription is for a person who “may be in a position to assist another individual during an overdose”, then set up a separate profile, similar to a prescription, for an annual “caregiver” or “first responder” so that it is readily retrievable. You can place notes in the profile if you wish, but the prescription should not be included in any drug utilization review. These scripts should not be processed through insurance. Counseling need not be provided, as the statute provides that the patient will receive information from the physician or other sources.*

The Board recognizes that in accordance with the new law that pharmacists filling a prescription for Naloxone or other opioid antidote may rely upon the judgment of the physician and be assured that the requisite counseling and instruction information was provided.

Thomas Bender moved, seconded by Margherita Cardello, to accept the document as Board Guidance until the Board can move forward with developing regulations.

The Guidance Letter is to be posted on the web with a link to the law.
Motion passed 9-0.

IX. COMMITTEE REPORTS

Matthew Wetzel gave an update on the New Jersey Prescription Blanks:

The Division continues to review samples from the various approved printer vendors. Currently there are three (3) printer vendor's approved to print the new templates and several more printers are undergoing the Division's review process. Starting on May 19, 2014 the printer vendor's must cease selling the old "blue" prescription blanks. The new "green" prescription blanks are being shipped to prescribers already, so patients will probably be presenting the new blanks at pharmacies over the next few months. A description of the new security features will be published in the Board of Pharmacy's April Newsletter and the Division encourages all pharmacists to download, read and educate the pharmacy staff of the new security features. Also the Board will be mailing to all the pharmacies in the State a color range chart that will show the acceptable color range for the new prescription blanks; the printer vendor's will be producing prescription blanks which fall within the color range.

X. APPROVAL OF MINUTES

March 26, 2014 Public Session Minutes

Stephen Lieberman moved, seconded by Mahesh Shah, to approve the March 26, 2014 Public Session Minutes as amended. **Motion passed 9-0.**

XI. ADJOURNMENT

At 12:40p.m. Mitch Sobel moved, seconded by Mahesh Shah, to adjourn Public session and move into the Executive Session for review of 6 Complaints, 7 Old Business Items, 4 New Business Items, the Secretary's Report and Recommendation on Retail and Institutional Permits, the Secretary's Report and Recommendation on Inspection Reports and Approval of the March 26, 2014 Executive Session Minutes.
Motion passed 9-0.