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BOARD OF PHARMACY PUBLIC SESSION MEETING MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR November 13, 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 November 13, 2013, at 9:10 a.m. All members were duly notified of the time and place and all pertinent materials were provided to the Board Members.

II. SUNSHINE LAW ANNOUNCEMENT

President Thomas Bender read a statement that the newspapers and appropriate elected officials have been notified of the meeting according to the requirements of the Open Public Meetings Act N.J.S.A. Chapter 231, P.L.1975, C.10:4-8

III. ROLL CALL

Thomas Bender, R.Ph.	President
Richard Palombo, R.Ph.	Vice President
Margherita Cardello, R.Ph.	Late Arrival 9:14 a.m.
Marc Sturgill, PharmD	Late Arrival 9:24 a.m.
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
Megan Cordoma	Deputy Attorney General

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of October \$ 16,193 in fines and penalties were collected. The following permits, licenses, and registrations were issued during the month of August:

- Technicians - 72
- Pharmacist - 97 (80 by examination/score transfer and 17 by reciprocity)
- Out-of-state pharmacies - 8
- In-state pharmacies - 12
- Pharmacists receiving immunization approval - 81
- Interns - 7

Executive Director Rubinaccio asked Richard Palombo and Marc Sturgill to provide an overview of the Committees that they recently participated in at NABP headquarters in Illinois:

Richard Palombo provided an overview of the NABP Pharmacy Benefits Manager (“PBM”) Taskforce Committee findings. A similar taskforce first met in 1999. The committee’s charter was to review the status of PBM regulations in the states, determine the level of cooperation and collaboration among the states in regard to regulating PBMs, and review and propose recommendations to the Model Act language pertaining to PBMs to provide a cohesive and current guideline for states to utilize in developing regulations. Much of the discussion was focused on functions currently being performed by licensed pharmacists for the PBMs, with a primary focus being Drug Utilization Review (“DUR”), which is aimed at patient safety and optimal therapeutic medication management. The committee did not focus on auditing or reimbursement issues, as these items are not under the control of a majority of state Boards of Pharmacy. The recommendations of the committee will be reviewed by the chair of the taskforce and the Executive Committee liaison for final review and approval. Findings should be available in March 2014.

Marc Sturgill provided an overview of the NABP Committee to review item writing for the Pharmacist Assessment for Remediation Evaluation (“PARE”) examination, which provides a multi-dimensional assessment that the Boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist practice deficiencies that are due to noncompliance with pharmacy practice standards, laws or regulations, and result in compromises to patient safety. There were nine attendees from various states who contributed by writing questions that will be considered to be included on the examination. The PARE is a computer-based assessment that consists of 210 multiple choice questions. Examinees have a maximum of 4.5 hours to complete the exam. The questions will be drawn from three content domains:

- Medication Safety and the Practice of Pharmacy (Area 1 - 50% of questions)
- Professional Ethics/Pharmacist Judgment (Area 2 - 25% of questions)
- Clinical Pharmacy Practice (Area 3 - 25% of questions)

Thomas Bender indicated that the New Jersey Board is using this correctly, as a tool when a licensee is returning to practice from an absence. Edward McGinley noted that NABP indicates that the examination is given to approximately 5-6 licensees per state per year. The results indicate that the most difficult section appears to be the Clinical Pharmacy Practice area. Also noted is that there is currently no comprehensive study guide available for test takers to utilize to prepare for the examination.

V. OLD BUSINESS

1) Public Orders Filed

- a. Brian A. Jackson, Order of Summary Suspension, 10/23/2013
- b. Danny Scarano, R.Ph., Order of Summary Suspension, 10/23/2013
- c. Ashraf T. Hanna, Provisional Order of Denial of Licensure, 10/23/2013
- d. Ashraf T. Hanna, Provisional Order of Discipline, 10/23/2013
- e. William A. Carlucci, Jr., R.Ph., Consent Order of Surrender to be Deemed a Revocation, 10/28/2013

2) Angela Sarrazola, Pharmacy Technician - Provisional Order of Discipline for Finalization

The POD was mailed to the address of record, but was returned as undeliverable. Edward McGinley moved, seconded by Mahesh Shah, to finalize the order without modification by default. **Motion passed 7-0.**

3) Dennis Kelly, Pharmacy Technician - Provisional Order of Discipline For Finalization

The POD was mailed to the address of record, but no response was received by the Board office. Stephen Lieberman moved, seconded by Richard Palombo, to finalize the order without modification by default. **Motion passed 7-0.**

4) Helen S. Chavarriaga, Pharmacy Technician- Provisional Order of Discipline for Finalization

The POD was mailed to the address of record, but no response was received by the Board office. Edward McGinley moved, seconded by Mahesh Shah, to finalize the order without modification by default. **Motion passed 7-0.**

5) Kenneth W. Grossett II, R.Ph. - Request for Unrestricted Licensure

Mr. Grossett is requesting an unrestricted license. At the Board's request, he supplied a Demand for Statement under Oath indicating he has been unemployed since April 14, 2007, and his source of income is social security payments.

His license to practice pharmacy was reinstated since 2010. While there is no work history or employer endorsement to substantiate the lifting of restrictions, it is noted that he has complied with all the Board's requests.

Marc Sturgill moved, seconded by Stephen Lieberman to remove restrictions and provide him with an unrestricted license. Margherita Cardello and Thomas Bender opposed the motion. **Motion passed 5-2.**

6) **Maritza Mieles, Pharmacy Technician – Request for Reinstatement of Registration**

Ms. Mieles did not respond appropriately to a request from the Board for information regarding an arrest. A POD was issued for failure to respond. Since she never responded to the POD, an FOD was issued. She has now provided all requested information to the Board. She has also paid her \$250 fine for failure to respond.

Marc Sturgill moved, seconded by Mahesh Shah, that she has cooperated with the Board's request, and that her suspension should be lifted. She may continue with her reinstatement. **Motion passed 4-3.** Richard Palombo, Edward McGinley and Thomas Bender opposed the motion.

7) **George Rusuloj, RPIC, Bell Pharmacy, Edison, NJ – Additional Information Submitted for Mitigation Request**

Marc Sturgill was recused because he was affiliated with Mr. Rusuloj as a coworker on a number of projects.

Thomas Bender motioned, seconded by Edward McGinley, to deny the mitigation request for the citation for violating **N.J.A.C.13:39-11.7(a)** because there was no documentation presented that Mr. Rusuloj underwent sterile compounding training. His annual review of training procedures with staff does not fulfill this requirement. In addition, his written statement only addressed issues going forward, not those which existed at the time of the inspection. **Motion passed 6-0.**

Thomas Bender moved, seconded by Edward McGinley, to deny the mitigation request for the citation for violating **N.J.A.C.13:39-4.19(d)2** because the Central Prescription Handling Agreements were executed after the citations were issued. **Motion passed 6-0.**

Edward McGinley moved, seconded by Stephen Lieberman, to deny the mitigation request for the citation for violating **N.J.A.C.13:39-11.14(b)3** because the information presented was for post citation, not prior to the citations being issued. **Motion passed 6-0.**

VI. NEW BUSINESS

1) **University Medical Center of Princeton at Plainsboro - Waiver request**

for discontinuence of monthly monitoring of McKesson Robotics-ProManager. *(Tabled from 10-23-13 Agenda)*

Jacqueline D White, Pharm D at University Medical Center of Princeton at Plainsboro, stated that since the installation of the device in May of 2012, they have been checking 100% of all medications and logging examples of any QA issues uncovered. In June 2013, the pharmacy department had a complete NJ BOP inspection and all requirements were met with satisfaction. Weights and Measures have also inspected the Robot and it has been stickered for the next inspection. All staff is now competent and proficient in using the equipment. Policies on the automation have been updated, and their process for checking manually pulled medications is in place. She is now requesting a waiver for a 5% random checking process of the ProManager Robot.

Marc Sturgill moved, seconded by Richard Palombo, to approve the waiver request to sample only 5%. **Motion passed 6-1.** Thomas Bender was opposed.

2) Bill Comment - A4357, Requires pharmacies and prescribers to notify patients about how to ensure proper and safe disposal of unused prescription drugs *(Tabled from 10-23-13 Agenda)*

Edward McGinley moved, seconded by Thomas Bender, to oppose the Bill as written. The Board noted that this Bill will increase the cost of dispensing medications, and is not business friendly. Posting a notice may be more effective for everyone. The Board understands the effort, but thinks there are more effective and economic ways to facilitate the intentions of this Bill. **Motion passed 7-0.**

3) Matt Mandel, Esq., on behalf of Alfredo Balleras, R.Ph. - Request for Modification of Consent Order. *(Tabled from 10-23-13 Agenda)*

Mr. Balleras' pharmacist license was suspended in 2010 for filling prescriptions for CDS via the Internet. His consent order called for 2 years active suspension, and 2 years of probation. Mr. Balleras is requesting to remove the requirement in his consent order to notify employers of this consent order.

Marc Sturgill moved, seconded by Edward McGinley, to approve this request. **Motion passed 7-0.**

4) Bishoy Roshdi - Request for Waiver of TOEFL Exam *(Tabled from 10-23-13 Agenda)*

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

Edward McGinley moved, seconded by Thomas Bender, to table this request, and for the Board office to ask Mr. Rosdhi to provide evidence he is obtaining

therapeutic intervention with the speech pathologist to indicate that he is trying to correct the speech impediment. **Motion passed 7-0.**

5) Board of Pharmacy 2014 Board Meeting Dates (*Tabled from 10-23-13 Agenda*)

- January 22, 2014
- February 26, 2014
- March 26, 2014
- April 23, 2014
- May 28, 2014
- June 25, 2014
- July 23, 2014
- August 27, 2014
- September 24, 2014
- October 22, 2014
- November 12, 2014
- December 10, 2014

6) Virtua - Central Prescription Handling Agreement Application

(*Tabled from 10-23-13 Agenda*)

Virtua has signed a contract with Health Robotics and will be installing their IV Station robot product into the Virtua Voorhees campus in the winter. The IV sterile products robot is an ISO Class 5 production robot that will be located in a pharmacy cleanroom. The robot is programmed with drug formulations by a Virtua pharmacist for which the robot then produces aseptic doses that are reconstituted, diluted, etc. by the robot. The robot also labels the final product prior to it being outputted. Multiple medication safety checks are provided through the system including barcoding of all source containers being used, pictures of all source containers being used and quality assurance parameters that "reject" a dose that is outside of defined dose parameters. The system is gravimetrically based to provide more precise dosing than volumetric manual preparation. Finally, the system provides a complete audit trail for each dose produced (e.g. who prepared, who checked, % error of the dose, timestamp of when dose was prepared, etc.) The reporting features of the system provide Pharmacy Administration much greater data than currently exist manually. Many of these systems are now being purchased by hospital pharmacies throughout the country as they provide numerous safety features that are not available via a manual production process.

They are seeking approval of a Central Prescription Handling Agreement which would allow their pharmacy in Voorhees, NJ to use this robot to compound sterile products which will then be distributed to other locations (ie. Berlin, Marlton, and Mount Holly NJ) within their healthcare system.

Richard Palombo moved, seconded by Marc Sturgill, to approve the Application. **Motion passed 7-0.**

The Board requires that this automated system be inspected by the Board of Pharmacy Enforcement Bureau inspectors, in conjunction with surveyors from NABP, prior to it being used in production. The Board also requires that the manufacturer be present during the inspection to answer any questions that may arise. Edward McGinley motioned, seconded by Thomas Bender, that prior to scheduling an inspection of the device, the hospital should submit the Policies and Procedures pertinent to the proper use and maintenance of the machine for Board review. **Motion passed 7-0.**

Chair Direct: Executive Director Rubinaccio will contact the hospital to ask if the Board members may visit to better understand the implementation of this technology.

7) Michael Jaffe, R.Ph. - Request for Unrestricted Licensure

On April 9, 2010, Mr. Jaffe entered into a Consent Order with a 3 year suspension which was served as probation. He is asking to remove the probationary status and other restrictions of his consent order.

Richard Palombo moved, seconded by Marc Sturgill, to grant him an unrestricted license. Margherita Cardello was recused due to her affiliation with RiteAid, and Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

Motion passed 5-0.

8) David Irisarri Vila - Request for Waiver of Pharmacy Internship Hours

Mr. Vila is requesting a waiver of the NJAC 13:39-2.1(b)3 requirement of 1500 pharmacy internship hours. The following summarizes his background, pharmacy experience, and general efforts to obtain licensure as a pharmacist in the State of New Jersey:

As of 2000, he was licensed to practice pharmacy in Spain, and the United Kingdom, where he worked as a full-time pharmacist for Lloyd's Pharmacy in England for a period of one year. In September 2010, Mr. Vila came to the United States and passed the FPGEE examination. In 2011, he moved to the United States, and since has been attempting to obtain the required TOEFL iBT speaking score of 26. He took the TOEFL iBT examination a total of eight times, and passed it on September 27, 2013.

During this period, he became a registered New Jersey Pharmacy Technician and obtained PTCB Certification as well. In January 2012, he obtained a full-time position as a Pharmacy Technician in the outpatient pharmacy located within Meadowlands Hospital Medical Center (MHMC) in Secaucus, NJ. In April 2013, he also started working part-time for the inpatient pharmacy of MHMC.

Stephen Lieberman moved, seconded by Margherita Cardello, to partially grant Mr. Vila's request based on his background of previously being licensed as a

Pharmacist and his prior work experience. Mr. Vila must register with the Board as an Intern, obtain a Preceptor (who must also register with, and be approved by, the Board), and complete a total of 500 hours of internship. **Motion passed 7-0.**

9) Reham Makled - Transfer of Internship Hours from Kentucky

Ms. Makled is requesting a waiver of the NJAC 13:39-2.1(b)3 requirement of 1500 pharmacy internship hours. She is asking that New Jersey accept the transfer of 1500 hours of internship which she completed in Kentucky toward her internship requirement for licensure as a pharmacist in New Jersey. She supplied a resume of her prior work experience (she was licensed as a pharmacist in Egypt in 2003), as well as a letter from her preceptor in Kentucky.

Thomas Bender moved, seconded by Edward McGinley, for the Board office to contact Ms. Makled, and have her ask her preceptor to complete evaluation form, supplied by the Board office, of her performance during her internship. If the evaluation results indicate there are no issues, her request will be approved. If any issues or concerns are present, the information will be brought back to the Board for further review and consideration. **Motion passed 7-0.**

10) Patrick J. Marks, R.Ph.- Reciprocity Applicant with Disciplinary Action

In February of 2002, Mr. Marks was cited with the following violations by the New York State Office of Professional Discipline while acting as the Supervising Pharmacist for ESI Mail Services:

- Failure to maintain required and adequate repacking records.
- Failure to properly supervise the pharmacy.
- Outdated/misbranded/adulterated drugs maintained in active drug stock

Mr. Marks disclosed this discipline on his application for reciprocity.

Edward McGinley moved, seconded by Mahesh Shah, to allow his reciprocity application to proceed. Richard Palombo was recused due to his affiliation with Express Scripts. **Motion passed 6-0.**

11) Kwadwo Asamoah Bekoe, R.Ph. - Reciprocity Applicant with Criminal Conviction

Mr. Bekoe's license to practice pharmacy in Virginia was suspended in October 2011 because he was convicted of one count of naturalization fraud. Also, on his application to New Jersey, he indicated he was delinquent on repayment of his student loan(s).

Richard Palombo moved, seconded by Edward McGinley, to allow his application to proceed contingent upon Mr. Bekoe providing satisfactory documentation that his student loan debt is undergoing acceptable repayment terms with the lenders. **Motion passed 7-0.**

12) inVentiv Patient Access Solutions - Request for Special Retail Pharmacy Permit

Victor Bakhoun, the Pharmacist in Charge, and Valerie Sullivan, Manager, presented an overview of the business model for their pharmacy. This pharmacy will function as an Intake pharmacy only. They will process eligibility of patients to participate in programs, then forward prescriptions to a mail order pharmacy to be filled. inVentiv will handle questions about prescriptions. They partner with MedVantex in South Dakota, a mail order pharmacy that will be filling the prescriptions and performing DUR. All calls will go to a call center at inVentiv. Pharmaceutical manufacturers are their clients. They only support patients that come to them through the Pharmaceutical Manufacturers (via the patient's physicians). Below is a description of the services/functions they will perform:

- inVentiv Patient Access Solutions Pharmacy will not serve walk in patients and will be a closed door pharmacy.
- inVentiv Patient Access Solutions Pharmacy will not be a dispensing pharmacy. No drugs or pharmaceutical products will be stocked or stored on site.
- The Pharmacy main function will be to process patients' eligibility for assistance programs offered by pharmaceutical companies for prescription drugs.
- The pharmacy will be receiving prescriptions via mail (from patients or prescribers) and/or fax (from prescribers only) as part of eligibility processing. The pharmacy will forward all prescriptions or refill requests electronically via secured file feed to the mail order pharmacy contracted with inVentiv Patient Access Solutions to dispense all prescriptions and refills.
- Electronic images of all prescriptions will be stored in inVentiv Patient Access Solutions Pharmacy database.
- inVentiv Patient Access Solutions pharmacists will perform the following functions:
 - Access REMS (Risk Evaluation and Mitigation Strategies) drugs websites to verify prescribers are certified prior to forwarding all prescriptions prescribed for REMS drug to the dispensing pharmacy.
 - Access iPLEDGE website to verify that prescribers and patients are compliant with program requirements prior to forwarding all isotretinoin prescriptions to the dispensing pharmacy.
 - Provide counseling to patients regarding medications dispensed through the programs administered by the pharmacy.
 - Pharmacist (s) will contact patients and prescribers when patient health and safety is an issue to discuss possible resolutions and/or provide counseling.

inVentiv Patient Access Solutions Pharmacy will process prescription claim adjudication for some programs.

Based on the limited functions that inVentiv Patient Access Solutions Pharmacy will be performing, they are requesting the New Jersey Board of Pharmacy to waive the following requirements:

- 1- Posted signs on the exterior of the building.
- 2- Prescription Area sink.
- 3- Prescription Counter.
- 4- Spatial requirement of pharmacy prescription area.
- 5- Prescription Counter.
- 6- Adequate Storage requirement for prescription drugs.
- 7- Over the counter schedule V record book.
- 8- Storage space for schedule II substances.
- 9- Volumetric device.
- 10- Steel Spatula and rubber spatula.
- 11- Counting trays and counting devices.
- 12- Labels
- 13- Auxiliary labels
- 14- DUR council placards.
- 15- Prescription containers and child safety closures.
- 16- Class A prescription balance
- 17- Glass mortar and pestle
- 18- Glass funnels
- 19- Ointment tile or parchment paper
- 20- Suppository mold
- 21- Monitored Security System
- 22- Patient's signature forms for accepting/declining offer for dispensing counseling.

Richard Palombo moved, seconded by Edward McGinley, to approve the waivers contingent on inVentiv submitting a signed affidavit to the Board attesting that no drugs will be stored or dispensed at this location. They must also submit separate Central Prescription Handling Agreements with each pharmacy that they partner with. They will also be reminded that they need to provide adequate security for patients' protected health information. **Motion passed 7-0.**

13) Project Medicine Drop – Request from the Director's Office

Maryann Sheehan spoke with the Board regarding Project Medicine Drop, an initiative to provide central locations for consumers to dispose of unwanted prescription medication, which was launched over a year ago. The Division of Consumer Affairs would like to increase awareness of this program, and is asking the Board to endorse an initiative to ask Pharmacies to display a poster in each pharmacy which indicates location of drop boxes in the county in which the stores are located. The Division is partnering with funeral homes and other consumer access points as well. The purpose of this initiative is to help consumers be more aware of where they can safely dispose of medications they no longer need.

The Division is doing a mailing next week, and would like to include a statement regarding this as a heads up to each retail Pharmacy in the state. The Division is willing to furnish the posters, and will ask they be posted in a conspicuous area.

John Covello, of the Independent Pharmacy Alliance, offered to assist the Division in contacting retail pharmacies. The Board would also like to include this topic in the quarterly New Jersey Pharmacy Newsletter. A link will also be included on the Board of Pharmacy website to information on Project Medicine Drop.

Richard Palombo moved, seconded by Margherita Cardello, for the Board to partner with the Division, and agrees to include an announcement regarding this initiative in the PMP mailing. The Board requested to be kept updated on further developments with this initiative. **Motion passed 7-0.**

VII. MITIGATION/HEARING REQUEST

- 1) **Mangeesh Joglebar, RPIC, Sav-On Pharmacy, Yardville, NJ**
(Tabled from 10-23-13 Agenda)

Edward McGinley moved, seconded by Stephen Lieberman, to remove the citation for violating N.J.A.C.13:39-7.12(a)12 based on the mitigation request submitted by Mangeesh Joglebar . **Motion passed 7-0.**

- 2) **Young Sub Kim, RPIC, Toledo Pharmacy, Union City, NJ**
(Tabled from 10-23-13 Agenda)

Edward McGinley moved, seconded by Richard Palombo, to remove the citation for violating N.J.A.C.13:45H-S.7 based on the mitigation response sent by Young Sub Kim. The citation and fines related to the library reference violations remain. **Motion passed 7-0.**

VIII. INFORMATIONAL

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

The Board took this item as informational.

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

Bob DuFour and Loreto Grimaldi of MedAvail provided an introductory overview of a pharmacist-centric medication dispensing system, that is currently

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

The Board took this item as informational.

IX. COMMITTEE REPORTS

N/A

X. APPROVAL OF MINUTES

October 2, 2013 Public Session Minutes (*Tabled from 10-23-13 Agenda*)

Richard Palombo moved, seconded by Margherita Cardello, to approve the October 2, 2013 Public Session Minutes as amended. **Motion passed 7-0.**

October 23, 2013 Public Session Minutes

Marc Sturgill moved, seconded by Stephen Lieberman, to approve the October 23, 2013 Public Session Minutes as amended. **Motion passed 7-0.**

Marc Sturgill moved, seconded by Mahesh Shah, to adjourn the Public session and move to Executive session at 12:14 p.m. **Motion passed 7-0.**