

## **BOARD MEETING MINUTES**

**Oregon Board of Pharmacy  
800 NE Oregon Street  
Portland, OR 97232  
December 17-18, 2013**

*The mission of the Oregon State Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale and distribution of drugs.*

### **TUESDAY, DECEMBER 17, 2013**

Penny Reher, R.Ph. Board President, called the meeting to order at 8:30AM.

The following Board Members were present:

Penny Reher, President	Dianna Pimlott, Vice President
Christine Chute	Ken Wells
Roberto Linares	Heather Anderson
Brad Fujisaki	

The following staff members will be present for all or part of this session:

Gary Miner, Interim Executive Director	Karen MacLean, Administrative Director
Chrisy Hennigan, Office Manager	Courtney Wilson, Project Manager
Joe Ball, Chief Investigator	Fiona Karbowicz, Pharmacist Consultant
Gregg Hyman, Inspector	Michele Cale, Inspector
Katie Baldwin, Inspector	Laura Elvers, Inspector
Annette Gearhart, Compliance Secretary	Kim Oster, Compliance Assistant

Thomas Cowan Sr. AAG Board Counsel

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Agenda Review and Approval

#### **MOTION**

**Motion to approve the agenda was made and unanimously carried (Motion by Pimlott, second by Wells).**

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## **II. EXECUTIVE SESSION - PUBLIC MAY NOT ATTEND, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (k).**

### **A. Items for Consideration and Discussion:**

1. Deliberation on Board Investigations and Disciplinary Cases
2. Personal Appearances
3. Warning Notices
4. Case Review

**MOTION**

**Motion to enter Executive Session at 8:34 AM was made and unanimously carried (Motion by Anderson, second by Wells).**

**MOTION**

**Motion to resume Open Session at 3:35 PM was made and unanimously carried (Motion by Fujisaki, second by Anderson).**

**MOTION**

**Motion to adjourn at 4:03 PM was made and unanimously carried (Motion by Anderson, second by Fujisaki).**

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**WEDNESDAY, DECEMBER 18, 2013**

Penny Reher, R.Ph. Board President, called the meeting to order at 8:30AM.

The following Board Members were present:

Penny Reher, President	Dianna Pimlott, Vice President
Christine Chute	Ken Wells
Roberto Linares	Heather Anderson
Brad Fujisaki	

The following staff members will be present for all or part of this session:

Gary Miner, Interim Executive Director	Karen MacLean, Administrative Director
Chrisy Hennigan, Office Manager	Courtney Wilson, Project Manager
Joe Ball, Chief Investigator	Fiona Karbowicz, Pharmacist Consultant
Gregg Hyman, Inspector	Michele Cale, Inspector
Katie Baldwin, Inspector	Laura Elvers, Inspector
Annette Gearhart, Compliance Secretary	Kim Oster, Compliance Assistant
Thomas Cowan Sr. AAG Board Counsel	

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Motions for Disciplinary Action - Please see Motions for Disciplinary Cases at the end of this document.

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**Intern License Extension**

**MOTION**

**Motion to grant D. McKay an intern license extension until April 30, 2014 was made and unanimously carried (Motion by Anderson, second by Wells).**

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## Approve Consent Agenda\*

\*Items listed under the consent agenda are considered to be routine agency matters and will be approved by a single motion of the Board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda.

1. NAPLEX Scores – (May 1, 2013-August 31, 2013)
2. MPJE Scores - (May 1, 2013-August 31, 2013)
3. Project Manager Report
4. License/Registration Ratification (October 12, 2013-December 13, 2013)
5. Extension Requests
6. Approval of Board Meeting Minutes (October 15-17, 2013)

## MOTION

**Motion to approve the consent agenda as *revised* was made and unanimously carried (Motion by Chute, second by Fujisaki).**

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## ISSUES/ACTIVITIES

### Reports:

Board President Penny Reher provided an update on the Executive Director recruitment. She indicates that Twyla Lawson from the Department of Administrative Services, Chief Human Resources Office is currently vetting applicants, these individuals are all pharmacists. She is hoping to have the names of the final candidates to the Board Members by Friday December 20<sup>th</sup>. On the morning on January 8<sup>th</sup> there will be a staff forum and staff will be able to provide comments about the applicants to the Board electronically. Twyla will compile the staff's comments and provide them to the Board. Board Members will conduct an interview in the afternoon and review the staff's comments. Open session will then take place and the public will be able to provide comments on the final candidates. The Board will then make a motion to appoint a new Executive Director.

Board Member Christine Chute reported that she had attended the October 29-30 Citizen Advocacy Center (CAC) 2013 Annual Meeting in Seattle, Washington. The meeting was targeted to public members and the healthcare regulatory, credentialing and governing Boards on which these members serve. Christine indicated that meeting was extremely useful and very interesting. She thought that Board Member Heather Anderson's written summation of the meeting was an excellent overview of the information presented. Christine provided an update on the Health Board's Peer Review Performance Audit Committee that she is currently the Public Member for. She indicates that the committee has just completed their draft report for the Board of Examiners for Speech-Language Pathology and Audiology.

Board Member Ken Wells shared that he had attended the November Pharmacy Coalition and Professional Practice Roundtable Meetings. Ken noted that he did not attend these meetings in the capacity of a Board Member.

Board Member Heather Anderson reported that she had also attended the October 29-30 Citizen Advocacy Center (CAC) 2013 Annual Meeting in Seattle, Washington. She also thought that the meeting was extremely interesting and will be discussing it further in the committee/meeting portion of the meeting.

Board Vice President Dianna Pimlott and Board Members Roberto Linares and Brad Fujisaki had nothing to report.

Board Counsel Tom Cowan had nothing to report.

Compliance Director/Interim Executive Director Gary Miner reported that 96% of pharmacies in Oregon have been inspected and that the Compliance Department is expected to meet its target goal of 100%. Gary also shared that there are currently 15 individuals enrolled in the Health Professional Services Program (HPSP). These are all Board enrollees, no self referrals. Gary indicates that the Compliance Department is making efforts to become paperless this includes using iPads on inspections and the scanning of case files. Gary also shared that Board Counsel Tom Cowan will be in the Board Office one day a month. Board staff is looking forward to this new addition.

Gary also provided the Board with an update on Medical Marijuana Facilities. He indicated that staff had met with the Oregon Health Authority (OHA) to discuss the licensure process of these outlets. It was determined that once OHA issued their Marijuana Registration this information could be confirmed and the applicant would be eligible for licensure with the Board of Pharmacy. Staff hopes to have proposed rules for Medical Marijuana Facilities in Division 080 and 110 to the Board after the first of the year for consideration.

Gary indicated that the 2014 Legislature will convene in February. During this session a legislative concept will be introduced to authorize practitioners to electronically transmit prescriptions for Schedule II Controlled Substances in nonemergency situations.

Administrative Director Karen MacLean provided a staffing update. She indicated that there is a vacant licensing and receptionist position and that she is hoping to have these positions filled shortly. Karen was pleased to announce that Kate Hill recently joined the agency and is working part time in the Licensing Department and that Pharmacy Inspector Fiona Karbowicz has been appointed to the Pharmacist Consultant position. Karen noted that there is a recruitment open for the Pharmacy Inspector position left vacant by Fiona.

Karen also stated that the Licensing Department is currently 75% of the way through the Non Prescription Drug Outlet Renewal Cycle. There are about 3000 outlets that renew their registration during this renewal cycle. Karen shared that she recently attended a meeting relating to credentialing along with Compliance Director/Interim Executive Director Gary Miner and Pharmacists Consultant Fiona Karbowicz. During the 2013 Legislative Session Senate Bill 604B was adopted. This measure requires the Oregon Health Authority to establish a program for the purpose of providing to a credentialing organization access to information that is necessary to credential or recredential a health care practitioner. This program is to become operative on January 1, 2016. Karen indicates that the agency is receiving more and more license verification requests referred to as credentialing requests and hospitals and insurance companies are now asking for pharmacists to be credentialed. Karen will continue to keep the Board updated on this topic.

Karen provided an update on the agency's progression towards a paperless office. She indicates that staff continues to work with HPTrim and that implementation has not yet begun agency wide. Karen also indicated that notification was received from NABP that the standards for the Test of English as a Foreign Language (TOEFL) will be changing. As a result, the Board will need to consider a rule change for OAR 855-019-0150 and a Temporary Rule will be drafted for review in

February. Karen shared that the Certified Pharmacy Technician (CPT) audit notifications went out of December 17, 2013 and that CPTs will have until January 31, 2014 to submit evidence of their national certification and continuing education. The pharmacist continuing education audit is complete and the background checks are in progress.

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### **Board Meeting Dates**

- February 4 - 6, 2014 Portland
- March 11 -12, 2014 Silverton - Strategic Planning
- April 8 - 9, 2014 Portland
- June 10 - 11, 2014 Portland
- August 12 - 14, 2014 Portland
- October 7 - 9, 2014 Portland
- December 2-3, 2014 Portland
- February 10-12, 2015 Portland
- March 17-18, 2015 TBA
- April 7-8, 2015 Portland
- June 9-10, 2015 Portland
- August 11-13, 2015 Portland
- October 6-7, 2015 Portland
- December 15-16, 2015 Portland

The Board approved the 2015 proposed Board Meeting dates.

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### **Rulemaking Hearing Dates**

- May 22, 2014
- November 25, 2014
- May 28, 2015
- November 24, 2015

The Board approved the 2015 proposed Rulemaking Hearing Dates.

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### **Board Member/Staff Presentations**

Board Member Ken Wells and Interim Executive Director/Compliance Director Gary Miner attended the November 12, 2013 Pharmacy Coalition Meeting.

Interim Executive Director/Compliance Director Gary Miner attended the Professional Practice Roundtable on November 5, 2013. Gary indicates that they discussed the retirement of Executive Director Gary Schnabel. They also discussed the community pharmacy accreditation process, as well as California's new advanced practice pharmacist law. It was noted that other health related professions in California tried to get the advanced practice designation for their profession. However, pharmacy was the only profession that was successful in getting the law passed.

Board President Penny Reher, Board Member Ken Wells and Inspector Gregg Hyman provided a presentation at the 2013 OSPA Annual Conference in Portland, Oregon on October 18<sup>th</sup>-20<sup>th</sup>. Their presentation consisted of discussing changes that licensees should be aware of. Board

Members thanked Gregg for his participation and contributions. Penny and Ken stated that the audience asked good questions.

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## **Committees/Meetings**

Board Members Christine Chute and Heather Anderson attended the Citizen Advocacy Center (CAC) Annual Meeting, October 29<sup>th</sup> – 30<sup>th</sup> in Seattle, Washington. Heather discussed a few topics that the Board may want to consider looking into when time allows. These topics are as followed:

- “Scope of Practice” Law, Managing by “Dangerous Acts”
- Metrics to Demographics
- Professor Barbara Safriet
  - Presentation Re: Certain Aspects of Licensing Anti-Trust, Anti-Consumer

Board Members Christine Chute and Heather Anderson thought that Professor Barbara Safriet provided an excellent presentation and that they would like her to provide the same presentation to the Board. Heather will reach out to Barbara to see if she would be available to appear at a future Board Meeting.

Interim Executive Director/Compliance Director Gary Miner attended the National Association of Boards of Pharmacy (NABP) Compliance Director and Legal Counsel Forum December 2-4<sup>th</sup> in Chicago, Illinois. Gary thanked the Board for allowing him to go to the meeting and stated that it was very valuable. At the meeting Gary learned that NABP will be providing Verified Accredited Wholesale Distributor accreditation to all disciplines of wholesale activities which includes activities that the Board has identified in its Drug Distribution Agent rules. In addition, he learned that other Boards are creating “Do Better” letters in lieu of letters of concern. Board Counsel Tom Cowan would like to review examples of these letters if the Board would like to look into utilizing such letters at a later date. NABP provided the meal and travel expenses associated with this trip.

Board President Penny Reher attended the American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting on December 9<sup>th</sup> in Orlando, Florida. Penny stated that 20 different states were represented at the meeting. She attended the sterile compounding seminar. ASHP has developed tools such as the Sterile Compounding Resource Center to ensure that sterile products are safe for patients. The resource center contains items such as the “Outsourcing Sterile Products Preparation: Contractor Assessment Tool” and publications such as a checklist of Eight Critical Steps Related to Sterile Compounding Services. Penny stated that the meeting focused a lot on technician regulation. It was noted that not all Boards license technicians. However, of those that do, some of them expressed some of the same concerns that our Board has. At the meeting Penny was appointed to the NABP Legislative Committee. She will be attending the January session. Penny attended this meeting on behalf of her employer and no Board of Pharmacy expenses were incurred.

Research Councils – None

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## **GENERAL ADMINISTRATION**

### **Rules & Policy Discussion**

Project Manager Courtney Wilson shared the Rulemaking Hearing Report with the Board. She indicated that the Board received one public comment on the rules during the public comment

period. There was no testimony provided at the Rulemaking Hearing. Staff made minor recommendations which were presented to the Board for their consideration.

Interim Executive Director/Compliance Director and Project Manager Courtney Wilson led a discussion on the following proposed rules and the Board determined which rules to permanently amend and adopt.

- Division 007 Public Health Emergencies
- Division 011 Health Professional's Service Program
- Division 019 Duty to Report
- Division 019 Administration of Vaccines by Pharmacists
- Division 041 Biosimilar Definitions
- Division 041 Distribution of Emergency Medication - Naloxone/ Epinephrine
- Division 041 Remote Dispensing Facilities
- Division 041 Reporting Drug Loss
- Division 110 Fees

The Public Health Emergency rules were amended and adopted to state that a pharmacist may administer vaccines to persons who are three years of age or older. These rules are required by the 2013 Legislature's Senate Bill 167.

#### **MOTION**

**Motion to amend & adopt Public Health Emergency rules in OAR 855-007-0080 was made and unanimously carried (Motion by Chute, second by Pimlott).**

The Health Professional's Service Program rules were amended and adopted to update a statute identified in the 2013 Legislature's House Bill 2124.

#### **MOTION**

**Motion to amend & adopt Health Professional's Service Program rules in OAR 855-011-0020 was made and unanimously carried (Motion by Anderson, second by Pimlott).**

The Duty to Report rules were amended and adopted to require a pharmacist to notify the Board within one business day in the event of a significant drug loss or violation related to drug theft.

#### **MOTION**

**Motion to amend & adopt Duty to Report rules in OAR Chapter 855-019-0205 was made and unanimously carried (Motion by Chute, second by Wells).**

The Licensing of Pharmacists, Administration of Vaccines by Pharmacists rules were amended and adopted to clarify that a pharmacist may administer a vaccine to a person who is at least three years of age when a public health emergency has been declared.

#### **MOTION**

**Motion to amend & adopt Licensing of Pharmacists, Administration of Vaccines by Pharmacists rules in OAR Chapter 855-019-0270 and 0280 was made and unanimously carried (Motion by Chute, second by Anderson).**

The Biosimilar rules were adopted as required by the 2013 Legislature's Senate Bill 460. These rules establish definitions for biological product, biosimilar product, interchangeable and reference biological product. In addition, they indicate when a pharmacy or pharmacist filling a prescription order for a biological product can substitute a biosimilar product for a prescribed biological product.

#### **MOTION**

**Motion to adopt Biosimilar rules in OAR 855-041-1001 and OAR 855-041-1105 was made and unanimously carried (Motion by Chute, second by Wells).**

The Naloxone/Epinephrine rules were adopted. These rules define the procedures for distributing naloxone and ephinephrine to certain authorized individuals for the use in emergency health circumstances. The naloxone rules were required by the 2013 Legislature's Senate Bill 384.

#### **MOTION**

**Motion to adopt Naloxone/Epinephrine rules in OAR 855-041-2300 through 2330 as revised was made and unanimously carried (Motion by Fujisaki, second by Anderson).**

The Remote Dispensing Facility rules were amended and adopted to change the title/name of remote dispensing facility to remote distribution facility for clarification purposes.

#### **MOTION**

**Motion to amend & adopt Remote Dispensing Facility rules to change the name to Remote Distribution Facility in OAR Chapter 855-041-4200 was made and unanimously carried (Motion by Anderson, second by Wells).**

The Reporting Drug Loss rules were amended and adopted to require a pharmacy to notify the Board within one business day in the event of a significant drug loss or violation related to drug theft.

#### **MOTION**

**Motion to amend & adopt Reporting Drug Loss rules in OAR 855-041-1030 as was made as revised and unanimously carried (Motion by Chute, second by Anderson).**

The Fee rules were amended and adopted to reduce the fees for Supervising Physician Dispensing Outlets and Score Transfers and change the name of remote dispensing facility to remote distribution facility.

#### **MOTION**

**Motion to amend & adopt Fee rules in OAR 855-110-0005 and 0007 for a temporary revenue surplus fee reduction pursuant to ORS 291.055(3) was made and unanimously carried (Motion by Anderson, second by Chute).**

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**Send Rules to Rulemaking Hearing – None**

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#### **Consider Adoption of Temporary Rule**

The Board adopted a temporary rule in Division 080's Controlled Substances Schedule I rules. This temporary rule corrects a filing error that omitted rules in Oregon Administrative Rules 855-080-0022.

## **MOTION**

**Motion to amend Controlled Substance rules in OAR 855-080-0022 as revised as a temporary rule was made and unanimously carried (Motion by Chute, second by Wells).**

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## **Policy Decisions**

### **Hydrocodone / Tramadol**

Interim Executive Director/Compliance Director Gary Miner provided an update on the rescheduling of Hydrocodone and the scheduling of Tramadol in the Controlled Substance Act. Gary indicated that he had spoken to Rob Bovett and that Rob recommended that the Board let the Federal Government handle the scheduling and rescheduling of these drugs. Currently the DEA is taking written comment through January 3, 2014 for the scheduling of Tramadol into Schedule IV of the Controlled Substance Act. In addition, on January 25, 2014 the US Food and Drug Administration's (FDA) Drug Safety and Risk Management Advisory Committee will make a recommendation as to whether or not pain medications containing Hydrocodone should be moved from Schedule III into Schedule II of the Controlled Substance Act. The FDA will then need to decide whether or not to follow the committee's recommendation.

The Board agreed that they should continue to monitor the Federal Government's progression in the scheduling and rescheduling of these two drugs. They do not want the scheduling and rescheduling of these drugs to go unaddressed.

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### **Practitioner Dispensing**

Interim Executive Director/Compliance Director Gary Miner provided an update on Practitioner Dispensing. He indicated that staff held another practitioner dispensing meeting on December 16<sup>th</sup>. Staff explained to the work-group that the Board would anticipate registering the location of each practitioner dispensing outlet and that only providing samples would not require a registration. The work-group asked about the cost of a potential registration with the Board of Pharmacy. Staff recommends that the practitioner dispensing outlets would potentially have the same fee structure as drug outlets that are inspected. The current registration fee of a drug outlet is \$175.00. These outlets also renew their registration annually. The work-group would like to form a Rules Advisory Committee. The Board agreed that a Rules Advisory Committee should be formed.

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### **Marijuana Dispensaries**

Interim Executive Director/Compliance Director Gary Miner indicated that staff had met with the Oregon Health Authority (OHA). It was determined that OHA will issue their license. Once their license has been issued, it is being proposed that they will be eligible for a Controlled Substance Registration with the Board of Pharmacy. Staff will develop rules in Division 080 and Division 110 for the Board's consideration. It is estimated that there will be between 300-400 applicants. The Board directed staff to review OHAs rules to ensure that proper vetting of applicants will be done.

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## Discussion Items

Interim Executive Director/Compliance Director Gary Miner and Administrative Director Karen MacLean presented three waiver requests to the Board for their consideration.

## Waiver/Exception Requests

Len's Drug Store requested an extension of their waiver from OAR 855-041-1135. The waiver will allow them to mix lot and expiration dates when filling their ScriptPro SP 200 robotic dispensing system cells.

### MOTION

**Motion to approve Len's Drug Store's request to renew waiver from OAR 855-041-1135 for five years was made and unanimously carried (Motion by Wells, second by Anderson).**

Payless Drug LTC Pharmacy requested a waiver from OAR 855-041-1140 (Customized Patient Medication Packages). The waiver will allow Payless to dispense in a bubble pack card that is perforated, but not require them to label the back of each perforated bubble pack with the name of each drug in them. This waiver will only apply to patients who have more than 16 prescriptions.

### MOTION

**Motion to approve Payless Drug LTC Pharmacy's request to waive OAR 855-041-1140 for patients who have more than 16 prescriptions for five years was made and unanimously carried (Motion by Fujisaki, second by Linares).**

Alfred Nakhnoukh requested a waiver from the FPGEC requirements. He has been licensed in Florida since 2002 with no disciplinary action. He never completed the FPGEC process with NABP, so he is not a full FPGEC candidate. After some discussion, the Board approved waiving the FPGEC requirements and authorized him to do a license transfer through the reciprocity process.

### MOTION

**Motion to waive FPGEC requirements for Alfred Nakhnoukh was made and unanimously carried (Motion by Chute, second by Wells).** Reher and Linares in favor of motion. Fujisaki, Anderson, and Pimlott opposed.

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## Oregon Modified High School Diploma

Administrative Director Karen MacLean presented this item. The Admissions Department of a local Community College asked whether or not the Board will accept the Oregon Modified High School Diploma to satisfy the high school diploma requirement for Certified Pharmacy Technicians. Board Counsel Tom Cowan stated that the Oregon Modified High School Diploma is not a diploma. Tom will prepare an opinion memo for the Board to refer to in the future. Staff will then advise the local Community College that the Oregon Modified High School Diploma is not considered to be a high school diploma by the Board of Pharmacy.

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## Certified Pharmacy Technician (CPT) Renewal Requirements

Administrative Director Karen MacLean and Interim Executive Director/Compliance Director Gary Miner reported back to the Board on a request for CPT renewal requirement changes discussed in October. The Board had some discussion about the renewal requirements for CPTs. Staff

recommended that the Board have a one-time requirement for CPTs to have their national certification and that the Board no longer require the renewal of national certification as a condition of licensure. It should be noted that nothing would prohibit employers from requiring ongoing national certification if they so choose. Additionally, staff recommended that the one hour of law continuing education requirement be removed and that the Board should instead require ongoing training. The Board liked staffs proposal and thought that the fiscal impact to CPT's and pharmacies would be minimal, as many employers are already providing site specific training.

It was recommended that the Board meet with some companies and review their formalized training programs. It was also suggested that the Board review the Washington Board of Pharmacy's requirements for technicians. They currently require around 500 hours of training and they approve every company's technician training program, which has to be reviewed and approved every five years. Washington also requires national certification and CE in pharmacy law. The Board liked the idea of requiring ongoing training relevant to the technicians practice and agreed that it would be the employer's responsibility to keep track of any required training. It was noted that unemployed technicians would not need to satisfy the ongoing training requirement. The Board directed staff to draft proposed rules in Division 025 and Division 041 to be effect prior to the upcoming renewal cycle. They would like to see the rules implemented by July 1<sup>st</sup>. The Board would like the proposed rules to be reviewed by the technician chapters of OSPA and OSAP.

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### **Licensing Out of State PIC's Update**

Interim Executive Director/Compliance Director Gary Miner provided an update on the Board's requirement to have non-resident pharmacies have an Oregon licensed Pharmacist-in-Charge (PIC) in order to qualify for licensure. Gary indicates that he still believes that the licensing requirement of the out-of-state pharmacist-in-charge is valuable, as it requires the PIC to be familiar with Oregon's laws and rules. Additionally, he commented that it is very beneficial for staff to be able to have direct contact with a licensed PIC. When the Board did not have the licensing requirement in place there were some out-of-state pharmacies that wouldn't respond to the Board when information was requested. There is fear that if the Board no longer had the licensing requirement in place that this may happen again. The Board has disciplined out-of-state pharmacies in the past such as New England Compounding Center. The Board was able to revoke the PIC and subsequently the outlet. This was an essential patient safety measure. It was recommended that educational opportunities are enhanced and that staff create information that shows how we are different in our laws and rules. The Board does have information on its website highlighted in the FAQs that has some of this information. Staff will review this information and highlight any additional information. The Board agreed that staff should continue to monitor the Arizona Board of Pharmacy's progress and any outcome that takes place after they remove their requirement of having a licensed PIC in order for a non-resident pharmacy to qualify for licensure as a pharmacy. Staff will continue to update the Board on this topic.

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### **New Pharmacy Model Discussion**

Staff had a few field questions regarding how the Board would like staff to proceed with the processing of any Central Fill, Remote Processing or Consulting or Drugless Pharmacy applications. The Board indicated that they would like to see the first few new Central Fill, Remote Processing or Consulting or Drugless Pharmacy applications and later they would consider delegating the authority of the review and approval of new applications to staff. After being licensed as either a Central Fill, Remote Processing or Consulting or Drugless Pharmacy for a period of one year the Board would like the pharmacies to make an appearance and provide

them with a status update. Pharmacies that are already licensed and engaged in the practice of central fill, remote processing or consulting can submit their policies and procedures to staff for review. The Board delegated the authority to approve their applications to staff. The Board also delegated the authority to staff to process any name changes for these licensees.

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### **Remote Processing Request**

Interim Executive Director/Compliance Director Gary Miner presented Providence's request to be licensed as a Remote Processing Drug Outlet. Pharmacists Greg Conrad and Ralph Thonstad from Providence appeared to answer any questions. Providence Plaza Pharmacy will serve as a Remote Processing Drug Outlet for seven other pharmacies. Greg and Ralph indicate that the remote processing structure will allow them to take advantage of the 340B program. Providence submitted their patient policies and procedures, as well as patient safety information to the Board for their consideration. The Board asked Greg and Ralph if the same inventory will be shared. They answered yes; the same inventory will be shared. The Board also asked if they will do counseling at discharge. They answered yes; they will do counseling at discharge. They also noted that there will be no refills. The Board approved Providence Plaza Pharmacy's application for a Remote Processing Drug Outlet Registration. They would like them to provide an appearance and status update in six months.

### **MOTION**

**Motion to approve the Providence request to implement remote processing was made and unanimously carried: (Motion by Pimlott, second by Fujisaki).**

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### **Consulting Pharmacy Application Request**

Interim Executive Director/Compliance Director Gary Miner presented a request from Cardinal Health Pharmacy Services LLC in Houston, Texas to operate as a Consulting or Drugless Pharmacy Outlet. Gary indicates that they have all of their pharmacists licensed. They will provide remote medication order entry and review 24 hours a day, seven days a week. More specifically they will be entering medication orders for a hospital pharmacy. All policies and procedures and patient safety information were submitted. Staff indicates that they submitted the Remote Processing Application in error and that the Consulting or Drugless Pharmacy Application is needed. They also directed Cardinal Health to re-title their policies and procedures with the term "Consulting/Drugless Pharmacy" rather than "Remote Order Entry Service" for clarity purposes. Upon receipt of these items, staff recommends issuing their registration. The Board approved their application with the condition that the correct application be submitted and that the term on the policies and procedures is corrected.

### **MOTION**

**Motion to approve Cardinal Health's consulting pharmacy checklist upon receipt of the correct completed application was made and unanimously carried: (Motion by Anderson, second by Chute).**

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### **Compounding Update**

Interim Executive Director/Compliance Director Gary Miner provided an update on compounding. He indicates that the FDA has now created an Out-Source Facility category so that these outlets can make non-patient specific drugs. These outlets are not required to register, it is voluntary. However, it costs around \$11,000 annually. The FDA's new legislation, H.R.3204, The Drug Quality and Security Act contains two titles. Title I, "The Compounding Quality Act," which

distinguishes between traditional compounders and outsourcing facilities. It establishes a uniform set of rules for outsourcing facilities while preserving the states' primary role in traditional pharmacy regulation. Title II, "The Drug Supply Chain Security Act," provides a uniform, national drug tracing framework to track prescription drugs from the manufacturer to the pharmacy and raises the standards for prescription drug wholesalers throughout the United States. The FDA is requiring public comment on the proposed legislation to be submitted by February 3, 2014. Multiple compounders were in attendance and would like to work with the Board on providing written comments. The Board directed staff to work with the compounders and draft a letter to submit to the FDA. The Board will review the letter at its January Board Meeting.

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### **U.S. Department of Health and Human Services, Federal Office of Inspector General's List of Excluded Individuals/Entities (LEIE)**

Administrative Director Karen MacLean and Interim Executive Director/Compliance Director Gary Miner reported and the Board had a discussion on the U.S. Department of Health and Human Services, Federal Office of Inspector General's (OIG) list of Excluded Individuals/Entities (LEIE) provides information to the health care industry, patients and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid and all other Federal health care programs. Individuals and entities who have been reinstated are removed from the LEIE. Staff indicates that the office has recently been receiving letters that notify the Board of pharmacists and technicians on the LEIE. The Board commented that the LEIE has been in existence for years and they are wondering why the Board is just now receiving notification. The Board had questions that they would like to ask of the OIG such as, how long it takes to get off of the list if someone is reinstated and how does this list relate to other related health professions. The Board asked staff to follow up with the (OIG) to see if someone from their office can make an appearance at a future Board Meeting so that the Board can ask questions for clarity purposes.

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### **Financial/Budget Report**

Administrative Director Karen MacLean provided a financial update. She indicates that the agency has not received its financial plan and that staff is hoping to have it by January 3<sup>rd</sup> for review. Karen and Office Manager Chrisy Hennigan are currently working on the plan based on past expenses. Karen presented a chart that detailed comparisons on the Board's expenditures comparing the current quarter to the last three biennia at this time. She noted that the variances can be attributed to training, hearing costs, criminal background checks.

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### **Legislative Update – None**

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### **Topics for Future Discussion**

- Best Practices for Retail Settings
- Responsibilities of the PIC
- Counseling on all Controlled Substance dispensing
- Workgroup for Working Conditions
- CCO's / Medical Home
- Temporary Pharmacies
- Long Term Care
- Collaborative Therapy vs Standing Orders
- Licensing Out of State PIC's

- How Final Orders are published on the BOP website.
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### **Strategic Planning 2014**

Administrative Director Karen MacLean and Interim Executive Director/Compliance Director Gary Miner presented a list of topics that have been discussed throughout the year which the Board may want to consider for discussion at their 2014 Strategic Planning Meeting. The Board reviewed the list which is as followed:

- Vision Update
- Legislative Concepts for 2015 – ORS 475 and 689
- Licensure Requirements for Pharmacy Technicians
- Pharmacy Technician Duties and Functions
- Communication Plan Re: Practitioner Dispensing
- Compounding Update
- Workflow in the Pharmacy Environment
- New Executive Director Vision
- Expunged Records
- Pharmacy Related Organizations and How they Fit in OAR 855
  - Surgery Centers
  - Hospice
  - Medical Homes
- 2015-17 Budget Development
  - Policy Packages
    - Scanning Part II
    - Possible Need for New Positions
      - Inspections of OTC

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**VII. OPEN FORUM** At the completion of regular Board Business, any Board licensee or member of the public is invited to meet with the Board to discuss issues of interest (typically the last item of the meeting)

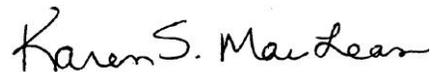
Board Member Dianna Pimlott indicated that she has been told that some physicians are providing standing orders for certain medical conditions that employees may have. The Human Resources Nurse is provided with the standing order from a physician. The nurse then would like to dispense medications from the employer pharmacy to employees for certain conditions. It was noted that the physician providing the standing order hasn't seen the patient and often times only provides a blanket signature on the form(s). The nurse diagnosis and prescribes. It is being asked if a patient can be in a collaborative therapy agreement. Interim Executive Director/Compliance Director Gary Miner indicates that in the Board's rules for collaborative therapy agreement a relationship can only exist between physicians and pharmacists. Gary would like to reach out to the Nursing Board to find out if this is out of the scope of the RNs practice. Gary is only aware of RNs being able to dispense if an outlet is registered as a County Health or Family Planning Clinic. He would also like to get clarification from the Medical Board to find out if physicians are allowed to do this. The Board directed Gary to reach out to the Nursing and Medical Board for more information.

## Adjourn

### MOTION

**Motion to adjourn at 3:56 PM was made and unanimously carried (Motion by Fujisaki, second by Anderson).**

Accepted by:

A handwritten signature in black ink that reads "Karen S. MacLean". The signature is written in a cursive style with a large initial 'K' and 'M'.

Karen MacLean  
Administrative Director

**Oregon Board of Pharmacy**  
800 NE Oregon Street  
Portland, OR 97232  
Penny Reher, R.Ph. Presiding

Tuesday, December 17, 2013 @ 8:30 AM, Conference Room 1A  
Wednesday, December 18, 2013 @ 8:30 AM, Conference Room 1A  
800 NE Oregon Street in Portland, Oregon

Executive Session of the Board was held on December 17, 2013 to discuss Compliance cases, followed by motions on December 18, 2013. Working lunch held.

Board Members present for all or part of compliance session:

Penny Reher, R.Ph., President  
Dianna Pimlott, R.Ph., Vice President  
Kenneth Wells, R.Ph.  
Brad Fujisaki, R.Ph.

Roberto Linares, R.Ph.  
Christine Chute, Public Member  
Heather Anderson, Public Member

Staff present for all or part of compliance session:

Gary Miner, R.Ph., Comp./Interim Exec. Director  
Joe Ball, R.Ph., Chief Investigator  
Katie Baldwin, R.Ph., Board Inspector  
Michele Cale, R.Ph., Board Inspector  
Gregg Hyman, R.Ph., Board Inspector  
Laura Elvers, R.Ph., Board Inspector

Fiona Karbowicz, R.Ph., Pharmacist Consultant  
Karen MacLean, Administrative Director  
Courtney Wilson, Project Manager  
Annette Gearhart, Compliance Secretary  
Kim Oster, Compliance Assistant  
Thomas Cowan, Senior AAG

**Case 2011-0278                      Motion to grant early release from HPSP probation upon completion of final HPSP requirements.**

Motion by: Brad Fujisaki; Seconded by: Roberto Linares. Motion unanimously carried.

**Case 2012-0451                      Motion to accept Ruling on Motion for Summary Determination and Proposed Order and issue Final Order.**

Motion by: Kenneth Wells; Seconded by: Heather Anderson. Motion unanimously carried.

**Case 2012-0550                      Motion to accept ALJ Ruling on Motion for Summary Determination and Proposed Order and issue Final Order.**

Motion by: Heather Anderson; Seconded by: Dianna Pimlott. Motion unanimously carried.

**Case 2009-0028                      Motion to grant request; reduce Pharmacist-in-Charge reporting to twice a year.**

Motion by: Roberto Linares; Seconded by: Dianna Pimlott. Motion carried with Kenneth Wells opposed.

**Case 2012-0367                      Motion to grant pharmacist's request.**

Motion by: Dianna Pimlott; Seconded by: Kenneth Wells. Motion unanimously carried.

**Case 2013-0164                      Motion to revoke license and impose \$10,000 civil penalty per violation against outlet;**

**Case 2013-0500                      Motion to revoke license and impose \$1,000 civil penalty per violation against Pharmacist-in-Charge; and**

**Case 2013-0501                      Motion to revoke license and impose \$1,000 civil penalty per violation against technician.**

Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

**Case 2013-0437                      Motion to impose \$1,000 civil penalty per violation against technician; and**

**Case 2013-0438                      Motion to impose \$10,000 civil penalty per violation against outlets.**

Motion by: Kenneth Wells; Seconded by: Heather Anderson. Motion unanimously carried.

**Case 2013-0439 Motion to impose \$1,000 civil penalty per violation against technician; and**  
**Case 2013-0440 Motion to issue letter of concern to outlet and Pharmacist-in-Charge.**  
Motion by: Dianna Pimlott; Seconded by: Heather Anderson. Motion unanimously carried.

**Case 2013-0272 Motion to impose \$10,000 civil penalty per violation against outlet; issue letter of concern to Pharmacist-in-Charge.**  
Motion by: Kenneth Wells; Seconded by: Heather Anderson. Motion unanimously carried.

**Case 2013-0331 Motion to revoke license and impose \$10,000 civil penalty per violation against outlet.**  
**Case 2013-0365 Motion to revoke license and impose \$1,000 civil penalty per violation against Pharmacist-in-Charge.**  
Motion by: Dianna Pimlott; Seconded by: Heather Anderson. Motion carried with Brad Fujisaki abstaining.

**Case 2013-0317 Motion to issue Letter of Concern to Pharmacist-in-Charge; and**  
**Case 2013-0492 Motion to issue Letter of Concern to pharmacist.**  
Motion by: Roberto Linares; Seconded by: Heather Anderson. Motion unanimously carried.

**Case 2013-0395 Motion to impose \$10,000 civil penalty per violation against outlet; issue letter of concern to Pharmacist-in-Charge and pharmacist.**  
Motion by: Kenneth Wells; Seconded by: Heather Anderson. Motion unanimously carried.

**Case 2013-0394 Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation; and**  
**Case 2013-0523 Motion to issue Letters of Concern to outlet, Pharmacist-in-Charge and pharmacist.**  
Motion by: Brad Fujisaki; Seconded by: Roberto Linares. Motion carried with Dianna Pimlott abstaining.

**Case 2013-0364 Motion to revoke technician license and impose \$1,000 civil penalty per violation.**  
Motion by: Heather Anderson; Seconded by: Kenneth Wells. Motion unanimously carried.

**Case 2013-0441 Motion to revoke technician license and impose \$1,000 civil penalty per violation.**  
Motion by: Brad Fujisaki; Seconded by: Heather Anderson. Motion unanimously carried.

**Case 2013-0479 Motion to impose \$1,000 civil penalty per violation against technician.**  
Motion by: Roberto Linares; Seconded by: Kenneth Wells. Motion unanimously carried.

**Case 2013-0393 Motion to deny pharmacist license.**  
Motion by: Kenneth Wells; Seconded by: Dianna Pimlott. Motion unanimously carried.

**Case 2013-0477 Motion to deny technician license and impose \$1,000 civil penalty per violation.**  
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

**Case 2013-0485 Motion to deny technician license and impose \$1,000 civil penalty per violation.**  
Motion by: Brad Fujisaki; Seconded by: Dianna Pimlott. Motion unanimously carried.

**Case 2013-0385 Motion to impose \$1,000 civil penalty per violation and deny technician application.**  
Motion by: Heather Anderson; Seconded by: Dianna Pimlott. Motion unanimously carried.

**Case 2013-0357 Motion to deny technician license and impose a \$1,000 civil penalty per violation.**  
Motion by: Kenneth Wells; Seconded by: Dianna Pimlott. Motion unanimously carried.

**Case 2013-0432 Motion to deny technician license and impose \$1,000 civil penalty per violation.**  
Motion by: Heather Anderson; Seconded by: Kenneth Wells. Motion unanimously carried.

**Case 2013-0433 Motion to deny technician license and impose \$1,000 civil penalty per violation.**  
Motion by: Kenneth Wells; Seconded by: Dianna Pimlott. Motion unanimously carried.

**Case 2013-0431 Motion to deny technician license.**  
Motion by: Dianna Pimlott; Seconded by: Kenneth Wells. Motion unanimously carried.

**Case 2013-0392 Motion to grant technician license.**  
Motion by: Brad Fujisaki; Seconded by: Roberto Linares. Motion unanimously carried.

**Case 2013-0486 Motion to grant technician license.**  
Motion by: Brad Fujisaki; Seconded by: Heather Anderson. Motion unanimously carried.

**Case 2013-0406 Motion to grant technician license.**  
Motion by: Kenneth Wells; Seconded by: Roberto Linares. Motion unanimously carried.

**Case 2013-0498 Motion to grant technician license.**  
Motion by: Heather Anderson; Seconded by: Kenneth Wells. Motion unanimously carried.

**Case 2013-0266 Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation.**  
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion carried with Christine Chute abstaining.

**Case 2013-0349 Motion to impose \$1,000 civil penalty per violation against Pharmacist-in-Charge, issue letter of concern to outlet; and**

**Case 2013-0388 Motion to impose \$1,000 civil penalty per violation against technician.**  
Motion by: Kenneth Wells; Seconded by: Dianna Pimlott. Motion unanimously carried.

**Case 2013-0478 Motion to impose \$1,000 civil penalty per violation against pharmacist; issue letter of concern to outlet and CC: Pharmacist-in-Charge.**  
Motion by: Heather Anderson; Seconded by: Kenneth Wells. Motion unanimously carried.

**Case 2013-0261 Motion to impose a \$1,000 civil penalty per violation against pharmacist; issue letter of concern to Pharmacist-in-Charge and CC: outlet.**  
Motion by: Kenneth Wells; Seconded by: Dianna Pimlott. Motion unanimously carried.

**Case 2013-0484 Motion to issue letter of concern to outlet and corporate office.**  
Motion by: Heather Anderson; Seconded by: Dianna Pimlott. Motion carried with Roberto Linares abstaining.

**Case 2013-0316 Motion to issue letter of concern to Pharmacist-in-Charge; CC: outlet.**  
Motion by: Kenneth Wells; Seconded by: Heather Anderson. Motion unanimously carried.

**Case 2013-0329 Motion to issue letters of No Violation to Pharmacist-in-Charge and pharmacist.**  
Motion by: Roberto Linares; Seconded by: Heather Anderson. Motion unanimously carried.

**Case 2013-0434 Motion to issue Letter of Concern to Pharmacist-in-Charge and cc outlet.**  
Motion by: Kenneth Wells; Seconded by: Dianna Pimlott. Motion unanimously carried.

**Consent Agenda Motion to accept the items on the consent agenda as presented with case 2013-0434 pulled for discussion.**  
Motion by: Brad Fujisaki; Seconded by: Heather Anderson. Motion unanimously carried.

## LETTERS OF CONCERN CASES:

- Case: 2013-0436** Issue Letter of Concern recommending 3 hours CE in Medication Error Reduction to pharmacist and technician; issue letter of concern to Pharmacist-in-Charge and CC: outlet.
- Case: 2013-0338** Issue letter of concern to outlet and CC: Pharmacist-in-Charge.
- Case: 2013-0378** Issue letter of concern to pharmacist; CC: pharmacy.
- Case: 2013-0363** Issue letter of concern recommending 3 hours CE in Medication Error Prevention to pharmacist and Intern; issue letter of concern to Pharmacist-in-Charge and CC: outlet.
- Case: 2013-0342** Issue letter of concern recommending 3 hours CE in Veterinary Medications to pharmacist; letter of concern to PIC and CC: letters to outlet.
- Case: 2013-0390** Letter of Concern recommending 3 hours CE in Medication Error Reduction to technician and pharmacist; issue letter of concern to Pharmacist-in-Charge and CC: outlet.
- Case: 2013-0396** Issue Letter of Concern recommending 3 hours CE in medication error reduction to pharmacist; and issue letter of concern to outlet.
- Case: 2013-0430** Issue letter of concern to Intern.

## DEFICIENCY NOTICES:

Cases: 2013-0130; 2013-0267; 2013-0307; 2013-0369; 2013-0372; 2013-0374; 2013-0381; 2013-0386; 2013-0387; 2013-0403; 2013-0404; 2013-0410; 2013-0411; 2013-0412; 2013-0413; 2013-0415; 2013-0416; 2013-0422; 2013-0424; 2013-0425; 2013-0428; 2013-0474; 2013-0475; 2013-0481; and 2013-0491.

## UNABLE TO SUBSTANTIATE:

Cases: 2013-0324; 2013-0389; 2013-0462; and 2013-0467.

## NO VIOLATION:

Cases: 2013-0288; 2013-0328; 2013-0340; 2013-0426; 2013-0429; 2013-0450; 2013-0468; 2013-0469; and 2013-0471.

## NO JURISDICTION:

Cases: 2013-0444 and 2013-0466.

## PHARMACIST C.E. AUDIT CASES:

Authority delegated to the Compliance Director by the Board [grant staff authority to issue LOC if CE completed in June or to take and pass MPJE (in lieu of discipline) within 120 days if CE not completed by end of June]. Staff authorized to issue NPDA to suspend pharmacist license if MPJE not taken and passed within 120 days.

- Case: 2013-0397 letters of concern
- Case: 2013-0398 MPJE audit letter
- Case: 2013-0399 letter of concern
- Case: 2013-0400 MPJE audit letter
- Case: 2013-0401 MPJE audit letter
- Case: 2013-0402 MPJE audit letter
- Case: 2013-0414 letter of concern
- Case: 2013-0418 MPJE audit letter
- Case: 2013-0420 MPJE audit letter
- Case: 2013-0453 MPJE audit letter
- Case: 2013-0454 MPJE audit letter
- Case: 2013-0455 MPJE audit letter
- Case: 2013-0456 MPJE audit letter
- Case: 2013-0457 MPJE audit letter
- Case: 2013-0458 MPJE audit letter
- Case: 2013-0461 proof of CE accepted 11/25/2013
- Case: 2013-0463 MPJE audit letter; and
- Case: 2013-0483 MPJE audit letter.

**UNREGISTERED OUTLET CASES:**

By authority delegated to Oregon Board of Pharmacy Staff by the Board notices to impose \$10,000 civil penalty notices have been issued to: (includes unregistered wholesalers, manufacturers and out-of-state pharmacies)

Cases: 2013-0417 and 2013-0427.

**UNSWORN FALSIFICATION:**

By authority delegated to Oregon Board of Pharmacy Staff by the Board, the following applicants and licensees have been issued Notice: Deny with \$1,000; proposed Consent: \$1,000 with \$850 stayed pending no further violations for 3 years and 3 hours of CE in law/ethics.

Cases: 2013-0354; 2013-0407; 2013-0442; 2013-0476; and 2013-0487.

**DENIAL OF TECHNICIAN APPLICATION ORDERS:**

By authority delegated to Oregon Board of Pharmacy Staff by the Board denial of technician licenses notices have been issued in:

Cases: 2013-0384 and 2013-0391.

**CASES CLOSED UNDER INVESTIGATION:**

Cases that have been opened and then "Closed Under Investigation" to preserve incoming complaint information should future action be necessary.

Case: 2013-0408

**FOR YOUR INFORMATION:**

Case No. 2011-0490 was presented at the October 2013 Board Meeting as Case No. 2012-0490.