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STATE OF DELAWARE
**DEPARTMENT OF STATE**

DIVISION OF PROFESSIONAL REGULATION

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| PUBLIC MEETING NOTICE: | **BOARD OF PHARMACY** |
| DATE AND TIME: | **Wednesday, April 17, 2013** |
| PLACE: | Conference Room A, Cannon Building<br>861 Silver Lake Blvd., Dover, DE 19904 |
| APPROVED: | May 15, 2013 |

## MEMBERS PRESENT

Howard Simon, R.Ph, Professional Member, President
Matthew Maher, Public Member, Vice President
Sandra Robinson, R.Ph, Professional Member
Joli Martini, R.Ph., PharmD, Professional Member
Kimberly Robbins, R.Ph, Professional Member
Sandra Zaragoza, R.Ph, Professional Member
Jay Galloway, Public Member
David W. Dryden, R.Ph., J.D., Executive Secretary

## MEMBERS ABSENT

None

## DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General
Catherine Simon, Administrative Specialist III
Alicia Kluger, Pharmacist Compliance Officer

## ALSO PRESENT

Ann Campagna
Lucy Somer
Jon Reitz
Don Holst
Joanne Krakowiak
Maryanne Holzapfel
Jessica Mills
Phil Anderson
Bill Harbester
Tanaya Hampton
Megan Torbert
Nwakaego Chukwunenye
Tiffany Sorey
Sindhuri Repaka
Kevin Musto
Rich Palombo
Kim Willson
Amy Dempster

Mary Wachter
Rebecca Byrd

## CALL TO ORDER

Mr. Simon called the meeting to order at 9:30a.m.

## REVIEW OF MINUTES

A motion was made by Ms. Zaragoza, seconded by Mr. Maher, to approve the meeting minutes for March 20, 2013 with three corrections noted by Ms. Robinson. The motion unanimously carried.

## PRESIDENT'S REPORT

Mr. Simon reported that he and Mr. Dryden will be attending the NABP Convention in St. Louis, MO from May 18-22, 2013.

## 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
13-02-12 – Assigned
13-03-12 – Assigned
13-04-12 – Assigned
13-05-12 – Assigned
13-07-12 – Assigned
13-08-12 – Closed
13-09-12 – Assigned
13-01-13 – Assigned
13-02-13 – Assigned
13-03-13 – Assigned
13-04-13 – Assigned
13-05-13 – Assigned
13-06-13 – Assigned

Prescription Monitoring Program (PMP) Update

David Dryden reported that Samantha Nettesheim is in the process of obtaining additional grants and working with the grants already received. Grants include but are not limited to those covering DHIN and law enforcement. Mr. Dryden stated that although the PMP is fairly new, things are going very well. About 1/3 of Delaware practitioners who have controlled substances registrations in Delaware are registered with the PMP. One of the items being discussed is the possibility of requiring registration for all practitioners in the future.

Review of Walgreens "Well Experience" Pharmacy

Don Holst submitted the policies and procedures manual for the Board's review. He detailed the main issues and answered questions from Board members. The number of technicians per store will vary depending on volume. Pharmacy reviews so far have been positive. Pharmacists feel they have more time to spend with patients. A motion was made by Mr. Maher, seconded by Ms. Zaragoza, to approve the new "Well Experience" model. The motion approved with Ms. Martini abstaining. Walgreens will forward error ratio information at established "Well Experience" pharmacies. This information was also requested last month.

## NEW BUSINESS

Pharmacist and Intern Licensure Approval Ratifications

A motion was made by Ms. Martini, seconded by Ms. Robinson, to ratify the approval of the pharmacist applications of Pullarao Jasti, Stephanie Simpson, Leslie Nkansah, Sharon Fine, Scott Cahayla, Karli Sartorio, Carl Engmann, Carolina Han and Charles Gachengo and the intern applications of David Sharkey, Tien Nguyen and David Bankes. The motion unanimously carried.

Facility Licensure Approval Ratifications

A motion was made by Ms. Martini, seconded by Mr. Maher, to ratify the approval of the facility applications of BesScription Inc., Cardinal Health 414, LLC, Greer Pharmacy, Shared Solutions Pharmacy, AcariaHealth Pharmacy #12, Inc., Specialty Rx, Inc., Specialty Therapeutic Care, LP, Butler Animal Health Supply, LLC d/b/a Butler Schien Animal Health Supply, RemedyRepack Inc., Penn Veterinary Supply, Inc., Rock Tenn Converting Company, Reckitt Benckiser LLC, Biogen Idec U.S. Corporation, TheraCom LLC, Clint Pharmaceuticals Inc., Airgas, Inc. (MD), Airgas, Inc. (NJ), Sav-On Pharmacy (7 locations due to ownership change), and Rehoboth Pharmacy Inc. The motion unanimously carried.

Proposal to Deny Hearing for Harshadrai Patel

Mr. Patel has requested a continuance of his Proposal to Deny hearing in order to obtain proper counsel. A motion was made by Ms. Robinson, seconded by Ms. Martini, to approve Harshadrai Patel's hearing continuance request. The motion unanimously carried.

Pharmacist-In-Charge Interview

A motion was made by Ms. Martini, seconded by Ms. Robbins, to amend the agenda to add Jessica Mills and Nwakaego Chukwunenye to the agenda for Pharmacist-In-Charge interview. The motion unanimously carried.

Ms. Robbins conducted a PIC interview for Ann Campagna. She is employed by CuraScript Specialty Pharmacy in New Castle.

Ms. Robbins conducted a PIC interview for Jessica Mills. She is employed by Walgreens Pharmacy in Dover.

Ms. Robbins conducted a PIC interview for Nwakaego Chukwunenye. She is employed by Rehoboth Pharmacy in Claymont.

Review of Pharmacy Application

The Board reviewed the Non-Resident Pharmacy Permit application of Trilogy Health Care, LLC due to previous disciplinary history in Missouri. A motion was made by Ms. Robbins, seconded by Mr. Galloway, to propose to deny the license of Trilogy Health Care, LLC. The motion unanimously carried.

Review Draft APN Consensus Model Bill

The Board received a draft of the APN Consensus Model Bill. Due to the extensive nature of the proposed language, the Board agreed they need more time to review and discuss the proposal. A motion was made by Mr. Galloway, seconded by Ms. Zaragoza, to table this discussion until next month. The motion unanimously carried.

Hearing Officer Recommendations

The Board reviewed the Hearing Officer Recommendations for Curtis Bare as a result of his hearing for continuing education deficiency. A motion was made by Ms. Robbins, seconded by Mr. Galloway, to accept the recommendations as written. Ms. Kelly will prepare the Order and President Simon signed the letter of reprimand.

The Board reviewed the Hearing Officer Recommendations for Kenneth Grossett as a result of his hearing for continuing education deficiency. A motion was made by Ms. Zaragoza, seconded by Mr. Galloway, to accept the recommendations as written. Ms. Kelly will prepare the Order and President Simon signed the letter of reprimand.

The Board reviewed the Hearing Officer Recommendations for Kay Marioni as a result of her hearing for continuing education deficiency. A motion was made by Mr. Galloway, seconded by Mr. Maher, to accept the recommendations as written. Ms. Kelly will prepare the Order and President Simon signed the letter of reprimand.

The Board reviewed the Hearing Officer Recommendations for Faith Stoy-Washington as a result of her hearing for continuing education deficiency. A motion was made by Mr. Galloway, seconded by Ms. Robinson, to accept the recommendations as written. Ms. Kelly will prepare the Order and President Simon signed the letter of reprimand.

Discussion of Drug Substitution Issue

Mr. Dryden reported that he was contacted by Rhett Ruggerio regarding an amendment to Delaware's drug substitution law. He advised Mr. Ruggerio that our statute covers this under 24 *Del.C.* §2549. Genentech representatives Kim Willson and Amy Dempster stated that they are looking at substitution laws for bio-similar drugs. They are planning to propose language to update the Delaware code to include several items - recordkeeping of 3-5 years regarding drug substitution; defining biologic and bio-similar; requiring that patients be notified at point of pickup of the drug substitution from biologic to bio-similar; and requiring that the prescribing practitioner be notified of the change as well. Mr. Dryden advised that the statute already requires recordkeeping for 3 years. It is the Board's opinion that substitution issues raised are already covered in the current statute.

Review of Statute §4762 (Syringe Law) Proposed Changes

The Board reviewed the proposed language suggestions of ExpressScripts and the Delaware Board of Nursing. Rebecca Byrd of ExpressScripts explained the reasoning behind their proposed language. After some discussion, the Board agreed that the ExpressScripts language is not the direction they wish to pursue. The Board is satisfied with the language they already drafted with the inclusion of the nursing language proposed. A motion was made by Ms. Robbins, seconded by Ms. Robinson, to accept the current draft with the addition of the nursing exception and move forward with pursing the change in bill form. The motion carried with Mr. Maher abstaining. Ms. Kelly will put this in bill form to be presented for legislation. Ms. Byrd agreed to make contacts on this new language.

Walgreens Controlled Substances Issue

Mr. Dryden received a few complaints from patients in the past week regarding a new Walgreens policy for obtaining controlled substances prescriptions. Walgreens drafted a letter to prescribing practitioners, a copy of which was submitted to the Board for review. Don Holst advised that the letter was sent to prescribers all across the country. Mr. Holst stated that the purpose is to reiterate the laws already in place as a reminder to prescribers. Jon Reitz of Walgreens stated that the DEA has recently come to the big chain pharmacies and emphasized that these laws need to

be followed, and that there are pending investigations on several pharmacies regarding these issues. Walgreens wants to be proactive by sending this letter and following this policy.

Mr. Dryden voiced his concerns with DEA actions on distributors and pharmacies based on quantities of controlled substances distributed and dispensed rather than on diversion and other important details. The dispensing is legitimate but the DEA is sometimes being subjective in their decisions/actions. Mr. Dryden objects to the way the DEA is going after the distributors and large chains and feels that patient care is being compromised. Mr. Galloway suggests the Board draft a letter of concern to the DEA and legislators regarding their concerns for patient care and safety. Mr. Dryden will draft the letter for Board review prior to sending.

## COMMITTEE REPORTS

**Legislative – Sandy Robinson, Howard Simon, Jay Galloway, Kim Robbins and David Dryden:**

No report.

**Continuing Education – Sandy Robinson and Joli Martini:**

No report.

**Consumer Affairs – Matthew Maher and Jay Galloway:**

No report.

**Professional Liaisons – Sandy Robinson and Sandra Zaragoza:**

Ms. Zaragoza reported that DPS met last night, April 16, 2013. She reported that more golfers and sponsors are needed for the golf tournament in May and registration forms are available on the DPS website. The award recipients for this year's convention have been notified and the agenda and CE schedule are available on the website. Online registration will begin on Friday April 19, 2013. One $2500 grant will be used to cover the costs of program printing but other sponsors are needed to pay for meals. Becky Snead, Executive Vice-President of NAPSA (National Alliance of State Pharmacy Associations) gave a video presentation and spoke about Provider Status Initiatives that are taking place on a national level.

The proposed changes to the Controlled Substances Regulations were presented to the DPS members. They asked that all Board members review the document and forward comments to Pat Carroll-Grant by May 7, 2013 for compilation and presentation at the next meeting on May 14, 2013. Hooshang Shanesaz reported on the latest meeting of PDAC (Prescription Drug Abuse Committee) which had taken place the evening before. The Committee stressed the important role of e-prescribing and the diligent monitoring of prescriptions by pharmacists in identifying substance abuse.

Kevin Musto reported on activities of the Delaware Medical Reserve Corp. A social event for Medical Reservists will take place at the Terry Campus of Delaware Tech on April 22, 2013 at 6pm. Volunteers are still needed to distribute Potassium Iodide at the Middletown Fire Company on April 25, 2013. Reponses for either event can be made to MRC office.

In response to the email sent by ExpressScripts regarding the proposed pen needle/syringe law change, DPS makes the following statement to the State Board of Pharmacy: "The Board of Directors of DPS supports the original language that they presented regarding the sale of hypodermic syringes or hypodermic needles. DPS maintains that the original wording serves the purpose of providing the best care possible for their patients."

**Controlled Substance Liaisons – Howard Simon, Jay Galloway and David Dryden:**

No report.

## 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:**

The Committee will be meeting Wednesday, April 24, 2013 at 9am at Governor Bacon to continue working on regulations for sterile compounding.

**Immunization/Pen Needle Committee – Howard Simon, Kim Robbins, Mark Freebery and David Dryden:**

No report.

**Pharmacy Technician Registration Committee – Howard Simon, Matt Maher, Sandy Robinson, Kim Robbins, Kevin Musto, Maryanne Holzapfel and David Dryden:**

The Committee met after the March Board of Pharmacy meeting. The next meeting will be held at the conclusion of this meeting.

## BOARD CORRESPONDENCE

None

## EXECUTIVE SECRETARY AND INSPECTION REPORT - David Dryden, Samantha Nettesheim and Alicia Kluger

Mr. Dryden reported that Delaware is ranked #1 in e-prescribing per capita. The next drug disposal event will be held April 27, 2013. There has recently been an issue regarding telemedicine. The Board of Medical Licensure and Discipline allows physicians to be licensed in Delaware but practice via Skype or other online technology to serve patients in Delaware. The physicians want the ability to prescribe controlled substances to these patients from their location outside of Delaware. This described procedure may be in conflict with Delaware law including the Internet Pharmacy Act. Mr. Dryden and DAG Kelly will review this issue next week and will discuss their findings with the Board.

The following inspections and activities were completed during the last 30 days:

- 1 routine pharmacy inspection and controlled substances audit
- 1 pharmacy opening inspection
- 7 retail pharmacy inspections due to change of ownership
- 1 hospital pharmacy inspection
- 1 pharmacy pre-inspection
- 2 pharmacy remodels
- 2 research/lab inspections
- 2 clinic inspections
- multiple drop-ins to evaluate prescription compliance and concerns

During the last 30 days the following theft/loss and robberies were reported:

Suspected loss reported by Rite Aid in Lewes, DE.

Ms. Kluger was informed of a case of a pharmacist who administered the shingles vaccine and contracted shingles about 7 days later. She is looking into the issue with the FDA, CDC and others.

Ms. Kluger informed the Board that she will be enforcing the requirements for temperature control monitoring for drugs that require refrigeration/freezing.

The FDA inspected 31 compounding pharmacies in 18 states over the last two months. Many deficiencies were found. Out of the 31 facilities inspected, 17 are registered in Delaware.

Ms. Kluger presented the Board members with a handout of the Virginia Board of Pharmacy Monetary Penalty Guide. She would like the Board to consider laws to allow the authority to charge monetary penalties for violations. She feels it may be a better deterrent than the deficiency letter process. DAG Kelly advised that the statute would have to give the Board authority to impose fines without hearings. She and Mr. Dryden will review this issue next week and will discuss their findings with the Board.

## NEWSLETTER UPDATES

No report.

## OTHER BUSINESS BEFORE THE BOARD

None.

## PUBLIC COMMENTS

Kevin Musto has a concern with e-prescribing errors. Prescribers may not be properly trained because he is finding prescriptions with incorrect dosages and sometimes even the wrong drugs/formulations. His pharmacy is spending increasingly more time on the phone to fix these errors and he feels that the issue needs to be addressed. It is more often the prescribers' subordinates (office staff, etc.) that are submitting the e-prescriptions on behalf of the practitioner and getting it wrong. Mr. Simon suggested that Mr. Musto take his concern before the Board of Medical Licensure and Discipline.

Bill Harbester would like to know if there will be a hearing next month regarding the student immunizing. Ms. Simon advised that the hearing is scheduled for the May 15, 2013 meeting.

Tiffany Sorey from Target Pharmacy stated that the PMP gives pharmacists access to a lot of objective data that helps decrease diversion. However, in light of the new issue with the DEA, she wants to ensure that patient care is not compromised. Due to patients having to go to multiple pharmacies in a drug shortage she is afraid that the PMP data may make it appear that the patient is pharmacy shopping. She stated that pharmacists just need to rely on their professional judgment.

## NEXT SCHEDULED MEETING

The next meeting is scheduled for May 15, 2013.

## ADJOURNMENT

There being no other business before the Board, a motion was made by Ms. Robbins, seconded by Ms. Robinson, to adjourn the meeting. The meeting was adjourned at 11:53am.

Respectfully submitted,

Catherine Simon
Administrative Specialist III