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CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

**STATE OF DELAWARE**

**BOARD OF PHARMACY**

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: DPR.DELAWARE.GOV
EMAIL: customerservice.dpr@state.de.us

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| PUBLIC MEETING NOTICE: | **BOARD OF PHARMACY** |
| DATE AND TIME: | **Wednesday, June 15, 2016 9:30 am** |
| PLACE: | Conference Room A, 2nd Floor Cannon Building<br>861 Silver Lake Blvd., Dover, DE 19904 |
| APPROVED: | August 17, 2016 |

## MEMBERS PRESENT

David W. Dryden, R.Ph., J.D., Executive Secretary
Susan Esposito, R.Ph., Professional Member, President
Hooshang Shanehsaz, R.Ph., Professional Member, Vice President
Bonnie Wallner, R.Ph., Professional Member
Kimberly Robbins, R.Ph., Professional Member
Jay Galloway, Public Member
Julia Wheatley, Public Member

## MEMBERS ABSENT

Tejal Patel, PharmD, Professional Member

## DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

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

## ALSO PRESENT

Bill Maguire
Chuck Frame
Albert Mannering
Amy Bixler
Jessica Puckett Beasley
Dale Clarke
Sinoe Naji-Taylor
Dr. Bob Thompson
Patrick Gallagher
C. Scott Kidner
Anthony Grzib
Jen Raibley
Marcy Bliss
Michelle Crosier
Thomas Rasnic
Suzanne Raab-Long
Nancy Sawyer
Mimi Ghassemi
Kara Gadomski

Stacy McGarry
Drew Litson
Parithran Gujja
Priti Patel
Steve Shipper

**CALL TO ORDER**
Ms. Esposito called the meeting to order at 9:30 a.m.

**REVIEW OF MINUTES**
A motion was made by Mr. Shanehsaz and seconded by Ms. Robbins, to approve the meeting minutes for April 20, 2016. The motion unanimously carried.

**UNFINISHED BUSINESS**
Propose to Deny Hearing – PharMEDium Services, LLC. (Sugarland, TX) – Ms. Kelly called the hearing to order and requested the Board members introduce themselves for the record. Ms. Kelly outlined the need for the hearing. The hearing proceeded with testimony from PharMedium representatives Albert Mannering and Tom Rasnic. The Board deliberated on the testimony heard. A motion to approve the application was made by Ms. Robbins seconded by Ms. Wallner. The motion carried unanimously.

Final Denial of Application – Doctor's Specialty Pharmacy – the Board initially reviewed the application during its August 19, 2015 meeting. The application was tabled for more information and a letter was drafted accordingly. There being no response to the request for more information from the Board the application was processed for final denial. A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to deny the application. The motion unanimously carried.

Statutory and Regulatory Discussion
Telemedicine Pharmacy Statute and Regulations Changes – Ms. Kelly is preparing draft regulations.

3PL Licensure Discussion – Ms. Kelly is preparing draft regulations.

Ongoing - Provision for Disciplinary Action – Ms. Kelly is preparing a draft bill for presentation to the director for review.

Ongoing - Clarification of 24 **Del. C**. §2512(e) (f), Inactive Status - Ms. Kelly is preparing a bill for presentation to the director for review.

Ongoing - Patient Practitioner Relationship & E-Prescribing Update – the bill is currently being reviewed by prospective legislative sponsorship.

**PRESIDENT'S REPORT**
Ms. Esposito stated

**NEW BUSINESS**
Delaware Veterinary Medical Association (DVMA) Veterinary Compounding Concerns –
Mr. Dryden discussed the changes in regulation to 503(a) and 503(b) compounding to reflect the changes made previously by the FDA. The DVMA contacted Mr. Dryden and requested to be added to the Board of Pharmacies agenda to discuss their concerns regarding these regulations changes. Mr. Scott Kidner thanked Mr. Dryden for attending a DVMA meeting to provide an explanation of the changes to regulation. Dr. Bob Thompson stated that they learned of this regulation change on March 9, 2016 during the executive board meeting of the DVMA. The regulations changes prevents necessary drugs required to save animal lives during emergent crisis by requiring a prescription for compounded medications per patient be received from a compounding pharmacy as opposed to having a supply available for office use. Dr. Thompson stated that office use regulations changes not only effects veterinary medicine it has also impacted other human specialty practices like ophthalmology. Dr. Thompson stated "all it will take is on legislator to lose their pet and the

regulations will get corrected". Mr. Patrick Gallagher, Attorney, Duane Morris, LLP, stated that the majority of his practice serves pharmacies and veterinary practices with respect to State statute, regulatory and Federal law changes that affect these industries. Mr. Gallagher stated that there are distinct differences noted in Federal law regarding use of compounded medication for human and animal use. He stated that the FDA has not made any change to compounded office use with regard to animal compounded medication. The change that the FDA made only pertains to human use. He made several references to the language stated in the FDA regulation that he feels supports this position. Mr. Gallagher stated that the FDA guidance information released for 503(a) and 503(b) is only relative to human use. His position for the veterinary community is that any guidance provided by the FDA has been for human use only and was not meant to change any guidance previously given for animal use. He stated that the FDA has on numerous occasions stated that newly released guidance provided regarding 503(a) or 503(b) only affects human use. He also stated that there has been no formal final guidance provided by the FDA for animal office use. The veterinary community has concerns regarding the unintended circumstances that these changes will have in the wellbeing of their animal patients up to and including death of the patient due to the inability of utilizing compounded medications for office use. Ms. Esposito stated that there have been and continue to be concerns with any office use compounded medication regarding diversion and safety and/or quality of the medication. Mr. Dryden explained that when the Board of Pharmacy first addressed this issue over two years ago and held the appropriate public hearings mirrored the Federal regulation which allows for office use if the compounded medication is received from a FDA registered "Outsourcing Facility". He stated that office use is only prohibited if compounded medications are received from a facility that has not been registered with the FDA as an Outsourcing Facility. The Board of Pharmacy made the regulations changes to provide a means for office use otherwise; office use would have been prohibited entirely. By changing the language in 5.1.7.1, office use is allowed if the compounded medication is received by an "Outsourcing Facility" registered with the FDA and also licensed in this state as an Outsourcing Facility. Mr. Dryden spoke with the FDA for clarification and guidance and he stated that the FDA relayed that current regulation only addresses human use which would prevent any animal use in its entirety. However, veterinary compounded medications can be obtained so long as 503(a) and 503(b) is being followed by an Outsourcing Facility and is properly registered with the FDA. Otherwise compounded medications would be limited to human use only based on current federal authority of the FDA. Mr. Dryden expressed that the Board of Pharmacy worked very hard on this issue and made the changes to regulation in order to allow office use in this state as long as the compounded medications are prepared in a FDA registered outsourcing facility and is licensed in this state as such. Mr. Dryden also stated that following the DVMA meeting he would be contacting the FDA regarding the certain availability of drugs needs for veterinary use that may not be available. He assured the DVMA community he would continue to get clarification once he receives the listing of medications of concern. Ms. Kelly has requested that Mr. Gallagher send to Ms. Mast his references to the federal regulations that are in support of office use for animal use. Ms. Esposito wanted to remind everyone that patient safety of compounded medication whether in human or animal use is part of the Boards responsibility. Mr. Shanehsaz expressed that the intention of the Board was to make sure compounded medications for office use continued to be available for human and animal patients by acquiring them through an Outsourcing Facility as required by federal law. The previous language in regulation could have prevented office use all together. Ms. Kelly would like to review this issue further and also review other states opinions and changes regarding this issue. She asked that this item be left on the agenda for further discussion. Ms. Wheatley expressed to the DVMA that the Board did not intend to appear as though they were hiding regulations changes and followed all the appropriate and required noticing of the hearing related to this issue. She invited the Veterinary community to attend their monthly Board meetings to assist in keeping up with the every changing requirements of the practice of pharmacy in the future. She also expressed that the Board of Pharmacy and its members regard patient safety whether a human or an animal very highly as their number one priority as a member of the board. For the record, based on the integrity of this Board, it does not matter whether it's a legislator or citizen of Delaware's animal, safety is the priority of this Board.

Ms. Esposito read into the record the following ratifications:

<u>Pharmacist and Intern Licensure Approval Ratifications</u>

**Pharmacist:**

A1-0004943 Veronica A. Crowder
A1-0004944 Jihyun Park

A1-0004945 Bhavesh Thakrar
A1-0004946 Ailin Azis
A1-0004947 Pinal G. Soni
A1-0004948 Johanna Rodriguez
A1-0004949 Tam K Nguyen

**Pharmacist Intern:**
A7-0002421 Sharif Elmenchawy
A7-0002422 Agnes K. Sweileh
A7-0002423 Peter Nikolos
A7-0002424 Kayla Marie Garzio
A7-0002425 Adam B Dryden
A7-0002426 Jasbir K. Deol
A7-0002427 Sarah Adeniran-Obe
A7-0002428 Erin Nicole Barton

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

Non-Resident Pharmacy Licensure Approval Ratifications

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| A9-0001841 | SP2, LLC |
| A9-0001842 | BeneVi Health LLC |
| A9-0001843 | Apothecary by Design Acquisition Co., LLC |
| A9-0001844 | Specialty Chemist Corp. |
| A9-0001845 | Wright Specialty Pharmacy and Diabetics Supply, LLC dba Benevere Specialty Pharmacy |
| A9-0001846 | CareZone Pharmacy |
| A9-0001847 | Medical Center Pharmacy of Wilmington, Inc. |
| A9-0001848 | OptiMed Pharmacy, Inc |
| A9-0001849 | Cottrill's Pharmacy, Inc. |
| A9-0001850 | Mail My Meds LLC |
| A9-0001851 | Specialty Med Services |
| A9-0001852 | Medstar Pharmacy LLC |
| A9-0001853 | Loudoun Pharmacy Corporation |
| A9-0001854 | miRx Pharmacy |
| A9-0001855 | JC & P Ventures PLLC |
| A9-0001856 | Millennium Pharmacy Systems, LLC |

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

Wholesale Distributor Licensure Approval Ratifications

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| A4-0002292 | Dispensary of Hope, LLC |
| A4-0002296 | Emerson Ecologics LLC |
| A4-0002297 | Medisca, Inc. |
| A4-0002298 | AngioDynamics, Inc. |
| A4-0002299 | The Procter & Gamble Distributing, LLC |
| A4-0002300 | The Procter & Gamble Distributing, LLC |
| A4-0002301 | Primary Pharmaceuticals, Inc. |
| A4-0002302 | Community Durable Medical Equipment Co. Inc. |
| A4-0002303 | Walgreens Specialty Pharmacy #16287 |
| A4-0002304 | Nitrous Oxide Corporation |
| A4-0002305 | West-Ward Pharmaceuticals Corp. |
| A4-0002306 | Cangene bioPharma LLC |
| A4-0002307 | Noramco, Inc. |

A4-0002308 AWC Specialty RX Consulting LLC
A4-0002309 Sanofi Pasteur Inc
A4-0002310 Kenco Logistic Services, LLC
A4-0002312 Sage Products LLC

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

Medical Gas Dispensers
None

Retail Pharmacy Licensure Approval Ratification
None

Pharmacy Manufacturer Approval Ratification
A5-0000071 Noramco, Inc.

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

Outsourcing Facility
None

Pharmacist-In-Charge Interviews
Ms. Robbins conducted PIC interviews with the following Pharmacists in Charge:
PIC, Chinedum Awakwe, Synergy Express Pharmacy, New Castle, De. (NO SHOW)
PIC, Pavithran Gujja, Express Discount Pharmacy, Wilmington, De.
PIC, Mimi Ghassemi, Walgreens, Middletown, De.
PIC, StacyMcGarry, Walgreens, Wilmington, De.
Consultant PIC, Priti Sarvil Patel, OmniCare
Consultant PIC, Sinoe Naji-Taylor, New Castle Rx, New Castle, De.

Review of Consent Agreement
Peter W. Hauss - a motion to reject the consent agreement as presented was made by Ms. Wallner and seconded by Mr. Shanehsaz. Ms. Wheatley abstained, the motion carried.

Peter K Agbo - a motion to approve the consent agreement as presented was made by Mr. Shanehsaz and seconded by Ms. Wallner. Ms. Wheatley abstained, the motion carried.

Board Review of Facility Applications
Eli Lilly and Company (Indianapolis, IN), a motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Wallner. The motion unanimously carried.

Wedgewood Village Pharmacy, LLC. (Swedesboro, NJ), a motion to approve the application was made by Mr. Shanehsaz and seconded by Mr. Galloway. Ms. Robbins was not present. The motion carried.

Long's Drugs of Lexington South Carolina, Inc., a motion to approve the application was made by Mr. Galloway and seconded by Mr. Shanehsaz. The motion unanimously carried.

Biologics, Inc. (Cary, NC), a motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Wallner. The motion unanimously carried.

KeySource Acquisition, LLC. (Cincinnati, OH), a motion to approve the application was made by Ms. Wallner and seconded by Mr. Shanehsaz. The motion unanimously carried.

Pharmacist & Pharmacy - Discussion/Action Items

Collaborative Care – Mr. Shanehsaz reported that there was a meeting held by Christiana Care on May 16, 2016 that included pulling the stakeholders together to review collaborative care. Christiana received correspondence that stated that collaborative care must include retail community and hospital pharmacy in order to be supported legislatively. Currently this initiative is stalled.

Review of Substantially Related Crimes List – Ms. Kelly requested that the Board review the crimes listing for items that could be removed from their current list. The Board would review this listing and be prepared to provide Ms. Kelly feedback at the next scheduled meeting.

OmniCell Automated System Unit Review, The Brakenville Center - a motion to approve the Omnicell models with Safety Stock Option included was made by Mr. Shanehsaz and seconded by Ms. Robbins. The motion unanimously carried.

OmniCell Automated System Unit Review, Manor House, Seaford, DE. - a motion to approve the Omnicell models with Safety Stock Option included was made by Mr. Shanehsaz and seconded by Ms. Robbins. The motion unanimously carried.

**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:
No Report
**Controlled Substance Liaisons –**Tejal Patel, Hooshang Shanehsaz, Jay Galloway and David Dryden:
No Report

Ms. Robbins asked for clarification regarding practitioner dispensing as related to regulatory guidelines that should be followed by the practitioner. Her concern is labeling of the dispensed drugs, currently she is seeing labeling issues from practitioner dispensed drugs. They are not following the labeling requirements in regulation 5 that a pharmacist is required to follow. Ms. Wallner stated that labeling regulation already exists that requires practitioners to follow certain labeling requirements. Ms. Robbins was advised to file a complaint against any practitioner not following the required labeling regulations so that an investigation could be conducted by the Division of Professional Regulation.

**EXECUTIVE SECRETARY, INSPECTION REPORT - David Dryden, Michelle McCreary**

Mr. Dryden had no report.

Michelle McCreary reported that she completed the following Inspections:
1 – Relocation Inspection
1 – Infusion Pharmacy Inspection
1 – Pre-Construction Inspections
1 – Change of Ownership Inspections
6 – Follow up Inspections
Continued – Routine Inspections

Ms. McCreary is conducting follow up calls resulting in questions received from PIC self-inspection forms that the division is receiving.

**BOARD CORRESPONDENCE**

Nanticoke Pharmacy, Bimal Das, R.Ph. – Centralized Prescription Processing

AMAG Pharmaceuticals Letter

NABP – Delegates Approve 5 Resolutions

NABP – Containment Technologies Group – Claims About CriticalPoint

NABP – Joint Letter to Senate SB2700

**NEWSLETTER UPDATES**
None

**OTHER BUSINESS BEFORE THE BOARD**
None

**PUBLIC COMMENT**
None

**NEXT SCHEDULED MEETING**
The next meeting is scheduled for August 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. Shanehsaz and seconded by Mr. Galloway at 1:11 pm. The motion unanimously carried.

Respectfully submitted,

Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy