



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

PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, February 21, 2018 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	April 18, 2018

MEMBERS PRESENT

Hooshang Shanehsaz, R.Ph., Professional Member, President
Tejal Patel, PharmD, MBA, Professional Member, Vice President
Bonnie Wallner, R.Ph., Professional Member
Kimberly Robbins, R.Ph., Professional Member
Susan Esposito, R.Ph., Professional Member,
Nicholas Juliano, PharmD, Professional Member
Jay Galloway, Public Member
Gayle MacAfee, Public Member

MEMBERS ABSENT

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Geoffrey N. Christ, R.Ph., J.D., Executive Director Board of Pharmacy
Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer
Jason Slavoski, Pharmacist Administrator (PMP)

ALSO PRESENT

Katherine Syphard
Tray Bungo
Marissa Siok
Bill Cover
Frank Tiano
Lisa Le Gette
Chris Burris
Saratei Diaby
Elizabeth Lewis
Lisa C Flaherty
Kara Gadoinski
Abhishek De
Kevin Musto

CALL TO ORDER

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

REVIEW OF MINUTES

A motion was made by Ms. Esposito and seconded by Ms. Patel to approve the meeting minutes for November 15, 2017. The motion carried.

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the January 17, 2018 meeting minutes. The motion carried.

UNFINISHED BUSINESS

Hearing Propose to Deny @9:30 am - Jubilant DraxImage Inc. (CANADA) – applicant requested hearing to be rescheduled. A motion to reschedule the hearing was made by Ms. Robbins and seconded by Ms. Esposito. The motion carried.

Deliberations – Proposed Rules and Regulations Changes –

Ms. Kelly provided the Board a summary of the regulation changes. Marlene Scadden, District Manager Rite Aid, testified during the hearing held January 17, 2018. Ms. Scadden stated that the requirement of a diagnosis code on the prescription order is not currently in statute or regulation under the Board of Medical Licensure & Discipline. Concern with increased communication with the practitioner and pharmacist will cause undue hardship on both practitioners and cause possible delay in treatment for the patient. The Board of Pharmacy cannot enforce the diagnosis code requirement as this is not part of the Board of Medical Licensure & Discipline statute or regulation. Ms. Kelly read into the record the written comments received and marked them as exhibits for the record. Mr. Christ provided comment regarding the diagnosis requirement. He stated that as a practicing pharmacist he feels this will cause undue hardship on practitioners, pharmacists and patients. Deliberations ensued. The Board discussed each exhibit received. A motion to strike the word diagnosis from regulation 5.1.12.2.6 was made by Ms. Esposito and seconded by Ms. Patel. Ms. Robbins opposed. The motion carried.

Ms. Kelly stated that the striking of the word diagnosis was not a substantive change to the regulation and would not require another hearing. She summarized the proposed regulations including the striking of the word diagnosis in regulation 5.1.12.2.6. A motion to approve the proposed regulations changes with the striking of the word diagnosis was made by Mr. Juliano and seconded by Ms. Patel. The motion carried.

Review and Signing of Final Orders

None

Statutory and Regulatory Discussion

Review of 24 Del. C. Sec. 2533 (a) and Regulation 3.6 "Closing of Pharmacy When Pharmacist not Present" – Ms. Kelly and Mr. Christ are currently reviewing other states statute to formulate a definition of premises.

Re-review of Tabled Application(s)

Athenex Pharma Solutions LLC. (NY) - a motion was made by Mr. Galloway and seconded by Ms. Robbins to approve the application. The motion unanimously carried.

PRESIDENT'S REPORT

Mr. Shanehsaz provided the following report:

- Attended Controlled Substance Advisory Committee (CSAC) meeting. Board of Pharmacy Syringe/Needles change of status was endorsed by CSAC at previous meeting so removed from agenda.
- Attended Substance Disorder Strategy Map Conference on January 29th, 2018. This is a comprehensive and inclusive initiative by DHSS (Delaware Health & Social Services) including DPH (Delaware Department of Public Health) and other stakeholders under Delaware Behavioral Health Consortium headed by Lieutenant Governor.
- On Friday February 2nd, 2018 attended SAMHSA (substance abuse and mental health services administration) Region III Naloxone Coordination Group. Group functions to discuss, exchange and share ideas and experiences in providing Naloxone initiatives.

- Attended and facilitated at Behavioral Health Consortium meetings held by Lieutenant Governor Bethany Hall-Long where public, stakeholders and interested parties were able to voice their concerns as well as ways they see for solutions.
- Spoke with Mr. Jamie Mack (Policy Lead and Technical Advisor) from DPH about Naloxone program. Any Pharmacy in Delaware interested in joining the Naloxone program may contact Mr. Mack Directly at Jaime.mack@state.de.us.
- Followed up with Delaware Medicaid. Ms. Denmark has been very helpful. Highmark stated all CVS stores will be able to fill specialty medications for their clients. Other chains are also in conversation to become specialty drug providers.
- Attended a meeting with AmeriHealth management. Management assured there will not be any problems with "Specialty Medication" and patient access. AmeriHealth Director of Pharmacy will be direct contact for any pharmacy issues.

NEW BUSINESS

Mr. Shanehsaz read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0005186 Andrew M. Nye
A1-0005187 Mayur Indravadan Patel
A1-0005188 Twillow R Rhodes
A1-0005189 Hannah Mary McGuigan
A1-0005190 Karen Gordon
A1-0005191 Andrea J. Samuels-Smith
A1-0005192 Sharon F. Rosal
A1-0005193 David S. Bourgeois
A1-0005194 Irene Toth
A1-0005195 Jacquelin S. Braner
A1-0005196 Linda K. Raleigh
A1-0005197 Samantha L. Landolfi
A1-0005198 William Todd Kautz

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

Pharmacist Intern:

A7-0002476 Kelly A. Scott

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

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0002126 Fountain Plaza Pharmacy
A9-0002127 Royal Pharmacy
A9-0002128 JSPLTC, LLC dba Curexa
A9-0002129 Pharmco, Inc.
A9-0002130 Direct Success Pharmacy Dept
A9-0002131 PillPack Austin
A9-0002132 Rx Acquisition Company dba RxCrossroads
A9-0002133 Performix Specialty Pharmacy, LLC
A9-0002134 Promise Pharmacy, LLC
A9-0002135 Encompass Rx LLC
A9-0002136 Rx One Pharmacy
A9-0002137 Hudgins Pharmacy, Inc.
A9-0002138 Medical Home Pharmacy
A9-0002139 Noble Health Services, Inc.
A9-0002140 Pharmacy Care Center, Inc

A9-0002141 McClure's Compounding Pharmacy

A9-0002142 EasyRx at Holy Reedemer

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

Wholesale Distributor Licensure Approval Ratifications

A4-0002470 RxC Acquisition Company

A4-0002471 RxC Acquisition Company

A4-0002472 R & S Solutions, LLC

A4-0002473 CK Solutions, LLC

A4-0002474 K Supply Company, Inc.

A4-0002475 Integrated Commercialization Solutions, LLC

A4-0002476 Lifeline Pharmaceuticals, LLC

A4-0002477 Jerome Stevens Pharmaceuticals, Inc.

A4-0002478 Wellgistics LLC

A4-0002479 Pharmox LLC

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

Medical Gas Distributor Licensure Approval Ratifications

None

Manufacturer

None

Retail Pharmacy Licensure Approval Ratification

None

Non-Retail Pharmacy Licensure Approval Ratification

None

Outsourcing Facility

AA-0000049 US Compounding

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

Board Review of Facility Applications

The Pharmacompoundia – Clinical Pharmaceuticals (TX) - a motion was made by Ms. Patel and seconded by Ms. Wallner to approve the application contingent upon receiving updated Pharmacist in Charge information.

The motion unanimously carried.

Zevacor Pharma, Inc. (NJ) - a motion was made by Ms. Patel and seconded by Ms. MacAfee to table the application for additional information. The motion unanimously carried.

Board Review of Pharmacist Applications

None

Review of Consent Agreement

None

Continuing Education Review

Jason Slavoski - Individual Program Approval - NASCSA Annual Conference, Mr. Slavoski provided certificate of attendance for this course. A motion was made by Ms. Wallner and seconded by Ms. Esposito to approve 11.25 credits. The motion unanimously carried.

Pharmacist and Pharmacy - Discussion/Action Items

Mr. Bill Cover, National Association of Boards of Pharmacy provided a presentation to the Board. The presentation included upcoming changes to the portal accessed by State Boards of Pharmacy, NABP's products and services provided to those Boards and changes to current services.

Executive Director's Report

Mr. Christ provided the following report:

Ms. Kelly and Mr. Christ are currently working on language defining premises as well as reviewing the continuing education language requirements.

Mr. Christ sent out an educational communication outlining the proper use of PMP information. This outlined to whom information may be provided and also to whom it cannot be provided.

Last meeting there were questions regarding information that can be written on a prescription order. Mr. Christ stated he could not locate any prohibitions for making notes on a prescription order. Information protected by HIPPA should not be written on the prescription, if this occurs redact the information to prevent HIPPA violations. PMP information cannot be noted on the prescription as this includes PMP information which is patient protected information.

Mr. Christ completed his review of all the outstanding disciplinary actions received. Most actions did not require any action from the Board. For those that required further attention they are being reviewed further for possible disciplinary action.

Mr. Christ has been working with staff reviewing processes and procedures. The current inspection report workflow is an antiquated paper process. Mr. Christ is currently working with our operations department to create fillable forms and a digital process. This would enable the Pharmacist Compliance Officer to work with an electronic device and enter information into a fillable form allowing the automation of letters and creating an electronic filing system. This will greatly improve the inspection process.

Mr. Christ and Mr. Slavoski have been working on integration of the PMP data with pharmacy software programs.

Mr. Christ attended the Controlled Substance Committee meeting January 24, 2018. He provided the committee information regarding the abuse of gabapentin. He suggested that this drug be made a drug of concern so that tracking can be utilized to provide knowledge of the dispensing of this medication.

Mr. Christ and Mr. Slavoski will be attending the NABP MPJE question writing project in March.

COMMITTEE REPORTS

Legislative – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz, Bonnie Wallner and Gayle MacAfee

Ms. Patel stated that the committee is currently reviewing chapters 1 & 2 of the statute. Ms. Wallner suggested review of the approval of continuing education providers. This will be added to the committee's agenda next meeting.

Continuing Education – Bonnie Wallner, Tejal Patel:

Ms. Wallner suggested that only ACPE approved courses be approved for continuing education credit. This will be added to the legislation committee agenda for the next meeting.

Consumer Affairs – Jay Galloway, Gayle MacAfee

No Report

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

Ms. Robbins stated that DPS general meeting was held in January. There were approved bylaws changes to include 2 members from each county and a specialty pharmacy member to be included in the Board. DPS is currently seeking nominations for several awards.

Controlled Substance Liaisons –Tejal Patel, Hooshang Shanehsaz:

Ms. Patel stated that the committee discussed current term limits and possible future changes. They discussed making gabapentin a drug of concern due to an increase of reported abuse. They discussed the number of unregistered prescription monitoring program (PMP) practitioners. The statute requires practitioners to register with the PMP within 90 days of receiving a controlled substance registration in this state.

INSPECTION REPORT - Michelle McCreary

Ms. McCreary reported the following inspection activities

- 2 – Wholesale Distributor Inspection
- 1 – Hospital/Clinic
- 1 – Narcotic Treatment Program
- 2 – Investigative Complaints
- 2 – Re-Inspections

PMP REPORT – Jason Slavoski

Mr. Slavoski provided some statistical information regarding users as follows:

7700+/- active approved users, 1300 are Pharmacist registered (there are 2500+/- Delaware licensed pharmacist in total) of which 559 are actively performing searches of the database.

There are currently 15 states in the PMP Interconnect including Delaware they are: Arkansas, Connecticut, Colorado, Indiana, Maine, Maryland, Minnesota, New Jersey, New York, North Carolina, North Dakota, Ohio, Pennsylvania, South Carolina, and Virginia.

Mr. Slavoski is currently reviewing Electronic Health Records (EHR) integration by using a PMP Gateway that would enable the Delaware PMP to be integrated with current pharmacy software. This would provide integral PMP information readily available through the pharmacy EHR software without exiting and entering additional software. There are fees associated with this gateway however; there are possible grants to waive the connection costs for up to 1 year. He has reached out to several pharmacies within the state to offer this gateway. The pharmacy would be required to pay for development costs for their software.

Mr. Slavoski stated there are new tools available within the prescription monitoring program. The MyRx allows searches to be completed by DEA number, and Prescriber Report Cards that will be processed quarterly and provided to practitioners which will allow them to see their prescribing habits in comparison to other practitioners in their specialty. After receiving their reports Mr. Slavoski has received calls from practitioners stating their PMP records indicate prescribing of certain drugs when in fact they had not. This is a direct result of dispensing pharmacies not selecting the correct practitioner. Mr. Slavoski stated that it is imperative that the dispensing pharmacist select the correct practitioner. If the pharmacy receives a call from a practitioner stating they need their records corrected, the correction should be handled expeditiously to prevent inaccurate information in the PMP. The State already pays for NarcsCare for the pharmacy. There is no additional charge for NarcsCare for the pharmacy.

Pharmacist-In-Charge Interviews

Jagadishkumar N Rabadia, Walgreens Wilmington, DE 19808 – rescheduled for March 21, 2018 meeting.

Physician Assisant Advisory Committee

Mr. Shanehsaz stated the next meeting is in approximately 2 weeks. The committee will be discussing collaboration of practitioners and allowing the rotation of 4 supervisors for this collaboration. He will provide a report next meeting.

BOARD CORRESPONDENCE

Mr. Shanehsaz reviewed the following correspondence with the Board.

National Healthcareer Association (NHA) – EXCPT Pharmacy Technician Certification Requirements, Mr. Shanehsaz will notify them to send a written request to appear before the Board to review the program.

NABP - Update on New Online Systems Launching in April 2018

OTHER BUSINESS BEFORE THE BOARD

None

PUBLIC COMMENT

Mr. Shanehsaz stated that Pharmacy Benefit Managers (PBM) patients that require specialty medications must utilize a specialty pharmacy. There are not enough specialty pharmacies within the State to accommodate the public that requires these medications. This is causing a delay in treatment that could potentially cause severe adverse effects to the patient. This concern is requested to be added to the legislative committee for further discussion and review of other states response to this issue as well as defining specialty pharmacy. Mr. Christ suggested getting stakeholders with similar concerns involved in the discussion.

Ms. Le Gette, Express Scripts (PBM) stated she represents Delaware from a regulatory stand point. Ms. Le Gette offered her assistance with the issue just discussed if needed. Express Scripts has a definition of specialty pharmacy, but she doesn't recall the specifics of the definition exactly. She will provide this to the Board. Insurers are making a push to narrow down their network to reduce costs.

Mr. Musto offered his support regarding the proposed regulations changes. He continues to have concerns with information or the lack of provided on the prescription blank that causes a delay in treatment. He also has concerns with gabapentin and is glad to hear the Board is aware as well. He stated that Seroquel® is also seeing an uptick in abuse. Mr. Musto continues to have concern regarding access of care due to specialty medications.

Mr. Shanehsaz stated that he has received questions regarding not dispensing a medication if the pharmacist feels it is not in the best interest of the patient. Mr. Christ stated that a pharmacist has the right to refuse to dispense any prescription based on their professional judgment. A pharmacist can make a professional judgment not to dispense a medication based on patient safety.

NEXT SCHEDULED MEETING

The next meeting is scheduled for March 21, 2018 at 9:30 a.m., 2nd Floor Conference Room.

ADJOURNMENT

There being no other business before the Board, a motion to adjourn the meeting was made by Ms. Patel and seconded by Ms. MacAfee at 1:15 pm. The motion unanimously carried.

Respectfully submitted,



Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy