CANNON BUILDING 861 SILVER LAKE BLVD., SUITE 203 Dover, Delaware 19904-2467

STATE OF DELAWARE BOARD OF PHARMACY



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PUBLIC MEETING NOTICE: **BOARD OF PHARMACY**

DATE AND TIME: Wednesday, February 19, 2014

Conference Room A, 2^{nd Floor} Cannon Building PLACE:

861 Silver Lake Blvd., Dover, DE 19904

APPROVED:

MEMBERS PRESENT

Joli Martini, R.Ph., PharmD, Professional Member, President Kimberly Robbins, R.Ph, Professional Member, Vice President Sandra Zaragoza, R.Ph, Professional Member Susan Esposito, R.Ph, Professional Member Tejal Patel, R.Ph, PharmD, Professional Member Bonnie Wallner, R.Ph, Professional Member Matthew Maher, Public Member Kenneth Sellers, Public Member Jay Galloway, Public Member David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General Christine Mast, Administrative Specialist III

ALSO PRESENT

Sam Wetherill Bill Harbester Richard Stewart Megan Hamilton Peter B Abby Horseman

Don Holst

Jon Reitz

Suzanne Raab-Long

Abhishek De

James Levit

Cheryl Heiks

Kevin Morgan

Nancy Sawyer

Sandra Robinson

Jaime Frink

Eric Brauch

Waheed Aziz

Tiffany Sorey

Brenda Pavlic

Kevin Musto

Keith Larson

CALL TO ORDER

Ms. Martini called the meeting to order at 9:32 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Zaragoza, seconded by Ms. Esposito, to approve the meeting minutes for November 20, 2013. The motion unanimously carried.

A motion was made by Ms. Zaragoza, seconded by Mr. Galloway, to approve the meeting minutes for January 15, 2014. The motion unanimously carried.

PRESIDENT'S REPORT

Ms. Martini reported that last month she attended the Collaborative Care committee meeting and they continue to work on proposed language for regulations. Ms. Martini stated that she and Mr. Dryden went to Christiana Care to see the new robotics system the ProManager Rx system. This will be presented later during the meeting.

UNFINISHED BUSINESS

Complaint Status

- 13-03-11 Assigned to Hearing Officer
- 13-09-11 Assigned to Hearing Officer
- 13-12-11 Forwarded to Office of Attorney General
- 13-19-11 Forwarded to Office of Attorney General
- 13-09-12 Assigned
- 13-01-13 Forwarded to Office of Attorney General
- 13-02-13 Assigned
- 13-03-13 Assigned
- 13-04-13 Forwarded to Office of Attorney General
- 13-05-13 Assigned
- 13-06-13 Forwarded to Office of Attorney General
- 13-07-13 Assigned
- 13-08-13 Assigned
- 13-09-13 Assigned
- 13-11-13 Forwarded to Office of Attorney General
- 13-13-13 Forwarded to Office of Attorney General
- 13-14-13 Assigned
- 13-15-13 Assigned
- 13-16-13 Assigned

13-17-13 – Assigned

13-18-13 - Assigned

13-19-13 - Assigned

13-20-13 - Assigned

13-21-13 – Assigned

13-22-13 - Assigned

13-23-13 - Assigned

13-24-13 - Assigned

UNFINISHED BUSINESS

A motion was made by Ms. Robbins, seconded by Mr. Maher, to move ahead in the agenda until 10:00 am to accommodate the hearing scheduled at 10:00 am.

Proposal To Deny Hearing-Lawrence J Lubonski

Ms. Kelly called the hearing to order at approximately 10:27 a.m. board members were introduced and Ms. Kelly stated today's hearing was the result of a proposal to deny the application of Lawrence J Lubonski pursuant to 24 Del. C. § 2508 (c)(1). Ms. Kelly marked exhibit #1 as the application, documents, and correspondence and notice of hearing. Mr. Lubonski was sworn in by DAG Eileen Kelly. Mr. Lubonski testified on his own behalf to explain the disciplinary actions he had previously received in Oregon, that were before the board for his proposal to deny hearing. Mr. Lubonski outlined the details regarding the situations that resulted in the disciplinary actions and answered questions from the members of the board. A motion was made by Mr. Galloway, seconded by Ms. Robbins to approve the Pharmacist application of Lawrence J Lubonski. The motion unanimously carried. The hearing concluded at 11:07 a.m.

Review of Applications for Final Denial

Trilogy Health Care - A motion was made by Ms. Zaragoza, seconded by Ms. Robbins, to Final Deny the application. The motion unanimously carried.

Vicksburg Special Care - A motion was made by Mr. Sellers, seconded by Ms. Robbins, to Final Deny the application. The motion unanimously carried.

Re-Review of Tabled Applications

Concierge Compounding Pharmaceuticals - A motion was made by Ms. Robbins, seconded by Ms. Zaragoza, to propose to deny the application. The motion unanimously carried

NEW BUSINESS

Public Hearing on Proposed Changes to Rules and Regulations

Deputy Attorney General Eileen Kelly went on record at 10:17 a.m. Ms. Kelly stated the hearing is to adopt proposed amendments to the Rules and Regulations which was published on February 1, 2014 in the Registrar. She marked as Board exhibit #1 as the publication of hearing in the News Journal Newspaper and Board exhibit #2 as the publication of hearing in the Delaware State Newspaper.

Ms. Kelly advised of changes reflected in the amended Rules and Regulations. There was no public comment at the meeting. Written comment will be accepted within 15 days after the hearing.

The Board will deliberate on the proposed regulations at the March meeting.

The hearing went off record at 10:18 am. The hearing was recorded by a court reporter.

Pharmacist and Intern Licensure Approval Ratifications

A motion was made by Ms. Zaragoza, seconded by Ms. Esposito, to ratify the approval of the Pharmacist applications: Joseph P Waters, Hamedat Okanlawon, Tanaya N. Hampton, Anthony B. Roane, and Joseph V. Tinelli. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A motion was made by Ms. Robbins, seconded by Mr. Maher to ratify the approval of the non-resident pharmacy applications: Magnolia Specialty Pharmacy Inc., Brown's Compounding Center, Complete Medical Homecare, Inc., CAP Rx Inc., Central Avenue Pharmacy, Akina Pharmacy, McDaniels Pharmacy, Pharmacy Rx Solutions Holding, Inc, OK Compounding, LLC, AbbVie Endocrinology Inc. DBA Pharmacy Solutions, BriovaRx, Maxor National Pharmacy Services LLC dba Maxor Correctional Pharmacy Services, Orchard Pharmaceutical Services, LLC, A & A Drug Co. d/b/a Sav-Rx Pharmacy, Grane Supply, Maxor Pharmacies, Coram Alternate Site Services, Inc., Care RX Pharmacy Group, LLC, Florida Pharmacy Solutions, Sheefa Pharmacy and Wellness Center, Zynex Medical, Inc., Philidor Rx Services, LLC, America's Compounding Center, Accredo Health Group, Inc., Accredo Health Group, Inc., Specialty Pharmacy Management, LLC, Cure Pharmacy, JCB Laboratories, Coram Alternate Site Services, Inc., Community Compounding Pharmacy, Cardinal Heatlh 414, LLC, CoramRx, LLC, Liberty For All Pharmacy Inc., The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A motion was made by Ms. Robbins, seconded by Mr. Maher to ratify the approval of the wholesale distributor applications: Exel Inc (9 locations), Cardinal Health 200, LLC, Technomed, Inc., The Harvard Drug Group, LLC., Expert Med, First Veterinary Supply, Pernix Therapeutics, LLC., Cardinal Health 200, LLC, DBA: Cardinal Health, Discus Dental, LLC, Merz Aesthetics, Inc., Clinical Solutions Wholesale, LLC., Amneal Institutional, LLC., Vaxserve, Inc., The Compounding Center, Inc., Septodont, Inc. The motion unanimously carried.

Medical Gas Dispensers

There were no applications to be ratified

Retail Pharmacy Licensure Approval Ratification

A motion was made by Ms. Robbins, seconded by Mr. Maher to ratify the approval of the retail pharmacy application: ShopRite Pharmacy #538. The motion unanimously carried.

Pharmacist-In-Charge Interviews

A motion was made to add Megan Hamilton to the agenda by Ms. Robbins, seconded by Mr. Maher. The motion unanimously carried.

Ms. Robbins conducted a PIC interview for Richard Stewart. He is employed by Harris-Teeter Selbyville, De.

Ms. Robbins conducted a PIC interview for Waheed Aziz. He is employed by Seaford Pharmacy.

Ms. Robbins conducted a PIC interview for Morgan Hamilton. She is employed Rite-Aid Millville, De.

Review of Applications by DAG

Pharmacy board DAG Eileen Kelly provided guidance on the following disciplinary actions for applications received followed by the board ruling:

Cardinal Health Pharmacy Services, a motion was made by Ms. Robbins, seconded by Mr. Galloway, to table the application for more information. The motion unanimously carried.

Express Plus Pharmacy, a motion was made by Mr. Galloway, seconded by Ms. Esposito, to approve the application. The motion unanimously carried.

Independence Holding Company, a motion was made by Mr. Sellers, seconded by Ms. Robbins, to approve the application. The motion unanimously carried.

PSS World Medical, Inc., a motion was made by Ms. Esposito, seconded by Ms. Mr. Galloway, to approve the application. The motion unanimously carried.

Christiana Hospital – ProManager Rx Overview

Mr. Sam Wetherill presented the board with information outlining the ProManager Rx system currently being used at Christiana Care. Ms. Martini and Mr. Dryden both visited Christiana Care to see the system in place

and set up. Both shared their experience with the board. A motion was made to approve the ProManager Rx system by Mr. Galloway, seconded by Ms. Esposito. The motion unanimously carried.

COMMITTEE REPORTS

Legislative – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel and David Dryden None

Continuing Education - Joli Martini, Bonnie Wallner, and David Dryden:

None

Consumer Affairs - Matthew Maher, Ken Sellers and Jay Galloway:

Professional Liaisons – Kim Robbins and Sandra Zaragoza:

Ms. Zaragoza provided the board of directors a report from the Delaware Pharmacists Society meeting which was held on Tuesday February 18, 2014.

Controlled Substance Liaisons – Joli Martini, Jay Galloway and David Dryden:

COMMITEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Sandy Robinson, Howard Simon, Alicia Kluger, Brenda Pavlic, Sandra Zaragoza, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

Pharmacy Technician Licensure Committee – Howard Simon, Matt Maher, Kim Robbins, Tejal Patel, Kevin Musto, Maryanne Holzapfel, Anne Pyle and David Dryden:

Collaborative Care Committee – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Howard Simon, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, Williamharbester, David Dryden:

BOARD CORRESPONDENCE

NABP, Drug Quality and Security Act handout provided.

NABP, New USP FAQ's regarding compounding handout provided.

NABP, Interest in Sterile Compounding Inspector Training brochure provided.

EXECUTIVE SECRETARY AND INSPECTION REPORT - David Dryden, Samantha Nettesheim

Mr. Dryden reported.

NEWSLETTER UPDATES

Newsletter for fourth quarter has been submitted for publication.

OTHER BUSINESS BEFORE THE BOARD

Mr. Dryden shared information from the NABP, VPP review of "Roxan" pharmacy.

PUBLIC COMMENT

NEXT SCHEDULED MEETING

The next meeting is scheduled for March 19, 2014 at 9:30 am., PSC Conference Room 1st floor.

<u>ADJOURNMENT</u>

There being no other business before the board. The meeting was adjourned at 12:35 pm.

Respectfully submitted,

Christine Mast

Administrative Specialist III