

**COMMONWEALTH OF MASSACHUSETTS  
Board of Registration in Pharmacy**

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

**August 14, 2020**

**Webex Information**

Call in Number: 1-203-607-0564 or toll free 1-866-692-3580

Access Code: 161 519 5776

Attendee: #

*If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Yulanda Kiner, Phone: 617-624-5848 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.*

**Agenda**

<b>Time</b>	<b>#</b>	<b>Item</b>
<b>8:00</b>	<b>I</b>	<b>CALL TO ORDER</b> <ul style="list-style-type: none"><li>• Introduction of Nancy Aleid – Pharmacy Investigation Coordinator</li></ul>
	<b>II</b>	<b>APPROVAL OF AGENDA</b>
<b>8:05</b>	<b>III</b>	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"><li>• Draft of July 31, 2020 Regular Session Minutes</li></ul>
<b>8:10</b>	<b>IV</b>	<b>REPORTS</b> <ul style="list-style-type: none"><li>• Applications approved pursuant to Licensure Policy 13-01</li><li>• Monthly report from probation</li><li>• Board Delegated Review pursuant to Licensure Policy 14-02</li><li>• Above Action Levels approved by Staff Action 16-04</li><li>• PSUD Report-Policy 17-03</li></ul>

8:15	V	<b>APPLICATIONS</b> <ul style="list-style-type: none"> <li>• Ethos Veterinary Health(DS90035)/ Ethos Compounding Pharmacy– Transfer of Ownership</li> <li>• Walden Behavioral Care– New Community Pharmacy/Request for Pilot Project</li> <li>• Acnos Pharmacy – Wholesale Distributor</li> </ul>												
8:45	VI	<b>FLEX</b> <ul style="list-style-type: none"> <li>• Pharmacy issues related to Covid-19 and the state of emergency</li> <li>• Board meeting dates for the rest of 2020</li> </ul>												
9:00	VII	<b>File Review</b> <table border="1" data-bbox="318 621 1192 827"> <tr> <td data-bbox="318 621 363 674">1</td> <td data-bbox="363 621 602 674">PHA-2020-0014</td> <td data-bbox="602 621 1192 674">Stop &amp; Shop #478, DS2172</td> </tr> <tr> <td data-bbox="318 674 363 726">2</td> <td data-bbox="363 674 602 726">PHA-2020-0008</td> <td data-bbox="602 674 1192 726">Osco #4596, DS3268</td> </tr> <tr> <td data-bbox="318 726 363 779">3</td> <td data-bbox="363 726 602 779">SA-INV-14296</td> <td data-bbox="602 726 1192 779">Seaside Pharmacy, DS89919</td> </tr> <tr> <td data-bbox="318 779 363 827">4</td> <td data-bbox="363 779 602 827">PHA-2019-0031</td> <td data-bbox="602 779 1192 827">Injured Workers Pharmacy, DS89727</td> </tr> </table>	1	PHA-2020-0014	Stop & Shop #478, DS2172	2	PHA-2020-0008	Osco #4596, DS3268	3	SA-INV-14296	Seaside Pharmacy, DS89919	4	PHA-2019-0031	Injured Workers Pharmacy, DS89727
1	PHA-2020-0014	Stop & Shop #478, DS2172												
2	PHA-2020-0008	Osco #4596, DS3268												
3	SA-INV-14296	Seaside Pharmacy, DS89919												
4	PHA-2019-0031	Injured Workers Pharmacy, DS89727												
9:30	VIII	<b>M.G.L. c. 112, § 65C SESSION</b>												
10:00	IX	<b>ADJOURNMENT</b>												

**COMMONWEALTH OF MASSACHUSETTS  
BOARD OF REGISTRATION IN PHARMACY**

**MINUTES OF THE GENERAL SESSION**

**Meeting held via WEBEX remotely**

**Boston, Massachusetts, 02114**

**August 14, 2020**

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**Board Members Present**

Kim Tanzer, PharmD, RPh. President  
Julie Lanza, CPhT, President Elect (leaves 9:30 AM)  
Leah Giambarresi, Pharm D, RPh, Secretary  
Sebastian Hamilton, Pharm D, RPh  
Dr. Richard Lopez, MD  
Andrew Stein, Pharm D  
Timothy Fensky, RPh  
Katie Thornell, RPh  
Susan Cornacchio JD, RN  
Stephanie Hernandez, Pharm D, BCGP, RPh (leaves 9:30 AM)  
Patrick Gannon, RPh  
Dawn Perry, JD (leaves 9 AM)

**Board Members Not Present**

Carly Jean-Francois, RN, NP

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Heather Engman, JD, Board Counsel  
William Frisch, RPh Director of Pharmacy Compliance  
Joanne Trifone, RPh, Director of Investigator  
Gregory Melton, Pharm D, JD, RPh Investigator  
Christina Mogni, RPh Investigator  
Stephen Horn, RPh Investigator  
Leo McKenna, PharmD, RPh Investigator  
John Murray, RPh Investigator  
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor  
Joanna Chow, Office Support Specialist

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**TOPIC I.** Attendance by roll call:

**CALL TO ORDER 8:01 AM**

A quorum of the Board was present, established by roll call. President K. Tanzer chaired the meeting. She explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: K. TANZER: yes, L. GIAMBARRESI: yes, A. STEIN: yes, S. HAMILTON: yes, D. PERRY: yes, S. CORNACCHIO: yes, S. HERNANDEZ: yes, T. FENSKY: yes, P. GANNON: yes, K. THORNELL: yes, J. LANZA; yes. Dr. Lopez joins the meeting at 8:04 AM.

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**Topic II.**

**Approval of Agenda**

**TIME 8:04 AM**

**Agenda July 31, 2020**

**DISCUSSION:**

Change to Agenda:

1. none

**ACTION:**

Motion by S. Hamilton, seconded by T. Fensky and voted unanimously by those present by roll call vote to approve the agenda with no changes.

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**Topic III**

**Approval of Board Minutes**

**TIME: 8:05 AM**

**Minutes**

1. **Draft 7/31/20 General Session Minutes**

No noted Changes.

**Action:**

Motion by L. Giambarresi, seconded by T. Fensky and voted unanimously by roll call vote to approve the regular session minutes of 7/31/20 with no noted changes.

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**TOPIC IV**

**Reports**

**Applications approved pursuant to Licensure Policy 13-01**

**Time: 8:06 AM**

**Discussion:** J. Chow presented the report submitted.

So noted

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**TOPIC IV**

**REPORTS**

**Monthly Report from Probation**

**Time: 8:36 AM**

**Discussion:** No report submitted for review.

So noted

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**TOPIC IV**

**REPORTS**

**Monthly Report from BDR pursuant to Policy 14-02**

**Time: 8:07 AM**

**Discussion:** Dave presented the submitted report.

So noted

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**TOPIC IV**  
**REPORTS**  
**Above Action Levels Approved by Staff Action 16-04**

**Time: 8:08 AM**

**Discussion:** J. Tran presented the submitted report.

So noted

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**TOPIC IV**  
**REPORTS**  
**PSUD Report by Staff Action 17-03**

**Time: 8:08 AM**

**Discussion:** E. Taglieri presented the submitted report.

So noted

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**TOPIC V**  
**Applications**

**1. Ethos Veterinary Health DS90035/Ethos Compounding  
Transfer of Ownership  
Represented by: Matt, Pat**

**TIME 8:09**

**Recusal: A. Stein**

**Discussion:** Veterinary hospital is selling the pharmacy as part of its consolidation plan. Ownership is transitioning to Andrew Stein and John Walczyk. The pharmacy will remain in the same location. Matthew Chan will remain the MOR and the pharmacy team will remain the same.

**Action:** Motion by T. Fensky, seconded by S. Hamilton, and voted unanimously by roll call by those present to approve the application for transfer of ownership pending the submission of an updated compounding attestation.

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**2. Walden Behavioral Care New Community Pharmacy/Pilot Project  
Represented by: Matt Moen and Michael Tocco  
Recusal:  
Discussion:**

**Time:8:11**

Pilot Project Program Discussion from (Edmund Taglieri)

- Department of Public Health
- DMH can have inpatient beds and give patient medication from stock without pharmacist help; obtain only MCSR
- Proposal for dual medication system in one pharmacy. One side will be the DS providing outpatient services the other side will be the inpatient services. Shared space; shared staff; however separate inventory and separate computer system management. Inpatient will utilize a Pixus type system.
- Walden is looking to have a pharmacy oversee medication management for both inpatient and outpatient in the same shared space.

(Matt Moen and Michael Tocco Discussion)

Matt and Michael presented the submitted power point presentation to the board.

Conclusion

-Proposed model provides a greater degree of pharmacist involvement and documentation of medication use, with inpatient psychiatric medication therapy than required by law within the commonwealth

Questions:

Timothy Fensky - Explain the computer system.

Utilize QS1 on pharmacy manager software side currently.

Separate inpatient and retail log-in.

How are you going to get the medication from the facility to the home?

1. Pharmacy first level – drop off and pick up window
2. Delivery piece certain to implement within a reasonable geography

Patrick Gannon: When QS1 is providing electronic support on the inpatient model is that side merely just bringing stock supplies to PXIS machine?

Matt Moen: Working on interface – will be PXIS type machine.

Sebastian Hamilton: What kind of volume are you seeing inpatient vs outpatient?

Matt Moen: Volume outpatient –Did not have a license

15 – 30 residency side

40 beds average 5 medication per person

Only looking at 100 prescriptions a month

Inpatient – 40 bed facility average low 200

Timothy Fensky: What are the safeguard systems?

Matt Moen: Different process on both sides – Receiving electronic prescriptions, the other point inpatient no third party billing – no addition so it is different in that manner – the pharmacy will be in different areas with retail stock and strong visual cues and signage – physically separate inventory

If Approved Edmund Taglieri explains recommend contingent on 3 items:

1. Executed Agreement with specifics for basis of monitoring
2. Successful Inspection
3. DEA licensure

Recommend 1-year pilot; Metrix will be spelled out in the agreement; recommend 3 months post opening to report back to Board and then the Board can determine when they should report back again. Since there are no specific laws or regulations to compliance and monitoring within DMH for inpatient pharmacy; recommendation is if pilot successful to consider coming out of pilot and making the executed agreement the basis for compliance and monitoring.

**Action:** Motion by T. Fensky, seconded by S. Stephanie, and voted unanimously by roll call by those present to approve the pilot project for 1 year with first report back to the Board at 3 months post commencement of operations and contingent on:

1. Executed Agreement with specifics for basis of monitoring
2. Successful Inspection
3. DEA licensure

**3. Acnos Pharmacy                      Wholesale Distributor                      TIME 8:44**  
**Represented by: Joanna Chow – Leah Brown, Tammy Bishop**

**Recusal:**

**Discussion:** Acnos supplies pharmaceutical companies with medications for head-to-head studies. They will be leasing 5,000 sq. ft. from Westnet in Canton. Westnet is a licensed wholesale distributor with the Board. Medications will not be stored at the facility. Acnos is acting as the middleman for clinical trials. They will not be shipping medications to patients, pharmacies, or hospitals. The Board members had concerns on the operations of Acnos and how it would affect Westnet’s facility footprint.

**Action:** Motion by P. Gannon, seconded by L. Giambarresi, and voted unanimously by roll call by those present to defer the matter until a more detailed description of services and blueprints are submitted for consideration by the Board.

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**D. Perry leaves the meeting at 9:00 AM**

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**1. Pharmacy issues related to Covid-19 and the state of emergency****Presented by:** Dave**Recusal:** None**Discussion:** None]

So noted

**2. Board meetings dates for the remainder of 2020****Presented by:** Dave**Recusal:** none**Discussion:** Dave presented the dates for proposed Board meetings for September to December. Two per month on Fridays starting at 8 AM; continued via remote Webex due to COVID-19 restrictions.**Action:** Motion by T. Fensky, seconded by L. Giambarresi, and voted unanimously by roll call by those present to approve the dates for Board meetings presented for September to December 2020 via remote Webex due to COVID-19 restrictions.**TOPIC VII****File Review**

Case #1

PHA-2020-0014

Stop &amp; Shop #478, DS2172

Time: 09:05 AM

**RECUSAL:** K. THORNELL recused and was not present for the discussion or vote in this matter.**DISCUSSION:** G. MELTON presented and summarized the investigative report that pertained to these matters.

- S&S #478 properly submitted a final report of an unknown loss on 2-4-20. S&S #478 indicated that an unknown loss of 100 amphetamine mixed salts 10mg tablets was discovered on 1-2-20. An internal investigation was conducted which included an audit of dispensing logs, invoices, and the perpetual inventory log, a search of the pharmacy, and a review of surveillance video. S&S #478 indicated that a reason for the loss was not determined.
- S&S #478 did note that staff were captured on surveillance video deviating from company policy and procedures for receipt of narcotic shipments. Specifically, staff allowed the delivery driver to leave before reconciling the narcotic shipment. However, the shipment was accurate despite the deviation from company policy and procedures.
- CA: MOR Cook wrote, "Narcotic deliveries are now checked in for accuracy before the delivery driver leaves... Narcotics and controlled are immediately checked in, logged in narcotic book, received in the pharmacy computer inventory system and immediately placed in the safe. CSOS receiving is done on the Cardinal ordering site to reconcile CSOS procedures"



ACTION: Motion by T.FENSKY, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2020-0014), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #2

PHA-2020-0008

Oscos #4596, DS3268

Time: 09:07 AM

RECUSAL: NONE

DISCUSSION: G. MELTON presented and summarized the investigative report that pertained to these matters.

- Oscos #4596 submitted an incomplete final report of loss form for 22mL hydrocodone-chlorpheniramine polistirex 10-8mg/5mL extended release suspension (suspension). In the report, the pharmacy indicated that the investigation of the loss was a “still active.” Thus, the Oscos #4596 submitted a final report of loss before the completion of their investigation in violation of BORP Policy 2018-05. In addition, the reason for the loss was listed as unknown in violation of 247 CMR 9.01(5).
- Oscos #4596 remediated by proper submission of a final report of loss form indicating the investigation into the incident was complete. In addition, the reason for the loss was amended to other known loss caused by a “packaging discrepancy.”
- Specifically, the suspension was switched from plastic to glass containers at the time the loss was discovered. Oscos #4596 learned from experimenting that the suspension remained adhered to the inner surface of the plastic containers for a longer period when compared to the glass container. Thus, the plastic bottles in hindsight were misjudged by staff as empty and discarded with small quantities of suspension left inside which overtime produced the loss of 22mL.
- CA: Oscos #4596’s staff members were reminded to pour in a more careful manner when preparing prescriptions for the suspension.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS the matter (PHA-2020-0008), No Discipline Warranted, Remediation Complete.

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Case #3

SA-INV-14296

Seaside Pharmacy, DS89919

Time: 09:09 AM

RECUSAL: NONE

DISCUSSION: G. MELTON presented and summarized the investigative report that pertained to these matters.

- Seaside was cited for multiple inspectional deficiencies involving the management, security, and dispensing of federally scheduled controlled substances were observed during a retail compliance inspection. For example, Seaside failed to exercise its corresponding responsibility. In fact, Seaside regularly filled prescriptions for patients on oxycodone with MMEDs > 1000, 500, & 300. As a result, a plan of correction (POC) was issued and DEA was contacted.

- DEA and BOP conducted three additional inspections between 12/18 and 3/19 to monitor Seaside's progress as the pharmacy implemented its POC. During this time, DEA was unable to reconcile Seaside's CII inventory because the pharmacy's record keeping was abysmal. Although, no criminal activity was suspected.
- Seaside did improve on exercising its corresponding responsibility over this time. The pharmacy ceased accepting prescriptions from physicians who would not provide acceptable rationalizations for high dose/large quantities of CII prescriptions (opioids and amphetamines) issued to patients.
- DEA issued the pharmacy a Letter of Admonition on 05/16/2019 for (1) failing to maintain accurate CII records, (2) failing to exercise its corresponding responsibility, and (3) failing to properly screen employees' backgrounds. DEA required Seaside to correct the issues. DEA then visited Seaside on its own in 8/2019 after the LOA was issued and confirmed that Seaside had satisfactorily corrected the issues. BOP also followed up with a retail inspection during 10/2019 to confirm Seaside was maintaining its ongoing POC. Seaside's inspection was deemed satisfactory.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to elevate the matter (SA-INV-14296) to a complaint, and then refer the matter, to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND, and to refer the matter to the BORiM and BORN.

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Case #4

PHA-2019-0031

Injured Workers Pharmacy, DS89727

Time: 09:16 AM

RECUSAL: W. FRISCH recused and was not present for the discussion or vote in this matter.

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- During the Board meeting on 10/03/2019, an informational synopsis of this ongoing investigation was presented to the Board members. No action was taken by the Board members at that time as the investigation was still in pending status.
- Retail compliance inspection ISP-8767 conducted with the DEA on 06/25/2018 and 06/27/2018. At the time of inspection, there were concerns including, but not limited to, filling prescriptions with expired/invalid DEA numbers, filling prescriptions with "red flags" such as high risk medication combinations, and corresponding responsibility. Inspectional deficiencies cited and observations included data entry techs determining the validity of controlled substance prescriptions, CPhT PDMP delegates reviewing PDMP, some pharmacists without MA PMP accounts, perpetual inventory not reconciled every 10 days, controlled substance recordkeeping discrepancies, inaccurate CII disposal records, not appropriately filing prescriptions according to Schedule CII, CIII-CV, and CVI, undeliverable medications returned to stock, multiple prescriptions on one blank from multiple states, and inadequate DUR.
- IWP enrollment team determines a valid relationship with a prescriber during patient enrollment, data entry pharmacy technicians determine if the prescriber has a valid DEA number and CPhT PDMP delegates will review state PDMP for the patient and determine if there is any issue to be brought to

the pharmacist's attention. At the time of inspection, 2 of 4 CPhTs identified as PDMP delegates did not have approved delegate accounts.

- The PV1 pharmacist verifies the prescription but does not automatically see the patient profile with only "Severe Risk" DURs for 6 categories of interactions alerted. Prescriptions were not reviewed for "red flags". High risk combinations of opioids, benzodiazepines and carisoprodol or promethazine/codeine were dispensed.
- Controlled substance discrepancies could not be reconciled during the inspection. The perpetual inventory did not reflect when reconciliation is performed and showed unexplained adjustments including adjustments to drugs with no activity without information of who made the adjustment. Medications that were undeliverable by FedEx were returned and put back into active stock for re-dispensing. Ketamine-containing pain creams were dispensed with quantities greater than a 30 day supply. Prescriptions with multiple drugs in multiple schedules on one blank were filed under only one drug schedule.
- CA: Under Current MOR Welch, who started in October 2018, extensive corrective actions were implemented. DEA lookup software was implemented; all pharmacists have MassPAT accounts; there are now 5 CPhT PDMP delegates; P&P for validating controlled substance prescriptions has been reviewed with all pharmacists; MOR will ensure all controlled substance recordkeeping requirements are met; prescriptions with more than one CII ordered will not be accepted from any state; IWP staff has been made aware of various state requirements for multiple medications ordered on one prescription; all returns are deemed unsalable; additional DUR alerts were added including "Moderate Risk" and high risk drug combinations. Policy "PDMP Query" was amended on 12/07/2018 to indicate a pharmacist will review and document all PDMP results. The PDMP is checked for all CII and new controlled substance prescriptions. An inspection conducted on 10/22/2019 confirmed controlled substance recordkeeping compliance and remediation of all deficiencies.
- On 6/24/20, the MA AG's Office filed a complaint based on their investigation of IWP for violating Massachusetts consumer protection law by failing to implement effective policies and procedures for reviewing prescriptions to determine whether they were legitimate and by engaging in unlawful marketing practices to drive sales, including paying law firms for patient referrals. On 6/24/20, IWP agreed to a voluntary Consent Judgment including IWP's payment of a monetary fine of \$11 million and implementation of specific practice requirements.

ACTION: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2019-0031), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 2 years.

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**Kim Tanzer announces at 9:25 AM the general session will be ending, and the Board will be going into private session. The Board will not cover any other general session items today.**

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**S. Cornacchio; J. Lanza; S. Hernandez leave meeting at this time and do not attend 65C**

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**Topic VIII:**

**M.G.L. 65 C #1**

**Time: 8:25 AM**

DISCUSSION: None

ACTION: President K. Tanzer request a motion to enter M.G.L 65 c Session.

At 8:25 AM L. Giambarresi, seconded by S. Hamilton and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

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**Topic XI:**

**ADJOURNMENT OF MEETING**

**TIME: 9:39 AM**

ACTION: Motion by S. Hamilton seconded by T. Fensky, and voted unanimously by those present, to adjourn from General Session.

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EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 8/14/20 General Session
2. Draft Minutes of the 7/31/20 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on Board Delegated Complaint Review to licensure policy 14-02
5. Report on Above Action Levels approved by Staff Action 16-04
6. Report on PSUD 17-03
7. Applications: Ethos Veterinary Health DS900356 Transfer of ownership
8. Applications: Walden Behavioral Care New Community Pharmacy/Pilot Project Request
9. Application: Acnos Pharmacy Wholesale Distributor
10. PHA-2020-0014 Stop and Shop #478 DS2172
11. PHA-2020-0008 OSCO #4596 DS3268
12. SA-INV-14296 Seaside Pharmacy DS89919
13. PHA-2019-0031 Injured Workers Pharmacy DS89919

Respectfully Submitted,  
Leah Giambarresi, PharmD, RPh, Secretary