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BOARD OF PHARMACY PUBLIC SESSION MEETING MINUTES HUDSON CONFERENCE ROOM, 6th FLOOR OCTOBER 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 F.X. Bender in the Hudson Conference Room at 124 Halsey Street, Newark, New Jersey on October 29, 2014, at 9:08 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 F.X. 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 F.X. Bender, R.Ph.	President
Richard Palombo, R.Ph.	Vice President
Margherita Cardello, R.Ph.	
Stephen Lieberman, R.Ph.	
Edward McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Linda Witzal, R.Ph.	Late arrival, 9:20 a.m.
Mitch G. Sobel, R.Ph.	
Calliope Alexander	
Carol Jacobson, Esq.	

OTHERS IN ATTENDANCE

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

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of September, \$24,150 in fines and penalties were collected. The following permits, licenses, and registrations were issued during the month of September:

- Technicians - 344
- Pharmacist - 117 (103 by examination/score transfer and 14 by reciprocity)
- Out-of-state pharmacies - 56
- In-state pharmacies - 7
- Pharmacists receiving immunization approval - 92
- Interns - 9

Also this month, several Board Members and the Executive Director attended the National Association of Boards of Pharmacy (NABP) District II Annual Meeting in Williamsburg, VA. Several important topics were discussed at the meeting including inter-professional development, prescription drug abuse, compounding and the impact of the FDA 503B Outsourcing Facility registration, and the Drug Supply Chain Security Act.

Director Anthony Rubinaccio also attended a NABP Executive Officer Interactive Forum in Northbrook, IL, which covered a variety of topics including: collaborating on compounding safety and physician in-office compounding; medical cannabis and collaborating to ensure patient safety; collaborating with Board of Pharmacy and NABP Program Updates; inter-professional collaboration and tele-everything; and collaborating to decrease prescription drug abuse.

Vice President Richard Palombo was the Committee Chairman for a NABP Taskforce which focused on medication synchronization.

President Thomas F.X. Bender was a Committee Member of a NABP Taskforce which focused on prescription drug diversion.

Director Rubinaccio was the Committee Chairman for a NABP Taskforce which examined strategies for preventing and reacting to pharmacy robberies and thefts.

On October 21, 2014, the Division of Consumer Affairs hosted a Pain Management Committee meeting which brought together stakeholders from various fields including, prescribers, dispensers, educators, enforcement officers, and lobbyists. The group was tasked with discussing three main topics: medical curriculum and continuing education curriculum; addressing the issue of opioid diversion and abuse; and managing pain.

Acting Manager Matthew Wetzel attended the National Association of State Controlled Substance Authorities (NASCSA) in Savannah, GA, on behalf of the Drug Control Unit and the Division of Consumer Affairs. The annual conference covered many important topics including: integration of prescription monitoring programs into electronic health records systems; the new Drug Enforcement Administration (DEA) drug take back and disposal rules; and identifying patterns or triggers of drug abuse and overdose.

V. **OLD BUSINESS**

- 1) **Public Orders Filed**
- 2) **AlixRx, Plano, TX – Out-of-State Pharmacy and Automated Medication Systems Requirements**

Joe DiNinno, R.Ph. and Al Barber representing AlixRx, appeared before the Board requesting guidance and approval to begin validation testing for their automated medication system that is installed in Golden LivingCenter in Old Bridge, NJ. The company has already provided the Board with its Policy and Procedures Manual and validation testing results from their machines located in other states. Currently AlixRx is operating automated machines in thirty-six (36) nursing home location in Pennsylvania, thirteen (13) in Virginia, one (1) in Ohio, four (4) in Maryland and three (3) in West Virginia.

Edward McGinley moved, seconded by Richard Palombo, for the Board to authorize AlixRx to begin validation testing subject to the following guidelines. Upon installation of the automated medication system in Golden LivingCenter-Old Bridge, one-hundred percent (100%) of the dispensed dosage packets must be checked and verified by a New Jersey licensed pharmacist for the first week. After the first week if there are no dispensing errors, then validation by a New Jersey licensed pharmacist can be reduced to ten percent (10%) of the dispensed dosage packets per week. The reduced validation testing must be completed after the machine has been reloaded with medication or after routine maintenance of the machine has been completed. After one month, validation can be reduced in compliance with N.J.A.C. 13:39-10-3(b)2. The Board must be notified of any dispensing errors or issues with the automated system and a root cause analysis must be completed too. **Motion passed 8-2.** Linda Witzal and Calliope Alexander voted in opposition.

VI. **NEW BUSINESS**

- 1) **Bill Comment – A3712/S2366 – Requires Health Care Practitioners to Inform Patients of Addiction Potential of Controlled Dangerous Substances Prior to Issuing Prescription**

This bill would require that, prior to issuing a prescription for a controlled dangerous substance which is a prescription drug, a practitioner must inform the patient, or the patient's parent or guardian if the patient is under 18 years of age, of the risks of developing a physical or psychological dependence on the controlled dangerous substance.

Richard Palombo moved, seconded by Mahesh Shah, for the Board to support both A3712 and S2366 in concept. The Board would prefer the amended version of S2366 because the notification requirement specifically targets Schedule II Controlled Substances which have the greatest risk of addiction.
Motion passed 10-0.

- a) **Bill Comment – S2378 – Extends "Overdose Prevention Act" immunity provisions to certain professionals and professional entities, and requires needle exchange programs to obtain standing order for opioid antidote dispensation, appropriates \$500,000.**

This bill would amend the "Overdose Prevention Act." P.L.2013.c.46. in order to extend the act's immunity provisions to certain professionals and professional entities that administer or dispense opioid antidotes.

Richard Palombo moved, seconded by Mahesh Shah, for the Board to support S2378 and if it is not already defined, the Board recommends the extension of the immunity provisions to cover pharmacists, who in an emergency overdose situation, have the expertise and training to play an active role to help a person in distress. No additional training or education would be needed for a pharmacist. **Motion passed 10-0.**

- 2) **Bill Comment – A3715/S2371 Directs poison control and drug information program to establish clearinghouse of drug overdose information, report on trends, and provide education on safe storage and disposal of medications; appropriates \$500,000**

This bill would expand the responsibilities of the State's poison control and drug information program ("program"), in order to facilitate the gathering and analysis of Statewide information related to drug overdoses, and foster improved public awareness in relation to overdose prevention methods.

Edward McGinley moved, seconded by Thomas F.X. Bender, for the Board to support A3715 and S2371, provided that the definition of a healthcare provider includes a pharmacist. **Motion passed 9-1.** Mitch G. Sobel voted in opposition.

- a) **Unified Mental Health Provider Act**

Deputy Attorney General Jodi Krugman provided an overview of the act and the scope of the inquiry from the United States Supreme Court. Dean Joseph Barone, PharmD, from the Ernest Mario School of Pharmacy at Rutgers University, submitted a letter to the court asking for pharmacists to be included in the definition of a practitioner, so that pharmacists would be afforded the same confidentiality and privacy protections. The main question is what expectation of privacy and confidentiality does a patient have when they talk to their pharmacist?

Stephen Lieberman moved, seconded by Mitch G. Sobel, for the Board to support the inclusion of pharmacists into the protections afforded to a practitioner when counseling or treating a patient. The Board also supports the creation of a written pharmacist-patient agreement. **Motion passed 9-1.** Carol Jacobson voted in opposition.

3) **NTSB New Safety Recommendation – Safety Study on Drug Use Trends In Aviation: Assessing the Risk of Pilot Impairment**

On September 9, 2014, the National Transportation Safety Board (NTSB) adopted its safety study, *Drug Use Trends in Aviation: Assessing the Risk of Pilot impairment*. As a result of this safety study, the NTSB issued six new recommendations, including four recommendations to the Federal Aviation Administration and the following two recommendations to the 50 states (including the state of New Jersey), the District of Columbia, and the Commonwealth of Puerto Rico. The NTSB requested a response from the Board within 90 days detailing the actions the Board has taken or intends to take to implement the new recommendations.

Chair Direct: The Board's Executive Director, Anthony Rubinaccio, will respond to the NTSB's request in writing, indicating that pharmacists and pharmacies currently provide proper warnings to patients who are prescribed controlled substances for pain. Patients are warned not to operate vehicles or heavy machinery while on certain controlled substances.

4) **Michael Inzerillo, R.Ph. – Applicant for Reciprocity**

Mr. Inzerillo submitted an application for licensure as a pharmacist by reciprocity. Since July 2014, Mr. Inzerillo has been a healthcare consultant and prior to his self-employment as a consultant, he was the Corporate Director of Pharmacy for ten (10) years at Mount Sinai Health System in New York, New York.

Richard Palombo moved, seconded by Stephen Lieberman, to allow Mr. Inzerillo's application for licensure as a pharmacist by reciprocity to continue without condition. Ms. Inzerillo's recent work experience is sufficient to meet the requirements of N.J.A.C. 13:39-2A.1(b)3. **Motion passed 10-0.**

5) **Deenaz Narvel, R.Ph. – Applicant for Reciprocity**

Richard Palombo moved, seconded by Edward McGinley, to allow Ms. Narvel to withdraw her application for licensure as a pharmacist by reciprocity because Ms. Narvel does not meet the requirements of N.J.A.C. 13:39-2A.1(b)3. Ms. Narvel will be advised to submit an application to become registered as an intern with the Board and complete the internship requirements. This is an alternative pathway for Ms. Narvel to become licensed as a pharmacist in the State of New Jersey. **Motion passed 10-0.**

6) **Steve Moyik, R.P. – Applicant for Reinstatement**

Mr. Moyik was licensed to practice pharmacy in the State of New Jersey through April 30, 1997. Mr. Moyik did not renew his license subsequent to its expiration in 1997 and has now submitted an application to reinstate his license to practice pharmacy in the State of New Jersey. Mr. Moyik provided documentation of completion of Continuing Education (CE) Credit for 47.0 hours from July 2010 through July 2013.

Chair Direct: Mr. Moyik's license to practice pharmacy has been expired since 1997. In accordance with the Uniform Enforcement Act, N.J.S.A. 45:7-1, Mr. Moyik will need to comply with the requirements of the law if his original state of licensure is New Jersey. If Mr. Moyik's original state of licensure is a State other than New Jersey, Mr. Moyik will need to submit to the Board, a certification of employment, curriculum vitae of his employment history, proof of completed Continuing Education (CE) credits for the current renewal cycle, and pay all applicable renewal and application fees.

7) **SCA Pharmaceuticals, Little Rock, AR – Out-of-State Pharmacy & Outsourcing Facility**

This agenda item was moved to Executive Session for advice of counsel.

SCA Pharmaceuticals, LLC has submitted an application to the Board to become registered as an out-of-state pharmacy. SCA Pharmaceuticals is registered with the Food and Drug Administration (FDA) as a 503B Outsourcing Facility. The company indicated that it does not provide prescription medication to individual patients, but instead it provided sterile compounded products for hospitals.

Edward McGinley moved, seconded by Thomas F.X. Bender, for the Board to go back into Open Session. **Motion passed 10-0.**

Thomas F.X. Bender moved, seconded by Edward McGinley, for the Board to allow SCA Pharmaceuticals, LLC to withdraw their application for registration as an out-of-state pharmacy in the State of New Jersey. The Board will advise SCA Pharmaceuticals that if it does not ship patient specific compounded medication to patients in New Jersey, the company does not have to register as an out-of-state pharmacy. If in the future, SCA Pharmaceuticals intends to ship patient specific compounded medication to New Jersey patients, then registration with the Board as an out-of-state pharmacy will be required. SCA Pharmaceuticals will also be advised to contact the New Jersey Department of Health Wholesale Drug Project to determine if additional registration is needed with the State of New Jersey to ship non-patient specific medications to New Jersey locations.

Motion passed 10-0.

8) **Kevin Tusso, R.Ph. – POD for Finalization**

On or about June 29, 2012, Mr. Tusso provided a handwritten, voluntary, signed, sworn statement to Tim Russell, Regional Loss Prevention Manager for CVS, admitting that he stole medication from his employer, CVS, for a period of about six months. Mr. Tusso used the stolen medication for personal use in order to self-treat his medical condition. A POD was issued on August 21, 2014 seeking a minimum two (2) year suspension.

Edward McGinley moved, seconded by Margherita Cardello, to finalize the POD by default without modification. The Board determined that service was adequate, and no response was received. **Motion passed 10-0.**

9) **Temperature Control Proposed Regulations**

Edward McGinley, seconded by Thomas F.X. Bender, for the Board to approve the temperature control regulation proposal with an amendment to allow the pharmacy to follow the manufacturer recommendations if the pharmacy is using a temperature monitoring device. **Motion passed 10-0.**

10) **Alero Health Waiver Request**

Alero Health requested a waiver of N.J.A.C. 13:39-5.3a & b, for pharmacy signs and N.J.A.C. 13:39-5.8(a)11, for drug utilization placards. The pharmacy's business model is to service and support large Managed Care Organizations and Specialty Pharmacies.

Edward McGinley, seconded by Richard Palombo, for the Board to grant Alero Health the above mentioned signage and placard waivers. **Motion passed 10-0.**

VII. MITIGATION/HEARING REQUEST

1) **Jaimin P. Patel, RPIC, Walgreens Pharmacy Dept. #13706, Warren, NJ**

Edward McGinley moved, seconded by Mahesh Shah, to remove the citation for violating N.J.A.C.13:39-5.3(c) based on the mitigation request and documentation submitted by Jaimin P. Patel. **Motion passed 9-0.** Thomas F.X. Bender was recused due to his affiliation with Walgreens.

VIII. INFORMATIONAL

IX. COMMITTEE REPORTS

X. APPROVAL OF MINUTES

Stephen Lieberman moved, seconded by Mitch G. Sobel, to approve the September 24, 2014 Public Session Minutes as amended. **Motion passed 10-0.**

Margherita Cardello moved, seconded by Mahesh Shah, to adjourn the Public Session and move to Executive Session at 12:56 p.m. **Motion passed 10-0.**