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BOARD OF PHARMACY MINUTES OF THE OPEN SESSION MONMOUTH CONFERENCE ROOM, 7th FLOOR OCTOBER 3, 2012

I. CALL TO ORDER

The Open Meeting of the New Jersey Board of Pharmacy was called to order by Board President Edward McGinley in the Monmouth Room, 7th floor at 124 Halsey Street, Newark, on October 3, 2012 at 9:10 a.m. All members were duly notified of the time, place and all pertinent materials were provided to members.

II. SUNSHINE LAW ANNOUNCEMENT

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

III. ROLL CALL

Edward G. McGinley, R.Ph.	President
Thomas Bender, R.Ph.	Vice President
Margherita Cardello, R.Ph.	Late Arrival 9:25 a.m.
Marc Sturgill, R.Ph.	Late Arrival 9:15 a.m.
Richard Palombo, R.Ph.	
Stephen Lieberman, R.Ph.	
Mahesh Shah R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio	Executive Director
Linda Brodie	Customer Service Rep I
Matthew Wetzel	Government Rep
Jodi Krugman	Deputy Attorney General
Robert Lake	Enforcement Bureau

IV. UPDATE BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of August, \$15,500 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month of August:

- Technicians – 72
- Pharmacists – 185 (166 by examination/score transfer, 19 by reciprocity)
- Out-of-state pharmacies – 9
- In-state pharmacies – 5
- Pharmacists receiving immunization approval – 121

- Interns (Foreign graduates) – 9

There was a second Pharmacy Security Summit on September 13th, held at 124 Halsey Street in the Monmouth Conference Room. A working draft for “Best Practices for Pharmacy Security” was created, distributed and feedback was accepted from those in attendance at the September 13th Summit meeting. The *Best Practices* draft document was submitted for review and comment by industry stakeholders. The comment period is open until October 24, 2012 and all comments should be submitted to the Executive Director’s office.

V. OLD BUSINESS

1. **Arun Kumar Gundaiah Ramesh** – Requesting TOEFL waiver

Mr. Ramesh, requested a waiver, from the Board, to the licensure requirement that he must pass the TOEFL exam. To date, he has been unable to pass any portion of the TOEFL exam.

There is a medical note accompanying his request, explaining why Mr. Ramesh was unable to study and pass the exam. Thomas Bender moved, seconded by Stephen Lieberman to deny the waiver request based on the fact that there is no medical impairment indicated by the physician, which prohibits him from passing or retaking the TOEFL exam.

Motion passed 6-0.

2. A. Cifaldi, Esq., on behalf of his client **AtlantiCare Regional Medical Center, ACRMC**

The Board reviewed AtlantiCare’s correspondence at the April 25, 2012 Board meeting regarding whether ACRMC would need additional permits to provide pharmaceutical service to the AtlantiCare Physician Group, P.C. (APG). The Board, at the time, requested additional information clarifying the types of clientele to be served by APG.

Mr. Cifaldi submitted additional information for the Board to review. Upon review by the Board, there does not appear to be a recognized legal connection between ACRMC and APG. Thomas Bender moved, seconded by Richard Palombo, to deny ACRMC to service, AtlantiCare Physician Group, P.C. (APG) to operate under an institutional permit. ACRMC will need to be licensed with a retail permit in order to service APG patients. Under an institutional permit, ACRMC would be subject to the 7 day rule governing physicians dispensing of medications. Mahesh Shah recused himself due to his affiliation with Mr. Cifaldi. **Motion passed 6-0.**

VI. NEW BUSINESS

1. **Ther-Rx Corporation** – Compounding copies of Makena

The Board reviewed the materials submitted by Ther-Rx and treated the materials as informational.

2. **Camille H. Small** – Pharmacist reciprocity applicant, request for waiver of

FPGEC

Camille Small is a licensed pharmacist in New York. The NY State Board of Pharmacy accepted her transcripts and curriculum reports from Robert Gordon University in Aberdeen, Scotland (5 year B.S.) and exempted her from FPGEC in 1989. She also has a Master's Degree in Industrial Pharmacy, from Long Island University.

Marc Sturgill moved, seconded by Margherita Cardello to waive the FPGEC requirement based on the following facts: Ms. Small has been practicing continually in New York for over 20 years with no disciplinary action and no FPGEC was required in NY at time she was initially licensed in that state. The Board cautioned that upon receiving her license in New Jersey, Ms. Small will not be able to reciprocate to any other state from NJ and recommends that Ms. Small keep her NY license active for purposes of reciprocity. The Board also noted that this waiver is being granted due to the unique set of circumstances that were presented. **Motion passed 7-0.**

3. **Pipeline Healthcare** – Request for remote medication order entry service

A company overview was given by Senior Vice President, Chris Clolko, R.Ph. The company is licensed as a telepharmacy for remote medication processing in several states. The company is headquartered in San Francisco, CA, with their operational field office located in Chicago, IL. Currently they are licensed in 28 states and have daily clinical operations in 10 states and they service exclusively for in-patient hospitals.

Richard Palombo moved, seconded by Marc Sturgill to have Pipeline Healthcare register as an out-of-state pharmacy and to execute central fill agreements for each client that Pipeline will have in New Jersey. Pipeline's policies and procedures should be included with their central fill agreements that are submitted for approval. To date, work from home regulations have not been promulgated by the Board and if regulations are still not in place when Pipeline has New Jersey clients, a Board approved pilot program for Pipeline may be needed, but the Board cannot determine that at this time; a review of Pipeline's applications will be needed first. **Motion passed 7-0.**

Chris Clolko will provide the Board with the rules and regulations from other states regarding telepharmacies. The Board will continue efforts to develop work at home regulations and look into adding a telepharmacy license into the NJ regulations.

4. **Draft Resolution Regarding Board Action between Meetings**

RESOLUTION REGARDING BOARD ACTION BETWEEN MEETINGS

PUBLIC SESSION

The Board of Pharmacy hereby moves to designate the Board President to function as Head of the Board of Pharmacy authorized to take action regarding certain events arising between Board meetings, where time is of the essence. Such actions would include:

1. Issuing an Order to Show Cause upon the filing by the Attorney General of a Verified Complaint seeking emergent relief;

2. Call a meeting of a committee of the Board to conduct an emergent Temporary Suspension hearing based upon such Complaint and issuing an Order to be ratified by the Board at its next meeting and having immediate effect, or call a meeting of the full Board to conduct an emergent Temporary Suspension hearing based upon such Complaint and issuing an Order having immediate effect.
3. Determining settlement terms of a disciplinary case pending review and approval of the full board, including but not limited to, those cases where a final determination by the board must be made on short notice to effectuate global settlement with other civil or criminal authorities or where there is an immediate danger to the public health safety and welfare should a licensee remain in practice.

Each of the above actions is subject to review by the full Board at the next meeting at which such review can be scheduled. The full Board may then ratify, modify or vacate the emergent action taken by the President.

In the absence, unavailability or ineligibility of the President to address the matter, said authority is conferred upon the Vice President of the Board, acting as President pro tempore, and then to remaining Board members in order of seniority.

The Board of Pharmacy hereby moves to authorize the Executive Director of the Board to approve routine applications that clearly meet the educational, exam and experience requirements for:

- 1) Pharmacist
- 2) Pharmacy technician
- 3) Pharmacy
- 4) Out-of-state pharmacy permits – where the pharmacy, owners and RPIC are in active good standing in their home state.

Marc Sturgill moved, seconded by Thomas Bender, to approve the resolution regarding Board actions between meetings. **Motion passed 7-0.**

VII. MITIGATION/HEARING REQUEST

1. **Christopher Socha, R.Ph.** – Texas Road Pharmacy

The Enforcement Bureau went to inspect the pharmacy prior to its opening. The pharmacy treated this inspection as informational regarding what would be needed to be done before they could open. The Enforcement Bureau cited the pharmacy on all found violations, totaling \$6,600.00.

Marc Sturgill moved, seconded by Stephen Lieberman, to remove all citations. Robert Lake of EB, will re-inspect the site before it can be opened. The pharmacy will bear the re-

inspection cost. The site cannot open until the re-inspection is completed and approved. **Motion passed 6-1.** Thomas Bender opposed.

2. **Mark Harris, R.Ph.** – Hackettstown Regional Medical Pharmacy

On April 27, 2012, Hackettstown Regional was cited for 13:39-11.19.(d), the citation was a warning. The chemotherapy clean room and the non-chemotherapy clean room were not yet certified as ISO Class 6; both clean rooms were certified as ISO Class 7 environments.

Mark Harris appeared before the Board today. Stephen Lieberman moved, seconded by Marc Sturgill to remove the warning. The Board recommended that Mr. Harris write to the Board requesting a waiver for the clean rooms to be certified as ISO Class 6, since the Board's regulations will be moving to ISO Class 7 in the near future. **Motion passed 7-0.**

3. **Barry Leskowitz, R.Ph.** – Pharmcare USA of Edison Pharmacy

Pharmcare was inspected on 4/9/12 and cited with several violations.

Chair Direct: The Board is to send Barry Leskowitz a letter regarding violation 11.14.(b).3 requesting how many types of sterile compound products they make and the composition of each product.

4. **Chiyon Kim, R.Ph.** – CVS Pharmacy

CVS was inspected on 3/12/12 and cited with N.J.A.C.13:39-6.2.(f).7

Richard Palombo moved, seconded by Marc Sturgill, to remove the citation based on when the item was returned to the stock shelf from customer pick-up bin. The returned prescription had the customer label removed and was re-labeled properly, except the new restocking label was adhered to bottle with a rubber band. **Motion passed 7-0.**

VIII. INFORMATIONAL

1. **NABP/AACP District 2 Draft Bylaws** – For review, discussion and comments by the Board

The NABP has drafted a set of bylaws for District 2. The District asked the Board for comments and edits to the draft bylaws and to provide appointees to the initial Board of Directors.

Richard Palombo moved, seconded by Margherita Cardello, to recommend that the Executive Director of the Board, be nominated for position of New Jersey's Board Member for District 2.

Motion passed 7-0.

2. **ScripTalk Station**

ScripTalk Station is an audible prescription labeling system. It provides those who cannot read their prescription labels a safe and easy way to manage their own medication regimen.

The Board accepted this as informational, but did not recommend the system.

3. NJ Pharmacist Association

Laurie Clark from the NJ Pharmacist Association appeared before the Board to introduce their new CEO, Elise Barry.

Ms. Clark noted that the Department of Health has posted the informational pamphlet on their website regarding the safe disposal of syringes, and information on addiction services. The Executive Director informed her that the Board of Pharmacy will provide a link from the Board's website to the Department of Health website.

IX. COMMITTEE REPORTS

During the month of August, Board Members Thomas Bender, Richard Palombo, Marc Strugill, Edward McGinley, and Margherita Cardello reviewed 2,500 potential questions relating to New Jersey Law for the new MPJE.

The Rules and Regulation Committee next meeting date is still pending.

X. APPROVAL OF MINUTES FOR AUGUST 22, 2012

Thomas Bender moved, seconded by Margherita Cardello, to approve the August 22, 2012, Open Session Minutes as amended. **Motion passed 7-0.**

XI. ADJOURNMENT

At 11:22 a.m. Margherita Cardello moved, seconded by Stephen Lieberman, to adjourn the Public Session and move into the Executive Session for review of 9 Complaints, 3 Old Business Items, 15 New Business Items, the Secretary's Report and Recommendation on Retail and Institutional Permits, the Secretary's Report and Recommendation on Inspection Reports and the approval of August 22, 2012, Executive Session Minutes.