

**COMMONWEALTH OF MASSACHUSETTS**

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

February 4, 2014  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

**Agenda**

Time	#	Item	Exhibits	Staff Contact
8:30	I.	<b>CALL TO ORDER</b>		
8:35	II.	<b>APPROVAL OF AGENDA</b>		
8:40	III	<b>APPLICATIONS</b>  1. <b>Fresenius Health Care of North America</b> - Petition for Waivers Frank Petrillo (PH23699)  2. <b>Sudbury Pharmacy</b> , 447 Boston Post Road, Sudbury (DS3406) Renovation request of non-sterile compounding room Joseph Chammas  3. <b>Seaside Pharmacy</b> , 169 Shirley Ave, Revere Application for New Community Tu-Anh Vo, Owner and Manager of Record (PH 27473)  4. <b>Benams Pharmacy</b> , 96 Long Pond Road Plymouth Application for New Community Pharmacy Maureen Ideham, Owner and Manager of Record (PH22874)  5. <b>Freedom Fertility Pharmacy</b> , 12 Kent Way, Suite 120F, Byfield Renovation/Expansion  6. <b>Open Source Pharmaceuticals</b> , 1208A VFW Pky, West Roxbury Reconsideration of Wholesale Distributor Application	M. Cittadino	Applications and supporting documentation
10.00	IV.	<b>APPROVAL OF BOARD MINUTES</b>  1. Draft September 26, 2013 Regular Session Minutes 2. Draft November 5, 2013 Regular Session Minutes 3. Draft December 3, 2013 Regular Session Minutes		
10:05	V.	<b>REPORTS</b>  1. Applications approved pursuant to Licensure Policy 13-01	Reports	M. Cittadino

10:10	VI.	<b>FILE REVIEW</b> 1. SA-INV-4837, PharmaHealth, DS89728 2. SA-INV-4998, Hopkinton Drug, DS8191 3. SA-INV-4997, IVG Veterinary Compounding Pharmacy, DS89887		
11:00	VII.	<b>PETITION</b>  Walgreens Corporation and Aids Action Committee Petition for Pilot Project: Steve Pashko, Marketing Pharmacy Director for Walgreens; Elizabeth Johnson, AIDS Action Committee; Chris Casale, Pharmacy Manager from Community, A Walgreens Pharmacy, Stanhope Street, Boston.		
11:30	VIII.	<b>FLEX SESSION</b>  1. Board Updates 2. CLEAR Board Member Webinar Series 3. Scales 4. 795 Attestations		
12:00		<b>LUNCH</b>		
1:00	IX.	<b>MPRS PRESENTATION</b> – Robert Hallisey, R.PH.		
1:30	X.	<b>EXECUTIVE SESSION</b> 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.  1. Specifically, the Board will discuss and evaluate the <u>Good Moral Character</u> as required for registration for pending applicants.  2. Approval of prior executive session minutes in accordance with M.G.L. ch.30A, § 22(f) for sessions held during the December 3, 2013 meetings.		CLOSED SESSION

2:00	XI.	M.G.L. c. 112, 65C SESSION	CLOSED SESSION	
4:15	XII.	ADJOURNMENT		

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, February 4, 2014

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**Board Members Present**

Patrick Gannon, RPh, MS, President-elect  
Edmund Taglieri, RPh, MSM, NHA,  
Secretary  
James DeVita, RPh (left @ 3:10 pm)  
Anthony Perrone, RPh, MD, MBA  
Richard Tinsley, MBA, MEd  
Joanne Trifone, RPh  
Anita Young, RPh, EdD

**Board Members Not Present**

Karen Ryle, RPh, President  
Jane F. Franke, RN, MHA

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Margaret Cittadino, MEd, Associate Director  
Heather Engman JD, MPH, Board Counsel  
Vita P. Berg, JD, Board Counsel (for MPRS)  
William E. Frisch, Jr., RPh, Investigator  
Supervisor  
Christina Mogni, RPh, Investigative Consultant  
Anthony Bartucca, RPh, Investigative Consultant  
David Dunn, RPh, Investigative Consultant  
Joseph Sceppa, Consultant

**Board Staff Not Present**

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

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TOPIC:

**I. CALL TO ORDER**

DISCUSSION: A quorum of the Board was present. President-elect, P. GANNON chaired the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting.

ACTION: At 8:32 a.m. P. GANNON, President-elect, called the February 4, 2014, meeting of the Board of Registration in Pharmacy to order.

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TOPIC:

**II. APPROVAL OF AGENDA**

DISCUSSION: Board members reviewed the tentative agenda. H. ENGMAN announced that III. Applications, #2 Sudbury Pharmacy, will be deferred to an upcoming meeting, and that #6 Open Source Pharmaceuticals was withdrawn. A. YOUNG asked that the Face of Pharmacy Day be added to the agenda

ACTION: Motion by, J. TRIFONE, seconded by A. YOUNG, and voted unanimously by roll call to approve the agenda with the above change. J. DEVITA: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; A. PERRONE: yes; R. TINSLEY: yes; P. GANNON: yes.

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TOPIC:

**III. APPLICATIONS**

**A. Petition for Waivers**

1. **Fresenius Health Care of North America**, (DS2969), 360 Cedar Hill St., Marlboro, MA, Frank Petrillo (PH23699)

DISCUSSION: W. FRISCH presented the Fresenius Health Care application to the Board for consideration after he conducted an inspection prior to licensure. Although Fresenius Medical Care North America is licensed as a retail pharmacy, it is a specialty dialysis services pharmacy located within a licensed dialysis wholesale distribution facility (WD424). The packages of medications are large, heavy, and are moved with a fork lift. Fresenius petitioned for the following waivers:

- a) 247 CMR 6.01, 5(b): There shall be within every pharmacy or pharmacy department a prescription area of not less than 300 square feet ...
- b) 247 CMR 8.02, 1(a)5: Training/Experience Requirement. An applicant for registration as a pharmacy technician must meet the following training program or experience requirements: ...
- c) 247 CMR 6.02, 9(a): A registered pharmacist shall be on duty and on the pharmacy premises at all times the pharmacy or pharmacy department is open for business and shall be present at all times when non-pharmacist personnel have unrestricted access to the pharmacy or pharmacy department.

Consistent with a prior decision concerning a pharmacy which dispenses only peritoneal dialysis products, the Board did not feel the need to grant a technician waiver. A non-licensed individual could assemble the products in a non-licensed space and the pharmacist would subsequently initial the prescription labels.

ACTION: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously to approve waiver request a) 247 CMR 6.01, 5(b) and c) 247 CMR 6.02, 9(a), and to deny waiver request b) 247 CMR 8.02, 1(a)5.

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TOPIC:

### **III. APPLICATIONS**

#### **B. Application for New Community Pharmacy**

##### **1. Seaside Pharmacy, 169 Shirley Avenue, Revere, MA**

DISCUSSION: Tu-Anh Vo, owner and proposed MOR and Dan Tran, husband and attorney, presented this application for a new community pharmacy. They feel that the Southeast Asian and Spanish speaking population in the Revere area is underserved. Ms. Vo distributed a copy of the floor plan. She has been an MOR for 1&1/2 years. M. Cittadino distributed the Attestation of Intent to Compound.

Ms. Vo currently intends to compound only "simple" non-sterile pharmaceuticals. She is planning to do an online self-assessment, has used the Prescription Monitoring Program @ Walgreens, and will contract for backup coverage.

In response to a Board question, Ms. Vo indicated that she inadvertently omitted non-narcotic Schedule II and narcotic Schedule III controlled substances from the application. She will modify the application.

ACTION: Motion by A. YOUNG, seconded by, J. DEVITA, and voted unanimously to approve the application for a new community pharmacy, pending receipt of the revised application and a successful inspection.

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TOPIC:

### **III. APPLICATIONS**

#### **B. Application for New Community Pharmacy**

##### **2. Benams Pharmacy, 96 Long Pond Road, Plymouth, MA**

RECUSAL: J. TRIFONE recused herself and was not present during the discussion or vote on this matter.

DISCUSSION: Maureen Idehen (PH19773), president and proposed MOR and Yvonne Rhone (PH223874), presented this application for a new community pharmacy. Ms. Idehen has lived in Plymouth for 12 years, has a significant amount of retail pharmacy experience, and been an MOR at a CVS for less than one year. The pharmacy will not compound sterile preparations. Ms. Idehen does not have experience with the Prescription Monitoring Program and has not made arrangements for a seal for the balance.

Board members were concerned that she did not have prospective arrangements with a wholesaler, computer system, and after-hour coverage. Ms. Idehen has not completed the Attestation of Intent to Conduct Nonsterile Compounding.

ACTION: Motion by J. DEVITA, seconded by, A. PERRONE, and voted unanimously to table this application for a new community pharmacy until applicant makes arrangements for security, sourcing, computer system, and after-hours coverage.

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TOPIC:

### **III. APPLICATIONS**

#### **C. Request for Renovation/Expansion**

##### **1. Freedom Fertility Pharmacy (DS89717), 12 Kent Way, Suite 120, Byfield, MA**

DISCUSSION: Brian Marquis (PH23304), MOR presented this application for renovation/expansion. In response to increased prescription volume, the proposal would expand the pharmacy from 8,635 to 12,631 ft<sup>2</sup>, adding additional refrigerators, storage

shelving, work stations, and security devices. Whenever possible work would be done after hours; after hour work will be supervised by a registered pharmacist. Increased environmental monitoring (particle counts) would be done daily (at the beginning, during, and after a shift). Renovations are tentatively scheduled to begin on February 8<sup>th</sup> and completed by March 1<sup>st</sup>.

ACTION: Motion by J. TRIFONE, seconded by, E. TAGLIERI, and voted unanimously to approve this application for expansion/renovation.

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TOPIC:

**IV. APPROVAL OF BOARD MINUTES**

**September 26, 2013 Regularly Scheduled Meeting**

DISCUSSION: H. ENGMAN presented the minutes of the September 26<sup>th</sup>, 2013 Regularly Scheduled Meeting. She reminded members to ensure that the minutes accurately reflected when they recused themselves from a discussion and vote.

ACTION: Motion by J. TRIFONE, seconded by, E. TAGLIERI, and voted unanimously to approve the minutes of the September 26, 2013 Regularly Scheduled Meeting with no changes.

**November 5, 2013 Regularly Scheduled Meeting**

DISCUSSION: H. ENGMAN presented the minutes of the November 5<sup>th</sup>, 2013 Regularly Scheduled Meeting. Board members suggested minor changes.

ACTION: Motion by A. YOUNG, seconded by, J. DEVITA, and voted unanimously to approve the minutes of the November 5, 2013 Regularly Scheduled Meeting with minor changes.

**December 3, 2013 Regularly Scheduled Meeting**

DISCUSSION: H. ENGMAN presented the minutes of the December 3<sup>rd</sup>, 2013 Regularly Scheduled Meeting.

ACTION: Motion by J. DEVITA, seconded by, J. TRIFONE, and voted unanimously to approve the minutes of the December 3, 2013 Regularly Scheduled Meeting with no changes.

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TOPIC:

**V. REPORTS**

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

DISCUSSION: M. CITTADINO noted that during the past month there has been one (1) new community pharmacy, one (1) renovation/expansion, and two (2) store closings, and one (1) certificate of fitness applications which were approved.

ACTION: So noted.

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TOPIC:

**VI. FILE REVIEW**

**1. SA-INV-4837, PharmaHealth Long Term Care (DS89728)**

DISCUSSION: This staff assignment was presented by W. Frisch. A PharmaHealth Specialty Pharmacy was to be located within the AIDS Community Action Center at 75 Amory Street, Boston. During a visit to the proposed location, Board investigators W. Frisch and C. Latham observed a sign "PharmaHealth Specialty" in the front of the facility and pharmacy technician, J. Diaz (PT13967) "enrolling" patients. Mr.

Diaz, a former MOMS Pharmacy employee, has been employed by PharmaHealth for 3 months, forwards prescriptions to PharmaHealth for filling, and then provides the medication to patients with an offer for a pharmacist to counsel by phone. Prescriptions that are not picked up are stored at 75 Armory Street in a location which is alarmed and under video monitoring from the Fairhaven location.

The Board had previously expressed concern about storing prescription medication in an unlicensed facility. Because the request for a permanent pharmacy has been denied, the Board felt there was no need to take action as the pharmacy is closing.

ACTIONS:

- a) Motion by J. DEVITA, seconded by A. YOUNG, and voted unanimously, to close the staff assignment due to insufficient evidence.
- b) Motion by J. TRIFONE, seconded by E. TAGLIERI, and voted unanimously, to send an advisory letter to Jennifer Torrey, the MOR, for conducting pharmacy activities in a non-licensed space and storing filled prescriptions overnight in an unlicensed space.

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TOPIC:

**VI. FILE REVIEW**

**2. SA-INV-4065, Hopkinton Drug (DS8191)**

DISCUSSION: This staff assignment was presented by W. Frisch. On 11/14/13, the Board received an independent laboratory report, forwarded by Hopkinton Drug of abnormal results (bacillus cereus) from a process validation study of ophthalmic solutions. The product was in a validation stage and was not dispensed to patients. A site visit on 11/25/13 confirmed that a root cause analysis and corrective action plan is being conducted. Environmental monitoring is conducted monthly (in excess of every six months monitoring by USP <797>.

Board members were pleased to learn of the prompt, comprehensive response by the facility.

ACTION: Motion by J. TRIFONE, seconded by R. TINSLEY, and voted unanimously, to close the staff assignment with no violation.

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TOPIC:

**VI. FILE REVIEW**

**3. SA-INV-4997, IVG Veterinary Compounding Pharmacy (DS89887)**

DISCUSSION: This staff assignment was presented by W. Frisch. On 11/5/13 the Board received a report from 10/31/13 of abnormal results indicating out-of-limit findings requiring cleaning and re-testing. The pharmacy recently opened for business and had not yet begun sterile compounding.

A site visit on 11/1/13, confirmed that sterile compounding had not yet begun. The sterile compounding areas were recertified that same day. It was felt that problem may be related to the effect of the high air currents on the non-sterile wrap-around gowns. The gowns have been replaced with "bunny suits". A faulty magnahelic gauge was also identified and replaced.

Board members were pleased to learn of the prompt response by the facility.

ACTION: Motion by A. YOUNG, seconded by J. TRIFONE, and voted unanimously, to close the staff assignment with no violation.

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BREAK 9:50 – 10:02 a.m.

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TOPIC:

**VII. APPLICATION for PILOT PROJECT**

**1. Walgreens and the AIDS Action Committee (AAC)**



RECUSAL: J. TRIFONE recused herself and was not present during the discussion or votes for these matters.

DISCUSSION: Christopher Casale (PH22005), a Walgreens MOR and Steve Pashko (Walgreens Marketing Director) and Elizabeth Johnson (AAC) presented an application for a pilot project to the Board. Since 1983, the AAC has provided no-cost care and prevention services to one-in-six MA residents living with or at risk of HIV/AIDS.

From 1/31/12 to 9/25/12, MOMS Pharmacy provided pharmacy services at an on-site pharmacy. From 11/1/12 to 12/31/13, PharmaHealth provided prescription courier services, along with medication adherence and Hepatitis C support programs from a Fairhaven facility. Recently, they were denied a request to establish an on-site pharmacy.

Walgreens intends to apply for a permanent on-site pharmacy at 75 Armory Street in Boston. Walgreens and AAC are requesting an interim solution until the permanent pharmacy can be built and licensed. The pilot project would involve obtaining a hard copy of the prescription; checking insurance coverage; transporting the prescription in a locked box; filling the prescription at either the Stanhope Street or Columbus Avenue Walgreens (often in blister packs for patients with cognitive dysfunction); transporting the medication to the AAC location in a locked box; and returning any unclaimed medication to one of the 2 Walgreens pharmacies. All pharmacy technicians involved in the program have been certified, in addition to being Board-registered. Board members complimented Walgreens on such a compassionate program.

ACTIONS: Motion by J. DEVITA, seconded by E. TAGLIERI, and voted unanimously, to approve the pilot project for a period of 12 months from today (2/4/2014)

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TOPIC:

**VIII. FLEX SESSION**

1. **Board Update**: D. Sencabaugh informed the Board of the following staff changes:
  - Bill Frisch had been promoted to Director of Compliance, effective January 13<sup>th</sup>,
  - Kelly Barnes has been named Director of Compliance, effective Mar 10, 2013
  - Leo McKenna has agreed to continue as a Board Inspector
  - Christina Mogni has been hired as a pharmacy investigative consultant
  - Anthony Bartucca has been hired as a pharmacy investigative consultant
  - David Dunn has been hired as a pharmacy investigative consultant
2. **CLEAR Board Member Webinar Series**: D. Sencabaugh distributed a list of 5 monthly Board member training webinars conducted by the Council on Licensure, Enforcement & Regulation (CLEAR). They will be broadcast in room 417 at 239 Causeway St. He encouraged members to attend if at all possible.
3. **Scales/Balances**: D. Sencabaugh informed the Board that the torsion balances in a few pharmacies failed recent inspections by local inspectors. He expects that it related to changes in the Fair Trade Standards, and is attempting to get further clarification.
4. **USP <795> Attestations**: D. Sencabaugh indicated that, of the 1,190 attestations mailed, 1,186 had been received. He acknowledged that Carolyn Reid had done a terrific job, entering the attestations into a spreadsheet. In addition to the types of formulations (Simple, Moderate, Complex), the data can be sorted by volume or risk (e.g., hazardous). It appears there are ~36 pharmacies compounding "Complex", and ~200 pharmacies compounding "Moderate" formulations.

5. **Face of Pharmacy Day:** A. Young announced that the Face of Pharmacy Day will be held on Tuesday, March 18<sup>th</sup> at 9 a.m. in the Gardner Auditorium at the State House. J. Trifone will be the keynote speaker. This will be an opportunity to meet with legislators and urge them to adopt pending legislation that, among other advances, would recognize pharmacists as healthcare providers (e.g., support pharmacy students as approved immunizers).

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TEMPORARILY ADJOURN REGULARILY SCHEDULED MEETING AND 10:52 – 11:56

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TOPIC:

M.G.L. c. 112 §65C SESSION

DISCUSSION: Since some agenda items were deferred, Board members recommended that rather than adjourn until the MPRS Presentation, it would be better to enter M.G.L. c. 112 65C Session at 10:52 a.m.

ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously by roll call to enter M.G.L. c. 112 65C Session. J. DEVITA: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; A. PERRONE: yes; R. TINSLEY: yes; P. GANNON: yes.

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LUNCH 11:56 a.m. – 12:25 p.m.

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TOPIC:

IX. MPRS PRESENTATION

DISCUSSION: Robert Hallisey, RPh, MS, MPRS Coordinator, described the MA Professional Recovery System to the Board. The voluntary program was started by Chuck Young (prior executive director of the Board) and the Board of Registration in Dentistry. Committee members (3 pharmacists and 3 dentists, all in recovery) are not paid. There is ½ FTE MPRS Coordinator.

The biggest costs are the urine tests (16-18/year @~\$60/test). There may be collection and/or counseling fees. Annual costs average ~\$1,800/year.

Individuals are self-referred or recommended by a Board. An MPRS coordinator does the initial screen. (Individuals deemed to be drug diverters may not be accepted.) If approved, the individual meets with the committee and is offered a 5-year contract. (The clock starts over if an individual relapses.) Individuals cannot practice for the first year of the program; they have to call-in every day. After the first year their license is returned to "Probation". MPRS has to approve any position. The supervisor has to submit quarterly reports to MPRS. Individuals must be compliant with all phases of the contract. At the completion of the program, MPRS notifies the Board.

Board members thanked Bob for his presentation and long-term commitment to MPRS.

ACTION: So noted.

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TOPIC:

X. EXECUTIVE SESSION

DISCUSSION: None

ACTION: At 1:35 p.m., motion by, J. DEVITA, seconded by E. TAGLIERI, and voted unanimously by roll call to enter Executive Session. J. DEVITA: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; P. GANNON: yes; A. PERRONE: yes; R. TINSLEY: yes.

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TOPIC:

XI. M.G.L. c. 112 §65C SESSION (2<sup>nd</sup> Time)

DISCUSSION: None.

ACTION: At 2:55 p.m., motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously by roll call to return to M.G.L. c. 112 65C Session. J. DEVITA: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; A. PERRONE: yes; R. TINSLEY: yes; P. GANNON: yes.

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TOPIC:

XII. ADJOURNMENT

DISCUSSION: None.

ACTION: At 4:50 p.m., motion by A. YOUNG, seconded by R. TINSLEY, and voted unanimously to adjourn. J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; A. PERRONE: yes; R. TINSLEY: yes; P. GANNON: yes.

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LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the February 4, 2014 Regularly Scheduled Meeting.
2. Petition for a Waiver, Fresenius Health Care of North America
3. Application for a New Community Pharmacy, Seaside Pharmacy
4. Attestation of Intent to Conduct Nonsterile Compounding, Seaside Pharmacy
5. Application for a New Community Pharmacy, Benams Pharmacy
6. Renovation/Expansion Request, Freedom Fertility Pharmacy
7. Draft Minutes of the September 26, 2013 Regularly Scheduled Meeting
8. Draft Minutes of the November 5, 2013 Regularly Scheduled Meeting
9. Draft Minutes of the December 3, 2013 Regularly Scheduled Meeting
10. Applications approved pursuant to Licensure Policy 13-01, February 2014
11. Investigative Report in the Matter of PharmaHealth, DS89728, SA-INV-4837
12. Investigative Report in the Matter of Hopkinton Drug, DS8191, SA-INV-4065
13. Investigative Report in the Matter of IVG Veterinary Compounding Pharmacy, DS89887, SA-INV-4997
14. Petition for Pilot Project, Walgreens Corporation and AIDS Action Committee
15. Board Member Training, CLEAR Series of Webinar Dates

Respectfully submitted,

Edmund Taglieri, RPh, MSM, NHA, Secretary