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BOARD OF PHARMACY PUBLIC SESSION MINUTES ESSEX CONFERENCE ROOM, 7th FLOOR December 16, 2015

I. CALL TO ORDER

The Open Session of the New Jersey Board of Pharmacy was called to order by the Board President, Thomas F.X. Bender, at 124 Halsey Street, Essex Conference Room, 7th floor, on December 16, 2015 at 9:02 a.m. All members were duly notified of the time, place and all pertinent materials were provided to the members.

II. SUNSHINE LAW ANNOUNCEMENT

President Thomas F.X. Bender read a statement that the newspapers and appropriate elected officials had been notified of the meeting according to the requirements of the Open Public Meetings Act N.J.S.A., Chapter 231, PL1975/C.10:4-8.

III. ROLL CALL

Thomas F.X. Bender, R.Ph.	President
Richard Palombo, R.Ph.	Vice-President Excused Absence
Margherita Cardello, R.Ph.	Late Arrival- 9:17 a.m.
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Linda Witzal, R.Ph.	
Mitch Sobel, R.Ph.	Excused Absence

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director
Megan Cordoma	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst
Jessica Kelley	Board Staff
Jennifer Wasiewicz	Board Staff

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of November, \$294,398 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 294
- Pharmacists licensed – 54 (45 by examination/score transfer and 9 by reciprocity)
- Out-of-State Pharmacies registered – 23
- In-State Pharmacies licensed – 3
- Pharmacists receiving immunization approval – 57
- Interns (foreign graduates) licensed – 2

Proposed revisions to USP <797>

The Executive Director informed the Board that a committee comprised of Board members, inspectors, and the Enforcement Bureau is scheduled to meet on January 13, 2016 to discuss and comment on the proposed revisions to USP <797>. Comments are due by January 31, 2016.

V. OLD BUSINESS

1) Public Orders Filed

- a. Howard Dukes – Final Order of Discipline
- b. Marvin Davis – Final Order of Discipline
- c. Barbara Holmes – Final Order of Discipline
- d. Amit Sen – Final Order of Discipline
- e. Elizabeth Balon – Final Order of Discipline
- f. Radia Hill-Owens – Provisional Order of Discipline

2) Randall Higgins – Request for unrestricted licensure

Item was tabled due to a lack of a quorum. Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

VI. NEW BUSINESS

1) Bill A4760 – Requires health care practitioners to discuss risk of addiction when prescribing certain drugs to patients who are minors

This bill requires health care practitioners to discuss the addiction potential of certain drugs prior to issuing a prescription for the drug to a patient who is under 18 years of age. The practitioner will have this discussion with the patient, if the patient is an emancipated minor, and with the patient's parent or guardian, if the patient is not an emancipated minor. The bill applies to Schedule II controlled dangerous substances and any prescription opioid drug, and practitioners are required to discuss the risk of developing a physical or psychological dependence on the substance or drug. Practitioners will also have discretion to discuss such alternative treatments as may be available.

The practitioner will be required to obtain, and include in the patient's medical record, written acknowledgement that the discussion took place using a form

which is to be developed by the Division of Consumer Affairs in the Department of Law and Public Safety in consultation with such medical professional societies and associations as may be designated by the Director of the Division of Consumer Affairs. The division will also be required to develop and make available to practitioners guidelines for the discussion required under the bill.

The provisions of the bill will not apply to a patient who is currently receiving hospice care from a licensed hospice.

Thomas Bender moved, seconded by Linda Witzal, to support the bill with the suggestion that this be extended to all patients regardless of age. **Motion passed 6-0.**

2) **Bill A4749** – Prohibits certain steering and marketing practices involving dispensing of prescription drugs and drug samples

This bill prohibits certain steering and other marketing practices involving devices, kiosks, machines, and other systems for the dispensing of prescription drugs to patients, including drug samples. This bill prohibits drug manufacturers, pharmacies, wholesalers, or other medication supply intermediaries from entering into agreements with health care practitioners to dispense prescription drugs and drug samples using a device, kiosk, machine, or other system which directs or diverts patients to a specified pharmacy or pharmacist for the filling of prescriptions, or which restrains in any way a patient's choice when selecting a pharmacy or pharmacist. This practice, which is sometimes referred to as "steering," improperly restricts patient choice.

Edward McGinley moved, seconded by Thomas Bender to support this bill with the following comments: Based upon information provided by the members of the public that attended the meeting, it doesn't appear that this bill addresses the concerns of the statutes. The Board recommends that the following be included: (1) the description of the penalty for a prescriber involved in this practice (2) penalty for drug manufacturers. The Board is concerned that this is to be enforced by each municipality (different, possibly non-uniform discipline). There are already legal provisions for steering and physician dispensing. The Bill as proposed does not seem comprehensive enough. **Motion passed 6-0**

3) **Bill A4722** – Prescription Drug Review Commission

This bill establishes the Prescription Drug Review Commission in the Division of Consumer Affairs in the Department of Law and Public Safety, which will be tasked with developing a list of critical prescription drugs for which drug manufacturers will be required to report certain information concerning development, production, and marketing costs. If the commission determines that a drug is priced excessively high in New Jersey, it will have the authority to establish a maximum price for the drug in the State.

Thomas Bender moved, seconded by Edward McGinley to oppose this Bill as presented. There is concern about the Commission being composed of public members, who are supposed to identify available or therapeutically equivalent drugs, possibly without having the requisite knowledge and training to perform this task. The Board questions what tools will they have to do this successfully. **Motion passed 6-0.**

4) **Bill S3254** – Pharmacist prescribe opioid antidote

This bill would expand public access to opioid antidotes, such as naloxone hydrochloride, by supplementing the "New Jersey Pharmacy Practice Act," P.L.2003, c.280 (C.45: 14-40 et seq.) and amending the provisions of the "Overdose Prevention Act," (OPA) P.L.2013, c.46 (C.24:6J-1 et seq.), in order to authorize pharmacists to supply opioid antidotes to patients without prescriptions under standardized protocols that are to be adopted by the Board of Pharmacy in accordance with the bill's provisions. The authority granted by the bill would be in addition to the existing authority of pharmacists to supply opioid antidotes to patients without prescriptions under a standing order issued by a physician.

The bill would define the term "patient" - consistent with the OPA - to mean a person who is at risk of an opioid overdose or a person who is not at risk of an opioid overdose who, in the person's individual capacity, obtains an opioid antidote from a pharmacist for the purpose of administering that antidote to another person in an emergency, in accordance with the provisions of the OPA. The bill would provide, in particular, that a licensed pharmacist may dispense or otherwise supply an opioid antidote to any patient who is deemed to be capable of administering the same, regardless of whether that patient presents an individual prescription for the antidote. The bill would require the Board of Pharmacy, within 90 days after the bill's effective date to adopt standardized protocols to be used by licensed pharmacists when furnishing an opioid antidote to a patient who does not present a prescription therefor. The protocols must be consistent with the provisions of the OPA, and must require a pharmacist to determine that the patient seeking the antidote is capable of administering the same to an overdose victim in an emergency. This is the same determination that must be made under the OPA before a pharmacist may dispense an opioid antidote to any person or entity under a standing order. Any pharmacist who acts in good faith. In accordance with the bill's requirements, in supplying an opioid antidote to a patient without a prescription, would be immune under the OPA from any civil or criminal liability or any professional disciplinary action stemming from such act.

The bill would also make minor technical and clarifying corrections to the OPA, in order to correct citations, ensure internal consistency, remove pejorative language, and clarify imprecise language therein.

Thomas Bender moved, seconded by Mahesh Shah to support this bill as presented and noted that the proposed bill would allow the Board to develop rules that are consistent with the Board's Best Practices document. **Motion passed 6.0**

- 5) **Bill A4735** – Regulates certain auditing and disclosure practices of pharmacy benefits management companies

This bill requires pharmacy benefits management companies to adhere to certain auditing practices and to disclose certain information regarding maximum allowable cost list.

Thomas Bender moved, seconded by Mahesh Shah to support this bill as presented. **Motion passed 6-0.**

- 6) **Bill A4695** – Requires health insurance coverage for contraceptives to include prescriptions for 12 months

This bill amends P.L.2005, c.251, the statute requiring health insurers that provide coverage for outpatient prescription drugs to cover prescription female contraceptives, to include a requirement for coverage of dispensing contraceptives for up to twelve months. Under the bill, the coverage provided shall include prescriptions for dispensing contraceptives for: (1) a three-month period for the first dispensing of the contraceptive; and (2) a twelve-month period for any subsequent dispensing of the same contraceptive, regardless of whether coverage under that policy or contract was in effect at the time of the first dispensing.

These amendments apply to hospital, medical, and health service corporations, commercial, individual, small employer and group health insurers, health maintenance organizations, prepaid prescription service organizations, and the State Health Benefits Program.

Edward McGinley moved, seconded by Linda Witzal to accept this as informational. **Motion passed 6-0.**

- 7) **Bill A2477** – Substitution with interchangeable biological products

In New Jersey, a bill (A2477) authorizing pharmacists filling a prescription for a biological medication to select an interchangeable biological product, was signed into law by Governor Chris Christie. A substitution cannot be made if the prescriber indicates that there shall be no substitution. The law requires the New Jersey State Board of Pharmacy to maintain a link on its website to FDA's current list of interchangeable biological products. Further, the law requires a pharmacist or designee to notify the prescriber of the biological product dispensed, including the name of the product and the manufacturer, within five days. This requirement may be fulfilled by making an entry in an interoperable electronic records system that can be accessed by the prescriber. Otherwise, the pharmacist may notify the prescriber of the substitution by using other electronic

means, such as facsimile. The pharmacist is also required to record on the prescription label, and record of dispensing, the product name of the interchangeable biological product, followed by the words "Substituted for" and the name of the biological medication for which the prescription was written, and the manufacturer of the interchangeable biological product.

The Board will post a link on the Board of Pharmacy website to the List of Biosimilars found on the FDA website, Amends Chapter 24.

8) Matthew Wetzel, Prescription Monitoring Program Regulations – New Law Nov 1, 2015

Mr. Wetzel appeared on behalf of the New Jersey Prescription Monitoring Program (NJMPMP) to give an overview of the NJMPMP's rule proposal that was published on November 16, 2015. The proposal intends to implement portions of the new NJMPMP law, S-1998, that became effective on November 1, 2015. In general most of the regulations impact prescribers and not pharmacies or pharmacists. Also many of the rules affecting pharmacists and pharmacies codify the current NJMPMP requirements, such as:

- Daily reporting of controlled dangerous substance prescription to the NJMPMP;
- Out-patient dispensing is to be reported to the NJMPMP, in-patient dispensing is exempt; and
- Only pharmacists can register and access the NJMPMP to perform patient look-ups.

One of the relevant rules impacting pharmacies and/or pharmacists is:

- N.J.A.C. 13:45A-35.9(b): If the pharmacist has a reasonable belief that the person may be seeking a CDS for any purpose other than the treatment of an existing medical condition, before dispensing a Schedule II CDS, a pharmacist must access the prescription monitoring information to determine if the person has received other prescriptions that indicate misuse, abuse, or diversion.

The public comment period for the proposal closes on January 15, 2016. The Division intends on a second round of rules in 2016 to implement the rest of the NJMPMP law, so portions of the new law that did not appear in the current rule proposal may be in a future rule proposal.

Thomas Bender moved, seconded by Mahesh Shah to accept as informational.
Motion passed 6-0.

9) Division of Consumer Affairs notice to patients about drug diversion and abuse

Laurie Clark, a member of the public, expressed concern over how to implement

the practice of distributing these flyers to patients.
Regulatory Analyst, Rachel Glasgow noted the above concern.

The Board accepted this as informational.

10) Sunset Rules

The Board of Pharmacy's rules will sunset in May 2017. The rules will be reviewed and the Board will determine if anything needs to be added, deleted, amended, etc.

11) Walgreens- Request for the Deployment of a Patient accessible ADS in the emergency department of Robert Wood Johnson University Hospital

Presentation by Walgreens:

Dan Luce RPh, MBA, National Director of Pharmacy Affairs for Walgreens, provided the Board with an overview of an Automated Dispensing System ("ADS") that they want to install in the emergency room at Robert Wood Johnson University hospital in Rahway, New Jersey as a pharmacy. Also in attendance were representatives from MedAvail Technologies and Robert Wood Johnson University Hospital. Mr. Luce supplied the following summary to the Board regarding this ADS:

The "The Walgreens Prescription Center (WPC)" is a fully functional patient facing automated dispensing device which performs all of the major functions of a community pharmacy. The WPC features Face-to-face audio/visual interaction and counseling between a patient and the pharmacist before dispensing any medication. The Prescription Center is able to receive electronic prescriptions directly from the prescriber as well as written prescriptions that are securely scanned and stored after submission by the patient. A Walgreen pharmacist located at a central pharmacy located in Orlando, Florida, will complete the prescription processing tasks, perform a full drug utilization review via our common electronic database, validate the prescription and medication dispensed, and provide patient consultation. The unit fills the prescription using multiple bar code scans and imaging of each surface of unit of use or pre counted drug containers. The unit does not require the presence of an on-site technician as the device is connected to the pharmacist and performs all drug selection, verification and labelling functions. After a medication is prepared it is verified by a pharmacist before being released to the patient.

The ADS is based on technology called MedAvail MedCenter, a patient facing, pharmacist-controlled remote dispensing solution for prescription and over-the-counter medications.

Mr. Luce indicated that this location was chosen because it made sense, to increase patient access and compliance with drug therapy. Patients have the option to utilize this ADS or have their prescription transferred to another

pharmacy of their choice.

Edward McGinley suggested that Walgreens review the New Jersey Board of Pharmacy Regulations, specifically subchapter 10 which addresses Automated Dispensing Systems. This ADS seems to fit better into this categorization rather than trying to make it fit the requirements of a ‘pharmacy’, and asking for many waivers to do so. Mr. Luce will review the regulatory requirements for ADS, and may request to come back to the Board to seek authorization to implement the WPC as an ADS in this setting.

Thomas Bender was recused from the discussion due to his affiliation with Walgreens.

12) Sejal Patel – Request to accept intern hours earned in New York

Thomas Bender moved, seconded by Mahesh Shah to grant Ms. Patel 630 hours of intern credit hours for the time completed at the second location. **Motion passed 6-0.**

13) All-Scripts Pharmacy, Kissimmee, FL – Out-of-state applicant, misrepresentation on application

Edward McGinley moved, seconded by Stephen Lieberman to allow the application to pend until Tamer Girgis, the owner of All-Scripts provides documentation showing full compliance with PAP. If he has completed, the Board will allow them to withdraw the application, with no reapplication for two years. If Mr. Girgis did not comply, the Board will deny the application, due to the pharmacist misrepresentation on the application. **Motion passed 6-0.**

14) Dalton Pharmacy, Muscle Shoals, AL - Out of state pharmacy application with discipline

Stephen Lieberman moved, seconded by Edward McGinley to approve this application. **Motion passed 6-0.**

15) Avella of Deer Valley Inc. – Response to FDA 503-A inspection

The Board received and reviewed the sterile compounding questionnaire.

The Board accepted the response as informational. The response was appropriate, professional, and address all of the Board’s concerns.

16) CarePlus Specialty Pharmacy – Pharmacy application

Edward McGinley moved, seconded by Stephen Lieberman to allow CarePlus Pharmacy to withdraw their application. The current regulatory framework prohibits this proposed model. **Motion passed 6-0.**

17) CDS Guidance Letter to Pharmacist

Edward McGinley crafted a guidance document for the Board to endorse and put on the website. The Board wants to coach and encourage younger pharmacists to use all the tools available to them to make a more informed decision so patients who are truly in need can have their valid prescriptions filled.

Thomas Bender moved, seconded by Linda Witzal to approve the letter as a guidance document which will be posted on the website and published in the quarterly State newsletter. **Motion passed 6-0.**

18) Pharmacist 2015 License Renewal Continuing Education Audit

The Board determined to conduct a random audit of all pharmacists renewing their license during the 2015 renewal period to ensure completion of all required CE credits. The Board office was instructed to obtain a random listing of 10% of the active pharmacists, and mail out letters requesting documentation substantiating completion of the required number of CEs pertaining to their specific licenses and approvals (Pharmacist license, immunization approval, etc.). The letter should advise that if the licensee does not respond, the Board may take action based on their failure to cooperate including the suspension of their license and imposition of fines.

If there is no response to the letter requesting proof of CEs, the Board office shall issue a self-finalizing Uniform Penalty Letter (UPL) or a Provisional Order of Discipline (POD) suspending their license until they cooperate and imposing a \$250 fine. The UPL or POD should indicate that if there is no response the matter will be finalized without further Board review. All instances where there is a response will be agendized for Board review prior to finalization. If a licensee is ultimately suspended for failure to cooperate, that licensee must provide the requested information and submit an application for reinstatement. All such applications must be agendized for Board review.

Where audited licensees failed to complete CE credits in timely manner and/or misrepresented completion on the biennial renewal the Board Office will issue self-finalizing UPL's or POD's imposing fines of \$100 per missing credit and \$1000 for misrepresentation on renewal. If there is no response to the UPL and proof of service is available, the Board office is authorized to finalize the UPL without Board review. All instances where there is a response will be agendized

for Board review prior to finalization.

Edward McGinley moved, seconded by Linda Witzal to approve. **Motion passed 6-0.**

VII. MITIGATION REQUEST

N/A

VIII. INFORMATIONAL

N/A

IX. COMMITTEE REPORTS

N/A

X. APPROVAL OF MINUTES

Margherita Cardello moved, seconded by Mahesh Shah, to approve the November 18, 2015 Open Session minutes as amended. **Motion passed 6-0.**

XI. ADJOURNMENT

Stephen Lieberman moved, seconded by Margherita Cardello, to move into the Executive Session for review of 2 Complaints, 7 Old Business Items, 10 New Business Items, the Secretary's Report and Recommendation on Inspection Reports from, and the approval of the Executive Session Minutes. **Motion passed 6-0.**

At 12:10 p.m., Stephen Lieberman moved, seconded by Thomas Bender, to adjourn the Public Session. **Motion passed 6-0.**