

**COMMONWEALTH OF MASSACHUSETTS**

**NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE  
BOARD OF REGISTRATION IN PHARMACY**

August 5, 2014  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

**Agenda**

Time	I.	Item	Exhibits	Contact
9:00	II.	<b>CALL TO ORDER</b>		
9:05	III.	<b>APPROVAL OF AGENDA</b>		
9:10	IV.	<b>APPLICATIONS</b> 1. SJ Medsav - Wholesale Distributor Relocation		D. Sencabaugh
9:30	V.	<b>APPROVAL OF BOARD MINUTES</b> Draft July 1 , 2014 Regular Session Minutes		
9:35	VI.	<b>REPORTS</b> 1. Applications approved pursuant to Licensure Policy 13-01	Reports	R. Harris
9:40	VII.	<b>FLEX SESSION</b> 1. Board Update a. New Associate Executive Director b. New Board Make Up c. Legislative Update: Implementation of Chapter 159 of the Acts of 2014 d. Formation of Advisory Committee		D. Sencabaugh
10:00	VIII.	<b>FILE REVIEW</b> 1. PHA-2013-0067, Kimberley Gould, PH27266 2. PHA-2012-0254, New England Home Therapies, DS3486 3. PHA-2014-0034, New England Home Therapies, DS3486		W. Frisch

10:30	IX.	<b>ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)</b>	CLOSED SESSION
10:50	X.	<b>M.G.L. c. 112, 65C SESSION</b>	CLOSED SESSION
12:30	XI.	<p><b>EXECUTIVE SESSION</b></p> <p>The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual.</p> <p>1. Specifically, the Board will review the report of the approval of <u>Good Moral Character</u> applicants pursuant to Licensure Policy 14-01.</p> <p>2. Approval of prior executive session minutes in accordance with M.G.L. ch.30A, § 22(f) for sessions held during the July 1, 2014</p> <p>The Board will also meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(3) for the purpose of discussing strategy with respect to litigation because discussing in open session would have a detrimental effect on the litigating position of the board. Specifically, the board members will discuss pending litigation: <i>Zogenix, Inc. v. Patrick, et al.</i>, United States District Court, District of Massachusetts, 1:14-CV-11689-RWZ.</p>	
1:00	XII.	<b>ADJOURNMENT</b>	

COMMONWEALTH OF MASSACHUSETTS  
BOARD OF REGISTRATION IN PHARMACY

**MINUTES OF THE REGULARLY SCHEDULED MEETING**

239 Causeway Street, Fourth Floor ~ Room 417A  
Boston, Massachusetts 02114

Tuesday, August 5, 2014

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**Board Members Present**

Karen Ryle, RPh, President  
Patrick Gannon, RPh, MS, President-elect  
Timothy Fensky, RPh  
Jane F. Franke, RN, MHA  
Anthony Perrone, MD  
Joanne Trifone, RPh  
Richard Tinsley, MBA, MEd  
Anita Young, RPh, EdD

**Board Members Not Present**

James DeVita  
Edmund Taglieri

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Heather Engman JD, MPH, Board Counsel  
Kelly Ann Barnes, JD, RPh, Dir. Quality Assurance  
David Dunn Assistant Executive Director  
Richard Harris, Program Analyst  
William Frisch, Jr., RPh, Director of Compliance  
Samuel Penta, RPh, Investigator  
Christina Mogni, RPh, Investigator  
Steven Horn, RPH, Investigator  
Anthony Bartucca, RPh, Investigative Consultant

**Board Staff Not Present**

Cheryl Lathum, RPh, PharmD, Investigator  
Leo McKenna, RPh, PharmD, Investigator

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**TOPIC:**

**I. CALL TO ORDER**

**DISCUSSION:** A quorum of the Board was present. President K.RYLE opened the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. She indicated that the Board was recording the meeting.

**ACTION:** At 9:19 a.m. K. RYLE, called the AUGUST 5, meeting of the Board of Registration in Pharmacy to order. R.TINSLEY was not present

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**TOPIC:**

**II. APPROVAL OF AGENDA**

**DISCUSSION:** A. YOUNG asked that the NABP District 1 meeting registration be added to the Flex Session. J. TRIFONE asked that the DEA schedule change for tramadol be added to the Flex Session.

**ACTION:** Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously to

approve the agenda with the noted changes. R. TINSLEY was not present for the vote.

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**TOPIC:**

**III. APPLICATIONS**

**9:21am**

**SJ MedSav 31 Pleasant St. Suite 1, Malden, MA. 02148**

R.TINSLEY arrived at 9:24AM and was not present at the start of the discussion  
DISCUSSION: Melvin Sparkman and Scott Finn President of SJ MedSav attended representing SJ MedSav. Mr. Finn informed the Board that due to a failed negotiation with its' landlord, SJ MedSav had already moved from its' previous location at 121 Brick Kiln Rd. Suite 235, Chelmsford, MA. SJ MedSav did have a satisfactory inspection at the former location. Executive Director D.SENCABAUGH asked Mr. Finn to elaborate for the Board on SJ MedSav's business model. The Board showed concern regarding the SJ MedSav business model. J. TRIFONE noted concern that the SJ MedSav had not received Board approval prior to the relocation. J. TRIFONE requested guidance in the event the Board denied the Applicant's request. Board Counsel H. ENGMAN informed the Board that the regulations were not specific on this topic. Board Counsel advised the Board to approve the application.

ACTIONS: Motion by P. GANNON seconded by A. Perrone and voted unanimously to approve the relocation application of Wholesale Distributor SJ MedSav conditioned on the receipt of a successful inspection.

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**TOPIC:**

**IV. APPROVAL OF BOARD MINUTES**

**9:29 am**

**1. Draft July 1, 2014 Regular Session of the Board**

DISCUSSION: No Discussion.

ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously to approve the minutes of the July 1, 2014 of the Regular Session of the Board with no changes.

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**TOPIC:**

**V. REPORTS**

**9:30 am**

**1. Applications Approved Pursuant to Licensure Policy 13-01**

DISCUSSION: R. HARRIS distributed a August 5, 2014 report which noted the, forty - two (42) change of managers, three (3) pharmacy closures, and four (4) renovations that had been approved pursuant to Licensure Policy 13-01.

ACTION: So noted.

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**TOPIC:**

**VI. FLEX SESSION**

**9:31 am**

**1. Board Update: Introductions**

Executive Director D. SENCABAUGH: Announced the retirement of Pharmacy Consultant Joseph Sceppa and thanked him for all of his service during the past year. Thanked Program Analyst Richard Harris for his service to the Board since the retirement of Associate Executive Director Margaret Cittadino

- Introduced new Associate Executive Director, David Dunn.
- Introduced new Pharmacy Inspector Steven Horn.
- Introduced Pharmacy Intern Andrew Lee from Northeastern College of Pharmacy.

ACTION: So noted

**2. New Board Make Up**

DISCUSSION: Executive Director D.SENCABAUGH informed the Board that with the passage of c.159 that the Board would be increasing to thirteen (13) members and that the new quorum for a meeting would require seven (7) Board members.

ACTION: So noted.

**3. Legislative Update: Implementation of Chapter 159 of the Acts of 2014**

DISCUSSION: Executive Director D.SENCABAUGH informed the Board of the possible need for additional meetings and the importance of having quorum.

ACTION: So noted.

**4. Formation of Advisory Committee**

DISCUSSION: Executive Director D.SENCABAUGH informed the Board on the formation of an Advisory Committee as required by c. 159 of the Acts of 2014.

D.SENCABAUGH defined the process and solicited Board members for feedback and possible candidates. D. SENCABAUGH noted that Director of Quality Assurance K. BARNES was the lead on the Advisory Committee formation. Division Director J. LAVERY indicated that Board staff would be soliciting input from stakeholders and that he would welcome any feedback. J. TRIFONE asked for the requirements for member participation

ACTION: So noted.

**5. NABP District 1 & 2 Meetings**

DISCUSSION: A. YOUNG informed the Board members of the NABP District 1& 2 meeting scheduled for October 5 thru 7 in Williamsburg, VA. A. YOUNG informed the Board members to review their correspondence for enrollment materials. A.YOUNG noted that the 2015 meeting would be held in Portsmouth, NH. A. YOUNG mentioned that the honorable State Senator John F Keenan, (D) (Norfolk & Plymouth District), to be in attendance at the meeting and speaking on the subject of prescription drug abuse.

ACTION: So noted.

**6. Change on DEA Schedule of Tramadol**

DISCUSSION: J.TRIFONE informed the Board of the DEA reclassification of tramadol from a federal legend drug to DEA class IV controlled substance. J. TRIFONE informed the Board that pharmacies would need to perform a physical count and add tramadol to their Biennial inventory on August 18, 2014. A.YOUNG asked that Board staff notify licensee of their responsibilities; Director of Quality Assurance K.BARNES indicated that she was preparing a draft notification for review.

ACTION: So Noted.

TOPIC:

**VII. FILE REVIEW**

1. PHA-2012-0254, New England Home Therapies, DS 3486, Southborough **9:46 am**

DISCUSSION: This complaint was presented by W.FRISCH and S.PENTA

As a result of a multiple Inspectional Deficiencies observed by OPP Pharmacy Compliance Investigators on 12/17-18/2012, 02/24/2014. These inspections noted several deficiencies that prompted two (2) complaints against New England Home Therapies (NEHT) and a companion complaint against the Manager of Record (MOR) Kimberly Gould.

On December 17-18, 2012, OPP Pharmacy Compliance investigators conducted a USP <797> Compliance audit. The inspection documented nineteen deficiencies. MOR Gould was required to provide a Plan of Correction (POC) which was received by OPP on December 12, 2012.

NEHT was re-inspected on July 16, 2013, a <797> audit yielded new deficiencies along with previous findings that were not addressed along with the recommendation of the need for the construction of a Negative Pressure Chemo Room along with upgrades to the existing HVAC system by the close of calendar 2013.

On October 7, 2013, OPP received a letter authored by Attorney Kathryn Stalmack representing both NEHT and MOR Gould. Attorney Stalmack detailed the timeline for the inspection conducted on December 17<sup>th</sup> and 18<sup>th</sup>, correctional measures put in place by MOR Gould in response to the complaint along with documents to show NEHT's compliance with USP <797>.

On February 24, 2014, OPP Investigators conducting a <797> audit at NEHT became aware of the following facts:

1. NEHT's failed to report to the Board the presence of Abnormal results for environmental contaminants received from its' environmental monitoring company on November 13, 2013, as required by 247 CMR 6.15 (7).
2. NEHT began construction of the new Negative Pressure Chemo Room and HVAC system upgrades prior to its' appearance before the Board on December 3, 2013.
3. NEHT post construction recertification of the cleanroom was incomplete.
4. NEHT failed to provide the bi-annual sterile compounding reporting, by the required deadline in compliance with 247 CMR 6.15(5).
5. OPP Investigators became aware that compounding had taken place during the construction timeframe.

On February 24, 2014, OPP Investigators informed NEHT that compounding was stop immediately based on the facts that clean room was not recertified after construction. NEHT was required to submit a continuity of care plan for its patients.

On February 26, 2014, NEHT was notified by letter to NEHT and Attorney Stalmack of a Cease and Desist and Quarantine Notice. NEHT was required to cease and desist all sterile compounding activity. OPP requested that NEHT provide the following

documentation:

1. NEHT's Policy and Procedure pertaining to recalls.
2. Detailed description of NEHT's plan recall non-expired medications currently in possession of patients
3. Detailed description of NEHT's plan for continuity of care while the Cease and Desist and Quarantine Notice was in effect.
4. List of products compounded since November 1, 2013.
5. End of Day reports from November 6, 2013, to February 26, 2014.
6. Detailed, day-by-day description of all construction and renovation performed in the pharmacy since November 1, 2013.
7. All reports of adverse patient events since November 6, 2013.
8. Detailed plan of correction pertaining to sterile compounding.

Note: NEHT did not provide documentation for item 7. NEHT indicated that it was not aware of any patient adverse events from compounded products from November 2013 to December 2013.

On March 19, 2014, Attorney Stalmack provided a POC and requested documentation to the OPP.

On April 18, 2014, OPP Compliance Investigators returned to NEHT to perform a USP <797> re-inspection. No deficiencies were noted during the re-inspection. The Cease and Desist Order was lifted and compounding activity resumed.

It was the recommendation of Director of Compliance William Frisch that file PHA-2012-0254 be considered separately as the case was at the beginning of the sterile compounding inspections and that a great deal of education has taken place since that time among inspectors and licensees. The Board inquired from inspectors if the NEHT's issues were related to the facility or the personnel. Investigator PENTA responded that the issue in his opinion was related to personnel. Investigator PENTA indicated that the NEHT now has continuous HVAC assessment with enhanced monthly monitoring. Compliance Director FRISCH indicated that NEHT had engaged an HVAC engineering firm. P.GANNON appreciated NEHT's POC correction. He questioned staff if in their opinion staff was appropriately trained. Director of Quality Assurance K. BARNES indicated that in her opinion NEHT required outside assistance.

Regarding compliant PHA-2013-0067, against MOR Kimberley Gould, Board Counsel H. Engman indicated that the complaint had already been adjudicated at the October, 2013 Board meeting with the Board direction to dismiss the complaint with discipline not warranted

ACTION:

PHA-2012-0254:

Motion by P. GANNON, seconded by J. TRIFONE, and voted unanimously to dismiss the complaint against New England Home Therapies, DS3486, with discipline not warranted.

PHA-2014-0034:

Motion by P. GANNON, seconded by T.FENSKY, and voted unanimously to refer the

matter of New England Home Therapies to the Office Prosecution for the authorization of a Consent Agreement for a two (2) year Probation with proof of staff training.

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Open Session concluded at 10:07AM.