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BOARD OF PHARMACY PUBLIC SESSION MEETING MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR December 11, 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 December 11, 2013, at 9:11 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 12:00 noon
Marc Sturgill, PharmD	Excused Absence
Mahesh Shah, R.Ph.	
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
Megan Cordoma	Deputy Attorney General

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of November, \$ 6,600 in fines and penalties were collected. The following permits, licenses, and registrations were issued during the month of November:

- Technicians - 133
- Pharmacist - 54 (34 by examination/score transfer and 20 by reciprocity)
- Out-of-state pharmacies - 11
- In-state pharmacies - 5
- Pharmacists receiving immunization approval - 102
- Interns - 10

Executive Director Rubinaccio asked Matthew Wetzel to provide an overview of the NABP Interactive Compliance Officer and Legal Counsel Forum that he recently participated in at NABP headquarters in Illinois on December 3-4, 2013. Below is a summary of that conference:

On December 3rd and 4th, the National Association of Boards of Pharmacy (NABP) held their second interactive forum for Compliance Officers, and their first Interactive Forum for Board Counsel, in Northbrook, IL. Matthew Wetzel, Board staff and Jodi Krugman, Esq, Deputy Attorney General, attended the forum as the New Jersey representatives. The two day forum covered a broad range of topics including: the internal interaction that states have between their compliance and legal offices; balancing discipline and education by the various state Board's; how to work towards greater uniformity by inspectors; the use of accreditation tools by a state Board; the different efforts by state Board's to inspect and regulate compounding pharmacies in the wake of NECC; and the legal issues states are facing with the increase in remote processing/tele-pharmacy and automated dispensing machines/systems. Both Ms. Krugman and Mr. Wetzel had many take away items that they will discuss with the Board Members over the coming months. Specifically, the Board President will allow Ms. Krugman and Mr. Wetzel to submit a list of recommendations for the Board's Rules and Regulations committee to consider for review.

Executive Director Rubinaccio also indicated that the new Drug Quality and Security Act is being reviewed by Board Counsel. The Board will alert licensees of any potential affects that this new legislation may have on existing laws in New Jersey, and directly on the licensees and the Board itself, as soon as the review has been completed.

V. OLD BUSINESS

1) Public Orders Filed

- a. David Samuels, R.Ph. - 11/13/13 Order Granting Unrestricted Licensure

- b. Crystal Hanscon, R.Ph. - 11/13/13 Order Granting Unrestricted Licensure
- c. Zachary Boyler, P.T. - 11/13/13 Consent Order
- d. Christopher Helvitson, P.T. - 11/13/13 Final Order of Discipline
- e. Jeremiah Burgert, R.Ph. - 11/13/13 Final Order of Discipline

2) Mary Ann Solomon, Pharmacy Technician - Provisional Order of Discipline for Finalization

Service to the address of record was effectuated; however no response was received by the Board office.

Edward McGinley moved, seconded by Richard Palombo, to finalize the order without modification by default. **Motion passed 5-0.**

3) Michael Cutruff, Pharmacy Technician applicant - Provisional Order of Discipline for Finalization

Service to the address of record was effectuated; however no response was received by the Board office.

Edward McGinley moved, seconded by Richard Palombo, to finalize the order without modification by default. **Motion passed 5-0.**

4) Christopher Pozarycki, RPIC, Partners LV. and Ancillary Healthcare Services, Cranford, NJ - Mitigation, Additional Documentation

Mr. Pozarycki provided additional documentation to the Board to support his request for mitigation of fines and penalties itemized on Inspection Report #8-5071 "B"-12-X, which resulted from an Inspection on April 23, 2012. The Board reviewed all the documentation supplied, however it was determined that the information supplied was not sufficient to support the mitigation request. Mr. Pozarycki also stated that he did not receive the initial Uniform Penalty Letter ("UPL"), even though it was delivered to the pharmacy's address of record, due to some internal mail delivery issues at his place of business. He explained that someone else had received the Board's correspondence, and he was unaware that it was delivered and required his attention. His lack of response to this UPL resulted in a Final Order being issued.

Edward McGinley moved, seconded by Thomas Bender, to deny the mitigation request based on information provided, and that the original Final Order should remain. **Motion passed 5-0.**

5) Waddah Azzawi - Waiver Request of TOEFL Requirement for Medical Condition

Mr. Azzawi was present at the meeting, and explained he has attempted to pass the TOEFL examination 17 times. He has been unable to pass all the competencies during the same test session.

Richard Palombo moved, seconded by Mahesh Shah, to ask Mr. Azzawi to pass all three sections of the TOEFL at one time. He is also to obtain a medical certification from a speech pathologist to substantiate his medical waiver request. When these two items have been accomplished, Mr. Azzawi may then petition the Board, in the future, with a new waiver request. **Motion passed 5-0.**

6) Twin City Specialty Pharmacy - Waiver Request N.J.S.A. 13:39-5.4, Spatial Requirement of Pharmacy Prescription Area

From the May 29, 2013 Open Session Meeting Minutes:

“Twin City Specialty Pharmacy went before the Board January 23, 2013, for a waiver request for not having the minimum required square footage. The Board members issued a Chair Direct for the Board office to obtain additional information as to why another permit is needed.

Twin City Specialty Pharmacy responded with the following information:

- *They will be a closed door pharmacy*
- *The proposed pharmacy will have a separate entrance, phone number, and address*
- *The computer system and software will be different, with separate filing systems*
- *The space will be used to dispense pre-formulated, bioengineered injectables*
- *The goal is to transfer hospice prescriptions from the existing retail pharmacy to the new closed door pharmacy*
- *The new permit will allow this pharmacy to join certain buying groups to obtain specialty pharmacy medications*

Richard Palombo moved, seconded by Marc Sturgill to table the waiver request pending additional information showing proof of undue hardship in accordance with N.J.A.C. 13:39-1.6.”

The Board reviewed the proposed schematic for the space to be occupied by the second pharmacy department. In discussions with Mr. Ashnault, they suggested an alternate design that would alleviate the Board’s concerns with the current proposed design, and the need for a waiver request.

Edward McGinley moved, seconded by Thomas Bender, to table the request for waivers presented at this time. They suggested that Mr. Ashnault reconfigure the

existing structure and submit the new design, storage, counter space, fixture layouts, security, and other spatial requirements to the Board as part of his application for a second permit. **Motion passed 5-0.**

VI. NEW BUSINESS

1) **Board of Pharmacy Rules and Regulations Proposal- N.J.S.A. 13:39-4A, Remote Processing**

With no further discussion required by the Board regarding the proposed Remote Processing regulations, Richard Palombo moved, seconded by Stephen Lieberman, for the Board to approve the regulations as submitted, and for Rachel Glasgow to facilitate the next steps in having the regulations move forward for final review and approval by the State. **Motion passed 5-0.**

2) **Bill Comment - A4443 , Requires Hospitals to Post Notice In Emergency Departments Concerning Prescription Drug Diversion**

This bill would require hospitals to post in their emergency departments a notice prepared by the Department of Health warning the public that hospital staff are monitoring for prescription drug diversion and that those who engage in prescription drug diversion may be subject to criminal prosecution.

Prescription drug diversion is the process of obtaining prescription medications for illegal use or sale and may involve such conduct as feigning symptoms to obtain prescriptions that are not medically necessary or visiting multiple doctors to obtain duplicate prescriptions.

Edward McGinley moved, seconded by Richard Palombo, to support the Bill with amendments. The Board recommends that it be expanded to include all practice sites where prescriptions are written, and that the bill should clearly indicate that drug diversion is not limited to the illegal sale of these drugs, but also includes the abuse of these potent medications. They also want the Division of Consumer Affairs to have input into the design and content of the notice. The Board also recommends that the Bill authors also get input and participation from the Board of Medical Examiners. **Motion passed 5-0.**

3) **Bill Comment - A4393, Establishes Statewide Opioid Law Enforcement Coordinating Task Force**

This bill requires the Attorney General to establish a Statewide Opioid Law Enforcement Coordinating Task Force within the Department of Law and Public Safety, implementing the third recommendation of the State Commission of Investigation's July 2013 report, "Scenes from an Epidemic."

The purpose of this bill is to strengthen federal, State, county, and local law enforcement efforts relating to opioid drugs. Although federal, State, county, and local law enforcement resources currently exist to appropriately investigate these cases, coordination of those resources is not always effective in combating drug diversion.

The task force will have as its purpose to: identify, investigate, and prosecute the illegal sources and distribution of prescription opioid drugs; and provide training for law enforcement officials, physicians, pharmacists, and other health care professionals in state-of-the-art methods to detect prescription drug diversion and related abuses.

The task force is to include: the First Assistant Attorney General, who is to serve as chair of the task force; the Director of the Division of Consumer Affairs, the Director of the Division of Criminal Justice, the Director of the New Jersey State Board of Pharmacy, the Director of the State Board of Medical Examiners, the Director of the New Jersey Board of Nursing, and the Director of the New Jersey State Board of Dentistry, or their designated representatives; at least one representative each from county prosecutors', sheriffs', and local law enforcement agencies; and any representatives of federal law enforcement agencies that are available and are invited by the Attorney General to serve on the task force.

The task force is to report at least quarterly to the Attorney General on its activities, and to include in that report any recommendations that it deems necessary to fulfill its purposes.

Richard Palombo moved, seconded by Mahesh Shah, to support this Bill with the recommendations that representatives from the Division of Consumer Affairs' Drug Control Unit and the Prescription Monitoring Program be included as participants of the Task Force. The Board also had concerns regarding the number of participants and suggested that the number of people involved in providing direction to the Task Force be limited to a number which can enable decision making to move forward in a timely manner. **Motion passed 5-0.**

4) Wedgewood Pharmacy - Request of approval of Pharmacy Technician Training Program

Wedgewood Pharmacy is seeking approval of their Pharmacy Technician Training program (in order to exceed the 2:1 Pharmacy Technician/Pharmacist ratio), as required in N.J.A.C 13:39-6.15(e).

Chair Direct: Board office is to correct the title of this agenda item. This manual will be assigned to Board member Marc Sturgill to review to verify that the manual meets all requirements in the pharmacy laws and regulations.

5) **Fresenius USA Manufacturing d/b/a Fresenius Medical Center North America – Waiver Request of N.J.A.C. 13:39-4.20(d), Requirement for Pharmacy Permit in Resident State of Licensure**

Fresenius has been providing End Stage Renal Disease patient pharmacy services, from locations other than Pennsylvania, to the State of New Jersey for over 20 years. Prior to 1999, Fresenius did hold a pharmacy permit in Pennsylvania, however, with the implementation in Pennsylvania of SB602, a pharmacy permit was no longer required. Due to changes in healthcare reimbursement and increasing transportation costs, Fresenius now must restructure to avoid undue economic burdens. There is newly proposed Federal Legislation that passed the House of Representatives on June 2, 2013, H.R. 1919 that proposes to exempt dialysis solutions from the definition of wholesale distribution. Although the full enactment of this new Federal Legislation, if it does become implemented, would likely result in the solution to many of the licensure issues unique to this realm, it may not pre-empt state laws like those in New Jersey and Fresenius states that this waiver continues to be of utmost important to their company and the patients of the State of New Jersey. Fresenius asked the Board to consider this brief explanation as a tool to evaluate the possibility of obtaining a waiver from the requirement of having a non-resident permit in the State of Pennsylvania prior to applying for a non-resident permit in New Jersey.

Thomas Bender moved, seconded by Stephen Lieberman, to deny this waiver request based on statutory regulations. **Motion passed 5-0.**

6) **Orphan Drug Professional Services - Waiver Request of N.J.S.A. 13:39-5.4, Spatial Requirement of Pharmacy Prescription Area**

Suja Alum, Pharmacist in Charge for Orphan Drug Professional Services, submitted a remodeling application to the Board which indicated they would like to add an area to their existing pharmacy that did not contain space which would be contiguous with the existing pharmacy floor plan.

The additional area that they would like to incorporate into the existing pharmacy permit is intended to comply with retail requirements ensuring that medications are always safe and secure. In her correspondence with the Board, Ms. Alum indicated that the area will be staffed by a registered pharmacist during business hours and will be available to provide counseling to patients.

The area will be situated such that patients can easily and safely access the pharmacy. The area is approximately 200 sq ft. There is only one main door to access the space and there are no windows. There will be a cash counter by the entrance, where patients can pick up and drop off their prescriptions. There will

be a separate area where counseling can be performed by a licensed pharmacist. The medications ready for pick up will be stored on shelves at the back of the room and patients will not have access to that area. There will be signs posted to identify this space as the pharmacy. Also posted will be the name of the Pharmacist-In-Charge and the hours of operation. The hours of operations will be the same as the main pharmacy.

The security of this area will be such that medications are secure at all times. There will be a closed circuit camera placed in this area including a security alarm system. There will also be a security guard stationed 24 hours at the security desk right outside to this area. It is important to note that all pharmacy inventories of medications will be stored in the main pharmacy. Additionally, all processing of prescriptions will be conducted in the main pharmacy under the supervision of a licensed pharmacist as well. On a daily basis prepared medications ready to be picked up will be moved into the additional area by utilizing pharmacy medication cart with Digilock single user lock. Subsequently, at the end of the day and prior to closing all prepared medications not picked by patients will be returned to the main pharmacy. No controlled drugs will be stored in this location.

Edward McGinley moved, seconded by Richard Palombo, to approve this waiver request contingent on an inspection addressing medication storage, how are drugs stored during business hours, security and general supervision. **Motion passed 5-0.**

7) Kira Fedorenko, R.Ph. - Request for Unrestricted Licensure

Angelo Cifaldi contacted the Board on behalf of Ms. Fedorenko. Mr. Cifaldi indicated that pursuant to Ms. Fedorenko's November 2012 Consent Order, Ms. Fedorenko's pharmacy license was placed on probation for a period of one year. The probationary period is scheduled to end November 28, 2013. She has not been the subject of any further adverse action. Furthermore, she has completed the terms of the Consent Order, having paid her \$1,000.00 fine in January 2013 and having completed the requisite continuing education coursework. Proof of the continuing education credits that she earned was supplied to the Board. Mr. Cifaldi respectfully requested that the probationary status be removed from Ms. Fedorenko's file. Furthermore, insofar as the probationary term has ended, he requested that the Board revise Ms. Fedorenko's licensure status and remove those restrictions that were imposed during the probationary period.

Edward McGinley moved, seconded by Richard Palombo, to approve this request and grant Ms. Fedorenko an unrestricted license. Mahesh Shah was recused due to his affiliation with Angelo Cifaldi. **Motion passed 4-0.**

8) Neelam Chand, R.Ph. - Request for Unrestricted Licensure

Mahesh Shah was recused due to his affiliation with Angelo Cifaldi. Richard Palombo was recused due to his affiliation with Medco. This item will be tabled until the full Board is available to review this request.

9) **Pravin K. Patel R.Ph. - Request for Reinstatement of Pharmacist License**

Ms. Pamela Mandel, counsel for Mr. Patel, contacted the Board office to ask the Board for Reinstatement with the understanding that the reinstatement will be conditioned upon Mr. Patel passing that NAPLEX examination after he has appeared before the Board. In her correspondence, Ms. Mandel respectfully urged the Board to consider that it would be unduly burdensome for Mr. Patel to have to score 75 or better on the NAPLEX licensing examination BEFORE being assured that he would be able to practice pharmacy once he obtains that score. Ms. Mandel asked the Board to consider this proposition for Mr. Patel to appear prior to his taking the NAPLEX.

Richard Palombo moved, seconded by Stephen Lieberman, to deny Ms. Mandel's request. The Board noted that Mr. Patel improperly dispensed CDS medication between 2006 and 2008. They also noted that the results of the NAPLEX will help the Board to assess Mr. Patel's competency in regards to his reinstatement request. **Motion passed 5-0.**

VII. MITIGATION/HEARING REQUEST

1) **Phillip M. Rizzo, RPIC - Rizzo's Pharmacy, Lodi, New Jersey**

Mr. Rizzo requested the Board to consider the following information in regards to a \$10,000 fine related to Inspection Report #8-2995-12-X (inspection date of November 16, 2012).

"In reference to our failure to renew our CDS license and the fine of \$10,000, I am appealing to the Board as an oversight stemming from the fact during hurricane Irene we were preoccupied with the cleanup to our property and trying to keep our business running efficiently and serve our community (also devastated by the storm). The intent was not fraudulent but a case of human error. When it came to our attention, after our wholesaler called for a copy of our license, we tried to correct the situation ourselves. As you can see from our past 52 years in business this type of incident has never occurred. Again we were deluged by destruction from flooding and the amount of the fine would negatively impact our business operations."

Mahesh Shah moved, seconded by Richard Palombo, to lower the fine to \$2500 because there may have been issues related to Hurricane Sandy which contributed to the failure to renew the Pharmacy's CDS license in a timely manner. **Motion passed 5-0.**

2) **Shyam Mudigonda, RPIC - Nick's Drugs, Newark, New Jersey**

Mr. Mudigonda explained that he had properly placed a sign at the front entrance of his pharmacy, but after approximately three months, he was advised to open the pharmacy via the back door for safety issues. On the day of the inspection he was not aware that there was a problem with the sign on the front door. In correspondence with the Board, he explained the steps he took to help prevent anyone from removing this sign going forward.

Edward McGinley moved, seconded by Richard Palombo to mitigate the \$ 50 fine to a warning. **Motion passed 4-1.** Stephen Lieberman opposed the motion.

3) **Christopher Pozarychi, RPIC - Partners LV. Dept. and Ancillary Healthcare Serv., Cranford, New Jersey**

This agenda item was previously addressed under "Old Business, agenda item #4" in these minutes.

VIII. INFORMATIONAL

1) **Millers of Wyckoff - Pharmacy Regulation Changes in Other States**

Mr. Miller submitted to the Board information that he has obtained while going through the process of reciprocity with many states, which he believes would greatly benefit Pharmacy practice in New Jersey. His letter expressed his comments on two simple provisions of the Arkansas State Board of Pharmacy regulations.

17-92-1201. Arkansas Pharmacy Audit Bill of Rights

This Bill spells out the allowable frequency, size, and type of claim allowed in an audit conducted by a Pharmacy Benefit Manager.

23-79-149. Prescription Drug Benefits

This regulation broadly protects Pharmacies from discriminatory Mail Order plans that compel patients to buy maintenance medications from these Pharmacies because the copays are less.

The Board took this item as informational.

2) **NJPMP mandatory reporting letter and the introduction to Project Medicine Drop**

The Board took this item as informational.

IX. COMMITTEE REPORTS

N/A

X. APPROVAL OF MINUTES

November 13, 2013 Public Session Minutes

Stephen Lieberman motioned, seconded by Edward McGinley to approve the minutes as amended. **Motion passed 5-0.**

Richard Palombo moved, seconded by Stephen Lieberman, to adjourn the Public session and move to Executive session at 12:06 p.m. **Motion passed 5-0.**