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BOARD OF PHARMACY PUBLIC SESSION MEETING MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR March 26, 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 March 26, 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.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Edward McGinley, R.Ph.	
Calliope Alexander	
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	Government Representative
Linda Brodie	Board Staff
Jodi Krugman	Deputy Attorney General

IV. UPDATES BY EXECUTIVE DIRECTOR

Director Rubinaccio reported for the month of February \$ 19,875 in fines and penalties were collected. The following permits, licenses, and registrations were issued during the month of February:

- Technicians - 131
- Pharmacist - 22 (17 by examination/score transfer and 5 by reciprocity)
- Out-of-state pharmacies – 6
- In-state pharmacies - 1
- Pharmacists receiving immunization approval - 19
- Interns – 6 (foreign graduates)

FDA inter-governmental working meeting:

On March 20-21, 2014, the FDA hosted an inter-governmental working meeting with state officials and their representatives at their headquarters in Silver Springs, Maryland to exchange information regarding the new Drug Quality and Security Act.

Director Rubinaccio and DAG Krugman attended representing New Jersey. Because this was not an open meeting, much of the discussion cannot be disclosed at this point in time. However, the meeting was productive as the states had the opportunity to voice many points of view, areas of concern and exchange information with the FDA to help them understand some of the issues the new law may pose for some states. It should also be noted that the FDA is working with NABP to craft a Memorandum of Understanding, as required by the new law.

Board Member appointments made by the Governor's office on 3/20/14 :

The following Board members were sworn in:

- Reappointed Margherita R. Cardello R.Ph. to succeed herself
- Reappointed the Honorable Richard A. Palombo, R.Ph. to succeed himself
- Appointed Mitch G. Sobel, R.Ph., M.A.S. to replace Jacqueline D. Sutton, Pharm.D., resigned
- Appointed Linda Witzal, R.Ph. to replace Marc G. Sturgill, Pharm.D.
- Appointed Carol G. Jacobson, Esq. to replace the Honorable Lucille E. Davy, Esq.
- Appointed Calliope C. Alexander to replace Jennifer L. Barron, resigned

President Bender welcomed the new members, and publicly recognized Dr. Marc Sturgill for his many years of dedicated service to the New Jersey Board of Pharmacy and the

citizens of New Jersey. Dr. Sturgill was a member of the New Jersey Board for nine years, having been appointed in March of 2005. He is presently the Chair of the Department of Pharmacy Practice and Administration at the College of Pharmacy at Rutgers University. During his tenure on the New Jersey Board, Dr. Sturgill, most notably, was the source of clinical expertise and experiential practice. He was the New Jersey Board's liaison to the NABP for publication of newsletter items and topics. He actively participated in the development of test questions for the MPJE and was instrumental in promulgating rules and regulations for sterile compounding, collaborative practice, technician registration and continuing education. He reviewed continuing education programs for content and applicability to the profession of Pharmacy. His presence on the Board and his many contributions will be missed. The New Jersey Board of Pharmacy wishes Dr. Sturgill well in all of his future endeavors and extends a heartfelt thank you to him for his service to the Board.

MPJE Item Writing Workshop:

President Bender visited NABP Headquarters in Illinois on March 19-20 for a two day Multistate Pharmacy Jurisprudence Examination ("MPJE") Item Writing workshop. President Bender indicated that he was able to add 25 questions to the pool of questions relating to Collaborative Practice, and sterile and non-sterile compounding.

NABP Fred T. Mahaffey Award:

Director Rubinaccio announced that the NABP Executive Committee decided, by a unanimous vote to recognize the New Jersey Board of Pharmacy with the Fred T. Mahaffey Award. NABP created the Fred T. Mahaffey Award in 1995 to recognize member boards of pharmacy that substantially contribute to the protection of the public health and welfare through the enforcement of state and federal laws and regulations.

In a letter received from Carmen Catizone, Executive Director for NABP, Mr. Catizone wrote that "the efforts of the New Jersey Board to address the compounding issue are ground breaking and should serve as guidance for other states. The Fred T. Mahaffey Award is the Executive Committee's way to recognize these efforts at the Annual Meeting and before all of the member states. It is a testament to the leadership of the New Jersey Board."

Director Rubinaccio thanked the Board members, members of the Board staff, Enforcement Bureau, Division of Law and the Director's Office for contributing to this significant accomplishment. He indicated that the Board's work has gotten off to a solid start, and he is sure that the Board's good work will continue and improve our efforts to protect the public moving forward.

V. OLD BUSINESS

1) Public Orders Filed

- a. Michael Stavitski, R.Ph.- Denial of Reinstatement of License (02/26/14)
- b. Angela Sarrazola, P.T. – FOD (02/26/14)
- c. Jacobs Pharmacy - Order of the Board (02/26/14)

VI. NEW BUSINESS

1) **Mark Cardis, R.Ph. - Request Modification of his Consent Order**

Mr. Cardis wrote to the Board requesting removal of restrictions in his Consent Order, specifically item #6, which was filed in July of 2011. Mr. Cardis cited five years of documented recovery time with PAP NJ, as well as a recommendation from Mr. Clark Boyd III, and from PAP as well.

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 did not pass 2-3. This item is tabled until a quorum can be reached.**”*

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.

2) **New Aces Pharmacy, LLC - Application for New In State Pharmacy**

Mr. Wong has submitted an application which would relocate his existing pharmacy from Jersey City to a unit in an office complex in Denville. The space will be shared with a podiatrist. The Board had concerns with this application, as outlined below.

Chair Direct: The Board office is to reach out to the applicant (Mr. Wong) to ask him to address the following :

- What is the process to handle the existing patients and patient records at the Jersey City location ?
- How will the closing of the existing location be handled ?
- The (physical) security concerns about the practice; there seems to be no demarcation between the physician and pharmacy spaces. Will there be a wall between the area of the unit occupied by the podiatrist’s office and the area occupied by the Pharmacy ?
- Who will have access to the space occupied by the Pharmacy ?
- The Board is not clear how the security of medications will be maintained based on the supplied floor plan. Please explain, in detail, how this security will be accomplished.

- Is there a separate space or room dedicated for patient consultation by the pharmacist ?
- There appears to be no plans to accommodate delivery drivers or technicians (technicians are not listed on the application).
- The hours of operation need to be articulated.

3) **Immunization Regulations Update On Pediatric Influenza**

Rachel Glasgow indicated that this new law, which goes into effect on May 1, 2014, will be reviewed by Rules and Regulations committee on March 27, 2014. She indicated the Board could move to have this law deemed to be “self-executing”: meaning that even though there are no regulations in place yet, a pharmacist may administer the influenza vaccination until the regulations are implemented. Ms. Glasgow indicated that her colleague is working with the Board of Medical Examiners, and she believes it is also inclined to agree that the law can be self-executing.

Edward McGinley moved, seconded by Richard Palombo, to deem this new law self-executing given the clear direction of the statute, that there is no risk to public health, and that this would allow the pharmacy community to plan for the upcoming flu season. **Motion passed 10-0.**

4) **Assembly Bill No. 711 (AsmWm. Angelini) - Require proof of identification for dispensation of certain prescription medications**

“This bill would require patients and their designated caregivers to provide a current and valid photo identification card when picking up prescriptions for narcotic medications, which include opium and opiates, opium and opiate derivatives, and certain stimulants. A designated caregiver would not be authorized to pick up a prescription for a narcotic drug on behalf of a patient unless the caregiver is at least 18 years of age, the patient identifies the caregiver at the time the prescription is issued, the practitioner issuing the prescription transmits the caregiver's name along with the prescription, and the caregiver's name appears on the prescription. In the case of a patient who is a minor, the patient's parent, resource family parent, or legal guardian would be identified as the designated caregiver except that, in the practitioner's discretion, another relative who is at least 18 years of age could be identified as the patient's designated caregiver.”

The Board commented that while the intent of bill is admirable, it produces a burden on pharmacists to validate the caregiver if an issue occurs, which delays providing medication to patient. Most pharmacists are performing their due diligence regarding controlled medications, including narcotics. The Bill is somewhat restrictive. There is a concern that it may delay patients receiving their medications in a timely manner. It is noted that the Prescriber community may

also not be able to comply with the requirements of this Bill due to limitations in the current technology dealing with formatting standards for the transmission of prescriptions electronically. The Board noted that there are drugs, which are not defined specifically in this Bill, that also are of concern and the potential for diversion and abuse.

Stephen Lieberman moved, seconded by Mahesh Shah, to oppose this Bill as presented. **Motion passed 10-0.**

5) Senate Bill No. 681 (Sen. Lesniak) - Provides for issuance of certificate of rehabilitation to certain offenders with substance abuse disorders

“This bill provides for the issuance of a certificate of rehabilitation by the court or State Parole Board to persons who have a substance abuse disorder and have been convicted of certain crimes...(see Bill for complete details).”

Edward McGinley moved, seconded by Stephen Lieberman, for the Board to take a neutral position on this Bill as it is currently written. Thomas Bender and Carol G. Jacobson were opposed. **Motion passed 8-2.**

6) Assembly Bill No. 2477 (AsmWm. Lampitt) - Permits pharmacists to substitute biosimilar biological product under certain circumstances

“The "Patient Protection and Affordable Care Act," Pub.L.111-148, amended the federal Public Health Service Act to create an abbreviated licensure pathway for biological products demonstrated to be biosimilar to, or interchangeable with, biological products licensed by the federal Food and Drug Administration (FDA). This bill allows for the substitution of these products by pharmacists, provided the conditions set forth in the bill are met...(see Bill for complete details).”

Edward McGinley moved, seconded by Richard Palombo, to not support this bill as presented. The Board noted that biosimilars have not been approved for use by the FDA in the USA. New Jersey has always followed the FDA guidelines (ie Orange Book) regarding 'substitution'. Pharmacists rely on science of FDA to tell them what can be substituted. This Bill would also require a software change that would be product and state specific regarding the phrase 'substituted for'. The labor and additional process costs would be passed to patients and possibly delay the delivery of medications to patients. **Motion passed 10-0.**

7) Assembly Bill No. 2332 (Asm. Wolfe, McGuckin & AsmWm Decroce) – Requires public body to publish notice of public meeting on official internet website

“This bill amends the definition of "adequate notice" and the requirements for holding a public meeting in the "Senator Byron M. Baer Open Public Meetings Act" to provide that a public body must post the required information on the official Internet website of the public body, if one exists, in addition to publishing a notice in two local newspapers, and in accordance with the applicable deadlines and standards for adequate notice set forth in the definition of "adequate notice." Currently, a public body must publish the notice in two newspapers to meet the standards for adequate notice, and no notice on the Internet is required. The bill also permits a public body to deliver notice of a public meeting to a newspaper by electronic mail or fax. Finally, the bill repeals sections 1 and 2 of P,L.2002, c.91(C,10:4-9.1 et seq.), which permitted a public body to post a notice of a public meeting on its Internet website in addition to publishing the notice in two newspapers, but did not require the Internet notice to be posted. “

Carol G. Jacobson moved, seconded by Edward McGinley, to support this Bill. The Board noted that the Board of Pharmacy already follows this process.
Motion passed 10-0.

8) Assembly Bill No. 1254 (Asm. Prieto) - Requires certain civil actions against certain licensed persons to be brought within two years

“This bill shortens the statute of limitations period for malpractice actions against certain licensed persons. Currently, N.J.S.A.2A: 14-1 provides that certain civil actions must be brought within six years after the cause of action accrues. Under the bill, actions for professional malpractice against any of the persons listed below would be required to be brought within two years: Any person who is licensed as: ... (see Bill for complete details-take note that ‘Pharmacists’ are among those licensed personnel listed in the Bill).”

Carol G. Jacobson moved, seconded by Mitch G. Sobel, to oppose this Bill, as two years may not be sufficient time to properly address issues that may arise. Mahesh Shah and Stephen Lieberman opposed the motion. **Motion passed 8-2.**

9) Assembly Bill No. 1436 (AsmWm. Caride) - Establishes Statewide Opioid Law Enforcement Coordinating Task Force

The Board took this as informational as the Board previously commented on the predecessor bill, A4393 (2012-2013 legislative session), and it was not amended.

10) Assembly Bill No. 606 (Asm. Webber) - Provides civil immunity to licensed health care professionals who provide care at health care facilities for no compensation

“This bill provides that a licensed health care professional who:

- *cares for or treats a patient at a licensed health care facility (including a federally qualified health care center), or a nonprofit free-standing clinic that is not owned or controlled by a licensed health care facility; and*
- *does not bill for, otherwise receive any compensation for, or have any expectation to receive compensation for, the care or treatment provided*

shall be immune from civil liability for any personal injury that is a result of the uncompensated care or treatment provided by that professional to the patient...(see Bill for complete details)."

Richard Palombo moved, seconded by Edward McGinley to support the Bill as written. The Board noted that this Bill does not apply to cases of gross negligence. **Motion passed 10-0.**

11) Senate Bill No. 614 (Sen. Thompson) - Reduces statute of limitations for Medical malpractice liability actions to four years

*"The statute of limitations for medical malpractice actions is two years. However, under the discovery rule, the statute is tolled and does not begin to run until the plaintiff knew or, through the exercise of reasonable due diligence should have known, of the injury. The result of this rule is that the tail for medical malpractice liability actions can be virtually infinite. This **bill** limits the discovery rule and provides that medical malpractice liability actions must be filed within four years of the occurrence of the professional negligence."*

Mitch Sobel, moved, seconded by Thomas Bender, to oppose this Bill as presented. The Board would like to see the data behind the act. Carol Jacobson is recused because her husband is a physician who testifies on medical malpractice liability actions. **Motion passed 9-0.**

12) Senate Bill No.365 (Sen. Oroho) - Implements recommendations of the SCI report entitled "Scenes from an Epidemic" concerning prescription drug and heroin abuse

Edward McGinley moved, seconded by Thomas Bender, to support the Bill with amendments. The Board thought it was a comprehensive bill addressing many areas in which pharmacy is interested (ie. Prescription Monitoring Program (PMP) reporting time frames, New Jersey Prescription Blanks Security measures, mandating use of PMP by physicians, etc.).

The Board would like to see changes to the Bill that promotes the sharing of (PMP) information through interoperability, and has concerns regarding granting access to PMP information to law enforcement without a grand jury subpoena, as well as concerns that the task force size may be too large to be effective, and that it contains appropriate representation from interested parties. To the extent the

Bill encompasses other bills which the Board previously commented on, the Board's prior comments are reiterated. **Motion passed 10-0.**

13) Srinivas Pisharath, R.Ph. - Non -Practicing Pharmacist requesting reactivation

Mr. Pisharath is a non-practicing pharmacist currently working for the pharmaceutical industry. He had previously maintained an active NJ pharmacist license until the due date for his license renewal in April 2013. He was unable to meet all CE requirements by the date due to personal and professional reasons, and as such, he opted to have his license placed on "inactive" status. He requested that the Board now allow him to reactivate his license.

Richard Palombo moved, seconded by Mahesh Shah, to allow Mr. Pisharath to reactivate his license contingent upon providing evidence of successful completion of all delinquent CEs credits (30), and the payment of required fees as per N.J.A.C. 13:39-3.9. **Motion passed 10-0.**

14) Shraddha Patel Pharmacist Candidate - Requesting approval to retake the NAPLEX

This applicant has taken the NAPLEX three times, receiving the scores below, and is asking the Board for permission to take the NAPLEX a fourth time:

<u>Date</u>	<u>Score</u>
12/05/11	66
11/17/12	53
02/22/14	71

Edward McGinley moved, seconded by Stephen Lieberman, for the Board office to direct this applicant to take the Pre-NAPLEX examination to identify areas of deficiency and report that information back to the Board for review as per N.J.A.C. 13:39-2.2(c). Mitch Sobel was opposed. **Motion passed 9-1.**

15) Pharmacists administration of Enoxaparin.

From February 26, 2014 minutes:

"Director Rubinaccio received the following inquiry from Richard J. Artymowicz, Pharm.D., Director, Pharmacy Services, Cape Regional Medical Center, Cape May Court House, NJ:

From: Artymowicz, Rich

Sent: Friday, February 14, 2014 1:48 PM

To: 'anthony.rubinaccio@ips.state.nj.us'

Subject: Pharmacist Administration of enoxaparin or fondaparinux

Hello Anthony:

Sorry I missed your call this afternoon, thank you for getting back to me so quickly.

My hospital has an outpatient antithrombosis service that is staffed by pharmacists. Some of the patients seen there are being bridged with injectable anticoagulants. Currently, we have the patients self-administer their sq injections at home, but some cannot manage this well. We would like for the pharmacist to be able to administer these sq injections while the patient is having their INR checked. I wasn't sure how to interpret the collaborative practice act to accomplish this and was looking for some guidance.

Any help you can provide would be greatly appreciated.

***This item was tabled** to allow Board members additional time to review this issue. It will be placed on the agenda for March.”*

Thomas Bender moved, seconded by Mitch Sobel, that this administration would be allowed under a Collaborative Practice Agreement (where an anticoagulant certification is available and has been obtained) as per N.J.A.C 13:39-13.5(a).

Motion passed 10-0.

16) Meditech Laboratories, Inc - Application for Out-of-State Pharmacy Registration Performing Sterile Compounding

Chair Direct: The Board office will ask the applicant to explain the discrepancy between the hours of operation noted on the application versus those listed on the Inspection report. The Board also is requesting updated certification and dynamic testing results for the laminar flow hood, as the results supplied are from May 2013.

17) AxelaCare Health Solutions, LLC - Application for Out-of-State Pharmacy Registration Performing Sterile Compounding

Chair Direct: The Board office will request that the applicant supply clarification on the types (risk levels) of the sterile compounding that they perform. The submitted Policy and Procedures information addresses medium risk compounding, however the applicant indicates they do not perform medium risk compounding, and that they only perform low risk compounding. The applicant is also requested to supply updated air quality reports.

18) Pamela Mandel Esq. Requesting Reinstatement for her client John Meo, R.Ph.

In November of 2008, Mr. Meo was charged with one count of Medicaid fraud in violation of N.J. S .A. 30:4 0-1 et seq. The criminal complaint-summons specifically alleges that Mr. Meo, while owning and operating a number of pharmacies in the Newark area, between May 28, 2003 and May 31, 2006,

submitted requests for payment for prescription drugs to Medicaid. During this period, in violation of N.J.S.A. 30-4D-17(b), he submitted such requests even though he had knowledge that the prescribed drugs were not actually being dispensed.

Mr. Meo testified that as part of the plea agreement, he had agreed to surrender his license to practice pharmacy and to be disqualified as a Medicaid provider. On May 27, 2009, Mr. Meo was sentenced to three years probation, ordered to perform ten hours of community service, and pay fees and restitution in the amount of \$500,000. Additionally, consistent with the plea agreement, Mr. Meo was disqualified as a provider from the Medicaid program and ordered to surrender his license as a pharmacist to be deemed a revocation.

On February 9, 2011, the Board offered a Consent Order for Mr. Meo to voluntarily surrender his license to practice pharmacy in the State of New Jersey to be deemed a revocation effective May 27, 2009. Respondent may not make application for reinstatement of his license for a minimum period of five years.

Richard Palombo moved, seconded by Margherita Cardello, to schedule Mr. Meo for an Investigative Inquiry. The Board noted that it appears Mr. Meo is still on the state and federal debarment lists. **Motion passed 10-0.**

19) Pamela Mandel Esq. Requesting Reinstatement for her client Francisco Marcos, R.Ph.

On June 3, 2010, Respondent entered into a plea agreement with the United States Attorney for the District of New Jersey and subsequently entered a guilty plea before U.S. District Judge Anne E. Thompson, admitting that he submitted at least 400 fraudulent claims to Federal Employees Health Benefits (FEHB) plans and received in excess of \$ 28,000 in reimbursement from FEHB plans based upon fraudulent claims in violation of 18 U.S.C. §1 347. Among the methods and means employed by Respondent to carry out the scheme, Respondent submitted fraudulent claims for reimbursement to FEHB plans based on prescriptions which were purportedly requested by employees of the United States Postal Service and their families, and filled by Respondent. In fact, these prescriptions were not requested by employees of the United States Postal Service and their families, and were not filled by Respondent.

On July 14, 2010, Mr. Marcos' license was suspended for a minimum period of three years. Mr. Marcos received credit on the period of suspension retroactive to June 3, 2010, the date he voluntarily ceased practicing pharmacy.

Stephen Lieberman moved, seconded by Mahesh Shah, to reinstate Mr. Marcos' license via a Consent Order. The terms include, but are not limited to, the following: Mr. Marcos must show the Consent Order to prospective employers, that he cannot be a RPIC, a preceptor or have ownership in a pharmacy. The terms of his consent order are to be in effect until he is no longer on the debarment list. **Motion passed 10-0.**

20) AtlantiCare Regional Medical Center - Waiver request Remodel Application

Andrew Karcsch PharmD., Director of Pharmacy Operations for AtlantiCare Regional Medical Center wrote the Board requesting a waiver of N.J.A.C. 13:39-11.7(g):

“We are in the process of evaluating a remodel of our cleanroom in order to become fully compliant with NJ Board of Pharmacy regulations. Due the structure and age of our building, we have limited space to work with. In particular, there is an expansion joint that is an obstacle in maintaining the layout that we currently are using. A new design layout that has been drafted and attached will permit 94 square feet of space in our buffer room. Based on the NJ BOP regulation 13:39-11.7 g, it is required that the buffer area be a minimum of 100 square feet. We are seeking a waiver on this requirement.”

Edward McGinley moved, seconded by Stephen Lieberman, to approve the waiver request. **Motion passed 10-0.**

21) Express Scripts: Pharmacy Permit Application Process Request for New Florence facility

Express Scripts requested that the Board issue a pharmacy permit to their new facility in Florence, New Jersey without yet having obtained a temporary certificate of occupancy. Express Scripts requested the permit as soon as possible, so that it can begin the process of applying for non-resident pharmacy permits in other jurisdictions requiring licensure in order to be able to perform dispensing at the new, larger facility as dispensing at the existing facility is phased out.

Lynda Doremus R.Ph., pharmacist-in-charge for the new facility, explained that the town of Florence will not issue a temporary certificate of occupancy until a permanent power source has been installed for the facility. Because of weather related delays, Express Scripts has been unable to install the permanent power source for the facility, and has been using generators to supply electricity to the facility. Ms. Doremus explained that they expect to have the temporary certificate of occupancy issued by the town by the first week of May, 2014.

The Board reviewed all the information and entertained an extensive discussion on this request. Thomas Bender moved, seconded by Stephen Lieberman, to approve the permit for the component of the pharmacy that meets the physical requirements of a pharmacy in order to ensure patient care and continuity of service, based on the unique situation presented to the Board for consideration. The specific conditions attached to the issuing of a permit in this particular instance include:

- Express Scripts must submit an Affidavit of Compliance to the Board attesting to the following conditions:

- Express Scripts agrees to make a room available in the facility for inspection by the Board that satisfies all the criteria for an eligible pharmacy
 - Express Scripts agrees that it will not bring product onsite until a Board inspector has had the opportunity to review the full site with the Pharmacist-in-charge, has been provided assurances about the security of the pharmacy's ability to maintain the integrity of product and security of the facility as applicable under New Jersey laws and regulations, and has received Board approval
 - Express Scripts agrees not to begin dispensing from the pharmacy until it receives approval from the Board
 - Express Scripts agrees not to use full automation until performing a full validation as agreed to with the Board, and as required by New Jersey regulations relating to automation
 - Express Scripts agrees to present findings to the Board as required by law regarding use and validation of its automated medication systems.
- Express Scripts must notify the Board in writing of any delays in obtaining the temporary certificate of occupancy that extend beyond the original projected date of May 5, 2014. This correspondence should include the reason for the delay, steps being taken to mitigate the reasons for the delay, and a revised date of when the temporary certificate of occupancy will be issued by the town.
 - Express Scripts will submit remodeling applications after the temporary certificate of occupancy, and they wish to have other areas of the new facility inspected as construction and build out is completed.
 - Express Scripts will supply the New Jersey Board of Pharmacy with the permanent certificate of occupancy as soon as it is issued.

Richard Palombo was recused due to his affiliation with Express Scripts.
Motion passed 9-0.

22) **Overdose Prevention Act**

This recently enacted law permits the prescribing and dispensing of naloxone (or other similar drugs) to a person who is not at risk for opioid overdose, but in the judgment of a physician, may be in a position to assist another individual during an overdose. It is contemplated that first responders, family members, or others such as residential monitors in halfway houses might be those likely to seek naloxone prescriptions under this law. The Board may need to amend its regulations to implement the law. There were extensive discussions regarding the new law, including participation from the public. Concerns were raised about insurance and whether payments could be subject to recoupment because the patient is not the same as the end user.

Chair Direct: Refer this task to the Rules and Regulations committee for review, discussion and action.

VII. MITIGATION/HEARING REQUEST

1) **Kajal Viradia, RPIC - Amcare RX Pharmacy, Newark, NJ**

Kajal Viradia had been issued two citations for violation of N.J.A.C.8.65-7.8(a), and N.J.A.C.8.65-7.5(a) , which indicates he had filled two (2) prescriptions with a prescriber and DEA registration number that was different than the actual prescriber; specifically CII Rx #232811N and CIII-V Rx #248812C. In his certification, Mr. Viradia indicated that he was requesting a hearing on this matter.

Chair Direct: DAG Krugman will reach out to Mr. Viradia to clarify the course of action that should be taken to address this UPL.

VIII. INFORMATIONAL

Silvergate Pharmaceuticals Inc. - Compounding of Enalapril Maleate

The Board office received a letter from Silvergate Pharmaceuticals indicating the following:

“This letter is to inform you of potential patient access issues that may develop in connection with pharmacies compounding the active ingredient in EPANED™ (enalapril maleate Powder for Oral Solution, 1 mg/mL, NDC 52652-1001-1), a product now commercially available in the United States. We understand that pharmacies may have historically compounded oral suspensions of enalapril maleate from enalapril tablets because there were no other commercially available options. However, this is no longer necessary....”

The Board took this as informational.

IX. COMMITTEE REPORTS

X. APPROVAL OF MINUTES

February 26, 2014 Public Session Minutes

Stephen Lieberman moved, seconded by Mahesh Shah, to approve the February 26, 2014 Public Session Minutes as amended. **Motion passed 10-0.**

XI. ADJOURNMENT

Edward McGinley moved, seconded by Margherita Cardello, to adjourn the Public session and move into Executive session at 2:10 PM for the review of:

- 4 complaints
- 2 old business items
- 13 new business items
- The Secretary's Report and Recommendations on Inspection Reports
- Approval of the March 26, 2014 Executive Session minutes

Motion passed 10-0.