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CANNON BUILDING
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**STATE OF DELAWARE
BOARD OF PHARMACY**

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| PUBLIC MEETING NOTICE: | BOARD OF PHARMACY |
| DATE AND TIME: | Wednesday, January 20, 2016 9:30 am |
| PLACE: | Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904 |
| APPROVED: | February 17, 2016 |

MEMBERS PRESENT

Susan Esposito, R.Ph., Professional Member, President
Hooshang Shanehsaz, R.Ph., Professional Member, Vice President
Kimberly Robbins, R.Ph., Professional Member
Tejal Patel, PharmD, Professional Member
Bonnie Wallner, R.Ph., Professional Member
Kenneth Sellers, Public Member
Julia Wheatley, Public Member
Jay Galloway, Public Member

MEMBERS ABSENT

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Tiffany Liu
Jacob Grobelny
Fidelia Bernice
Satyanarayana R Sama
Bill Harbester
Hillary Schlerf
Deborah Sarmiento
Joseph Peoples
Kevin M Moyz
Michelle McCreary
Amy Birder
Jaime Frink

CALL TO ORDER

Ms. Esposito called the meeting to order at 9:40 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel, to approve the meeting minutes for November 18, 2015 with corrections. The motion unanimously carried.

PRESIDENT'S REPORT

Ms. Esposito reported that she received some information from Delaware Pharmacist Society (DPS), regarding the representation of the Delaware Board at their meetings. Ms. Esposito informed DPS that Tejal Patel, Kimberly Robbins and Hooshang Shanehsaz would attend their meetings on behalf of the Delaware Board when they can fit it into their schedules.

Mr. Dryden will not be attending today's meeting he is currently attending a meeting at the National Association of Boards of Pharmacy (NABP) in Chicago, IL as the Chairman of the law enforcement committee for controlled substances.

UNFINISHED BUSINESS

Statutory and Regulatory Discussion

Ongoing - Practitioner/Pharmacy Ownership – Ms. Kelly presented the board with draft regulations changes for §2523(7) to review. Mr. Shanehsaz had concerns regarding the word “office” as related to the practitioner’s office; as well as controlled and non-controlled medications. The consensus of the board would be to add “or the practitioners designated agent” and remove the word “office”. The board felt as though controlled and non-controlled medications should be referred to separately. Ms. Kelly will continue to work on the language and will provide the board an updated draft to review during the next meeting.

Ms. Kelly stated that §2528(a) is really clear however (b) and (c) need more discussion so that the proposed language can be clearly stated. Ms. Kelly would like to review the NABP States Survey for information regarding what other states are doing related to Pharmacy/Practitioner ownership issues. One of the concerns of the board is urgent care facilities that currently are not required to hold any type of pharmacy license but can dispense medications to patients. Without a complete medication history, or a pharmacist on staff, medication contraindications have occurred as well as improper mixing of medications which causes great concern for patient safety. Mr. Mangler expressed concern placing restrictions on practitioners precluding them from ownership of a pharmacy. He stated that federal law prohibits the practitioner from forcing the patient to utilize any specific pharmacy. The board's concern is the practitioner that automatically fills the prescription at the time of the visit and has it prepared for the patient at the time of the discharge of the visit. This puts undue stress on the patient to automatically get the prescription from the practitioner. In some cases patients are not aware that they have a choice and can have their prescription filled at the pharmacy of their choice. Mr. Mangler asked if the board had contacted any stakeholders for input on the proposed regulations changes. He also asked the board to review and provide more detailed information to support the need of the proposed changes so that he could have a clearer understanding of the board's concerns. Ms. Kelly asked that this item remain on the agenda for further discussion.

Ongoing - Provision for Disciplinary Action – Ms. Kelly and Mr. Dryden to discuss further, tabled until next meeting.

Ongoing - Clarification of §2512(e)(f), Inactive Status - bill preparation in process, tabled until the next meeting.

Patient Practitioner Relationship & EPrescribing Update – Ms. Kelly stated the changes are provided for review. Ms. Kelly asked that this item remain on the agenda for further discussion.

NEW BUSINESS

Ms. Esposito read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist: A1-0004875 Jingbo Sun
A1-0004876 Karen Elizabeth Slagle
A1-0004877 Cheree T. Caesar
A1-0004878 Stacy M. Yoo

A1-0004879 Mayur S Tripathi
A1-0004880 Ryan P. Courtney
A1-0004881 Kawthar Elbishlawi
A1-0004882 Patrick Fuh
A1-0004883 Reshma Rao
A1-0004884 Michael C. Bartels
A1-0004885 Wendy Lisa Shore
A1-0004886 Russell B. Mantooth
A1-0004887 Christopher C. Williams
A1-0004888 Julius Asofar
A1-0004889 Carl J. Isenberg
A1-0004890 Kristin K. Ball
A1-0004891 Fabrice Afanyu-Lorater
A1-0004892 Elizabeth Ann Darbee
A1-0004893 Allison B. Henry
A1-0004894 Thanh Hien Thi Wang
A1-0004895 Latrina Denise Melton
A1-0004896 Warren L. Hill

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern: A7-0002408 Karlee Nikole Walklett
A7-0002409 Izetta C. Henry
A7-0002410 Blair G. Heckel

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001763 Affordable Pharmacy, Inc.
A9-0001764 Vicksburg Special Care Pharmacy & Compounding Inc. dba Aspire Rx
A9-0001765 Injury Med Express Pharmacy LLC
A9-0001766 CHP Acquisition Corp DBA Omnicare of Southern New Jersey
A9-0001767 IV Solutions of Lubbock
A9-0001768 Empire Specialty Pharmacy Corp
A9-0001769 Trilogy Pharmacy
A9-0001770 Cystic Fibrosis Services
A9-0001771 Caremark Arizona Specialty Pharmacy, LLC
A9-0001772 Keystone Choice Pharmacy, LLC
A9-0001773 Firmus Pharmacy, LLC
A9-0001774 Meijer Pharmacy #463
A9-0001775 Southside Pharmacy 3
A9-0001776 Ocean Breeze Pharmacy
A9-0001777 Gulf Coast Pharmacy, Inc.
A9-0001778 LLC Patient Services
A9-0001779 CentRx Pharmacy Northern Nevada
A9-0001780 Family L.T.C. Pharmacy, Inc
A9-0001781 Martinsville Family Pharmacy
A9-0001782 Women's International Pharmacy, Inc.
A9-0001783 Concierge Compounding Pharmaceuticals, Inc.
A9-0001784 RSVP Pharmacy #7, LLC
A9-0001785 BiologicTx, LLC

A9-0001786 Reliant Care Solutions
A9-0001787 Solera Specialty Pharmacy LLC
A9-0001788 Imprimis Pharmaceuticals, Inc.
A9-0001789 Lionville Natural Pharmacy
A9-0001790 MedRx Compounding & Pharmacy, LLC
A9-0001791 IBA Molecular North America, Inc.
A9-0001792 Healthcare Specialty Transaction Services, LLC
A9-0001793 Southlake Pharmacy Group, LLC dba United Specialty Pharmacy

A motion was made by Ms. Robbins and seconded by Ms. Patel to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0002258 Woodfield Distrubtion, LLC
A4-0002259 Hospira Worldwide, Inc.
A4-0002260 UPS Supply Chain Solutions, Inc.
A4-0002261 St. Mary's Medical Park Pharmacy, Inc.
A4-0002262 Advanced Pharma Inc.
A4-0002263 BioComp Pharma
A4-0002264 Boehringer Ingelheim Pharmaceuticals, Inc.
A4-0002265 Boehringer Ingelheim Pharmaceuticals, Inc.
A4-0002266 Hospira Worldwide, Inc.
A4-0002267 Hospira Worldwide, Inc.
A4-0002268 Independent Pharmacy Distributor, LLC
A4-0002269 PharMEDium Services, LLC
A4-0002270 Sigma Pharmaceuticals, LLC
A4-0002271 PharMEDium Services, LLC
A4-0002272 PharMEDium Services, LLC
A4-0002273 Reckitt Benckiser LLC
A4-0002274 Dsquared Pharmaceuticals Inc.
A4-0002275 Dendreon Pharmaceuticals, Inc.
A4-0002276 MD Logistics, Inc.

A motion was made by Ms. Robbins and seconded by Ms. Patel to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000137 Murphy Homecare, Inc.

A motion was made by Ms. Robbins and seconded by Ms. Patel to approve the ratification of the Medical Gas Distributor applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0000993 Acme Markets, Inc. dba Acme Pharmacy #2682
A3-0000994 Acme Markets, Inc. dba Acme Pharmacy #2680
A3-0000995 Delaware CVS Pharmacy, LLC
A3-0000996 Delaware CVS Pharmacy, LLC
A3-0000997 Delaware CVS Pharmacy, LLC
A3-0000998 Kmart Operations LLC, Kmart Pharmacy #7725

A motion was made by Ms. Robbins and seconded by Ms. Patel to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Retail Pharmacy Temporary Licensure Approval Ratification
None

Outsourcing Facility

AA-0000019 Isomeric Pharmacy Solutions LLC
AA-0000020 Advanced Pharma Inc.
AA-0000021 PharMEDium Services, LLC
AA-0000022 PharMEDium Services, LLC
AA-0000023 PharMEDium Services, LLC

A motion was made by Ms. Patel and seconded by Mr. Shanehsaz to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins conducted PIC interviews with the following Pharmacists In Charge:
Satyanarayana R Sama, Metro Pharmacy Newark, DE
Tiffany Liu, CVS/Target Dover, DE

Board Review of Hearing Officer Recommendations

George A Amoateng, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Shanehsaz and seconded by Mr. Galloway. The motion unanimously carried.

Kelly A Steele, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Shanehsaz and seconded by Ms. Wallner. The motion unanimously carried.

Gilbert C Gitau, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Shanehsaz and seconded by Mr. Sellers. The motion unanimously carried.

Nikia S Coefield, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Shanehsaz and seconded by Mr. Sellers. The motion unanimously carried.

Bernard S Walker, Jr., a motion to amend the Hearing Officer Recommendation to remove the letter of reprimand and leaving other recommendations in tact was made by Mr. Shanehsaz and seconded by Ms. Robbins. The motion unanimously carried.

Oladipo George, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Shanehsaz and seconded by Mr. Sellers. The motion unanimously carried.

Fallan Ovrutsky, a motion to amend the Hearing Officer Recommendation to remove the letter of reprimand and leaving other recommendations in tact was made by Ms. Patel and seconded by Ms. Wallner. The motion unanimously carried.

Frank O Prempeh, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Shanehsaz and seconded by Mr. Sellers. The motion unanimously carried.

Board Review of Consent Agreement

Joanne M D'Amico, a motion to approve the Consent Agreement as written was made by Mr. Shanehsaz and seconded by Ms. Robbins. The motion unanimously carried.

Board Review of Facility Applications

RxC Acquisition Company, a motion to approve the application was made by Mr. Galloway and seconded by Mr. Shanehsaz. The motion unanimously carried.

MEDISCA, Inc., a motion to propose to deny the application was made by Mr. Shanehsaz and seconded by Mr. Galloway. The motion unanimously carried.

Med-Pro Distributors, a motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Patel. The motion unanimously carried.

Zo Skin Health, Inc, a motion to approve the application was made by Mr. Shanehsaz and seconded by Mr. Galloway. The motion unanimously carried.

Home Towne Rx Department, a motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Patel. The motion unanimously carried.

American Specialty Pharmacy, a motion to table the application was made by Ms. Robbins and seconded by Ms. Patel. The motion unanimously carried.

Philidor Rx Services, a motion to table the application was made by Mr. Shanehsaz and seconded by Ms. Wheatley. The motion unanimously carried.

ProCare Pharmacy, a motion to approve the application was made by Ms. Robbins and seconded by Mr. Shanehsaz. The motion unanimously carried.

BeneVi Health, a motion to approve the application was made by Mr. Sellers and seconded by Mr. Galloway. The motion unanimously carried.

Continuing Education Approval

Ms. Susan Esposito submitted the required continuing education approval forms for review by the board requesting 6.0 credit hours. A motion to approve the request was made by Mr. Shanehsaz and seconded by Mr. Sellers. The motion unanimously carried.

Trinity Pharmacy Services (Harrison Senior Living) – MedDispense

MedDispense C45 is currently on the approved listing. A motion to accept the use of this medication equipment at the stated location was made by Mr. Shanehsaz and seconded by Mr. Galloway.

COMMITTEE REPORTS

Legislative – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and David Dryden

No Report

Continuing Education – Bonnie Wallner, Tejal Patel and David Dryden:

No Report

Consumer Affairs – Ken Sellers, Jay Galloway and Julia Wheatley

No Report

Professional Liaisons – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

Mr. Bill Harbester reported that DPS is working on a contract through the state focusing on cardio-vascular health. DPS continues to work continuing education opportunities for pharmacists. The annual convention dates have been scheduled for May 9-11, 2016. The convention will be held at the Hyatt, Dewey Beach, Delaware and will also provide continuing education opportunities for pharmacists.

Controlled Substance Liaisons – Tejal Patel, Hooshang Shanehsaz, Jay Galloway and David Dryden:

Mr. Shanehsaz stated that law enforcement is seeking to see if prescription blanks can have unique serial numbers to better assist in searching for stolen or misplaced blanks.

EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim

No Report

BOARD CORRESPONDENCE

Letter received from Animal Health Institute, Alexander S. Mathews – Ms. Esposito read the letter into the record. Ms. Kelly stated that the Veterinary board received the letter as well. Mr. Mathew's letter shared concerns related to regulation 10.0 changes.

Letter received from Downing Labs, LLC., Ashley Downing, Owner – alerted the board regarding a voluntary recall of sterile compounded medications based on an inspection conducted by the FDA of their outsourcing facility. They are using a third party auditor to ensure compliance with 503(b) guidelines.

NEWSLETTER UPDATES

Mr. Dryden wanted to inform the board that all of the continuing education information was added to the newsletter that will be published February 2016.

OTHER BUSINESS BEFORE THE BOARD

Ms. Patel stated that there are still issues with the public understanding of the syringe law. Ms. Patel requested assistance in providing the public with more information to help clarify the law. After review of the current syringe law the board agreed that the current legislation is clear regarding the dispensing of a syringe without a prescription. Prior to dispensing syringes to the public the Pharmacist must confirm that an injectable medication has been prescribed for the patient for whom the syringes are being requested. Ms. Patel suggested that a recommendation to the controlled substance advisory committee to revise the syringe law to include a log of all dispensed syringes be kept. The board agreed with Ms. Patel's recommendation to the controlled substance advisory committee.

Ms. Patel requested clarification regarding paperwork retention storage outside the facility into secured storage units. After a review of retention policy for safe storage of documents, it was determined that storage outside of the facility in a secure location is permitted.

Ms. Patel noted that the self-inspection of 2% is very narrow range to meet, taking into consideration of manufacturer defects alone, can we discuss and possibly reevaluate?

Ms. Kelly – requested that "Naloxone Standing Orders" be added to next month's agenda. Public health is currently reviewing and making procedural recommendations on this issue.

Ms. Kelly informed the board members of the passing of her mother-in-law, Mary Lou Anderson. Ms. Anderson was instrumental in the advancement of Pharmacy Practice both in Delaware and nationally through her involvement with APHA, serving as their first woman President. The Board expressed its condolences to Ms. Kelly and the Anderson family for their loss.

PUBLIC COMMENT

No comment

NEXT SCHEDULED MEETING

The next meeting is scheduled for February 17, 2016 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the Board a motion to adjourn the meeting was made by Mr. Sellers, and seconded by Ms. Patel at 12:40 pm. The motion unanimously carried.

Respectfully submitted,

A handwritten signature in black ink that reads "Mast". The signature is written in a cursive style with a large, looped initial 'M'.

Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy