Oregon Board of Pharmacy BOARD MEETING AGENDA

Meeting Location:
Portland State Office Building
800 NE Oregon Street, Portland, OR 97232
June 5-6, 2019

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.

Wednesday, June 5, 2019 @ 8:30AM – Conference Room 1A Thursday, June 6, 2019 @ 8:30AM – Conference Room 1A

≈ The meeting location is accessible to persons with disabilities. A request for hearing impaired assistance and accommodations for persons with disabilities should be made to Karen MacLean at 971-673-0001 at least 48 hours prior to the meeting. ≈

WEDNESDAY, JUNE 5, 2019

- I. 8:30AM OPEN SESSION, Rachael DeBarmore, R.Ph, Presiding
 - A. Roll Call
 - B. Agenda Review and Approval

Action Necessary

- II. Contested Case Deliberation pursuant to ORS 192.690(1) Not Open to the Public
- III. EXECUTIVE SESSION NOT OPEN TO THE PUBLIC, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (k).
 - A. Items for Consideration and Discussion:
 - 1. Deliberation on Disciplinary Cases and Investigations
 - 2. Personal Appearances
 - 3. Deficiency Notifications
 - 4. Case Review

IV. OPEN SESSION - PUBLIC MAY ATTEND - At the conclusion of Executive Session, the Board may convene Open Session to begin some of the following scheduled agenda items - time permitting at approximately 3:30PM.

THURSDAY, JUNE 6, 2019

8:30AM

- V. OPEN SESSION, Rachael DeBarmore, R.Ph, Presiding
 - A. Roll Call
 - B. Motions for Contested Cases & Disciplinary Action *Efremoff Action Necessary*

VI. GENERAL ADMINISTRATION

- A. Rules
 - 1. Review Rulemaking Hearing Report & Comments #A MacLean

 Action Necessary
 - 2. Consider Adoption of Rules *MacLean*

Action Necessary

- Div 110 **#A1** Fees
- 3. Consider Adoption of Temporary Rules none
- 4. Rules Update none
- 5. Consider rules and send to Rulemaking Hearing none
- 6. Policy Issues for Discussion / Updates Schnabel/Karbowicz
 - 6/1/19 USP 795 and 797
 - Compounding RAC update #A2-A4
- B. Public Health and Pharmacy Formulary Advisory Committee #B1

Schnabel/Karbowicz/MacLean/Efremoff

- 1. Committee Meeting (5/3/19) and Recommendation update
- 2. Consider rules & send to Rulemaking Hearing none
- C. Discussion Items:
 - 1. Requests:

Action Necessary

- a. Bay Area Hospital Request #C Hennigan/Efremoff
- b. Diabetes Community Care Team Request #C1 Efremoff/Karbowicz
- 2. Policy Discussion and Board Review:

Action Necessary

- a. Kaiser Request #D CONFIDENTIAL Efremoff/Karbowicz
- b. Providence Specialty Pharmacy LTC Request #D1 Efremoff/Karbowicz
- c. E-Verification #D2 Hennigan/MacLean
- 3. TCVP: none
- 4. Strategic Planning Schnabel/MacLean
- 5. Other:
 - a. CBD FAQ's #E Efremoff
 - b. Website Redesign Demo Melvin

Lunch – estimated time depending on the length of discussions

1:00PM - Appearance – Stephanie Vesik, PDMP Program Update

VII. ANNUAL BOARD BUSINESS MEETING

1) Election of New Officers

Action Necessary

2) Update on Board appointments - Schnabel/MacLean

Agenda – June 5-6, 2019

NOTE: The Board may rearrange its agenda to accommodate the Board or members of the public.

- 3) Review other Committee/Council appointments #F MacLean Action Necessary
 - a. Council on Naturopathic Physicians Formulary #F1, F2
 - b. Rural Health Coordinating Council update
 - c. Council on Optometric Non-Topical Formulary update
- 4) Delegation of Board Authority update **#F3** Efremoff Action Necessary
- 5) Board Best Practices update MacLean
- 5) Recognition of outgoing Board Member Penny Reher Action Necessary

VIII. ISSUES/ACTIVITIES

A. Board Meeting Dates

•	August 7-9, 2019*	Portland	(*3 day meeting)
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October 2-3, 2019
 Portland

November 6-7, 2019 Portland (Strategic Planning – subject to change)

December 11-12, 2019 Portland

• February 5-7, 2020* Portland (*3 day meeting)

April 15-16, 2020 Portland
 June 17-18, 2020 Portland

August 12-14, 2020*
 Portland (*3 day meeting)

October 14-15, 2020 Portland

November 18-19, 2020 TBA (Strategic Planning – subject to change)

December 16-17, 2020 Portland

B. Rulemaking Hearing Dates

(The following dates are reserved for potential rulemaking hearings and identified only for planning purposes and approved by the Board. Actual Rulemaking Activities will be noticed as required by law and may deviate from this schedule as needed.)

- September 24, 2019
- November 26, 2019

C. Committees/Meetings

- 1. OSHP Spring Meeting Sunriver 4/26-28/2019 Schnabel/Efremoff
- 2. NABP 2019 Annual meeting Minneapolis, MN May 16-18, 2019 Beaman/Schnabel
- 3. NABP District VI-VIII Mtg. Boise, ID, 10/6-9/2019 Action Necessary
- D. Board Member/Staff Presentations *DeBarmore*
 - Pharmacy Coalition 4/16/19
 - Professional Practice Roundtable 4/24/19, 6/12/19
- E. Financial/Budget Report #G-G2 MacLean
- F. Legislative update *Schnabel/Karbowicz/MacLean*
- G. Reports:
 - 1. Board President/Members
 - 2. Executive Director
 - 3. Board Counsel
 - 4. Compliance Director
 - 5. Pharmacist Consultant
 - 6. Administrative Director

Agenda – June 5-6, 2019

- 7. Licensing Program Supervisor
- 8. Project Manager

VIII. Approve Consent Agenda*

Action Necessary

*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 none
- 2. MPJE Scores none
- 3. License/Registration Ratification March 26, 2019 May 21, 2019

CONSENT - 1

- 4. Pharmacy Technician Extensions March 1, 2019 May 21, 2019 # CONSENT- 2
- 5. Board Minutes April 3-4, 2019 # CONSENT 3

IX. OPEN FORUM – At the completion of regular Board business, the Board provides an opportunity to make comments or present issues of general interest. The Board will not deliberate any issues or requests during Open Forum. Therefore, Open Forum <u>should not be used</u> to make formal requests to the Board, nor to address issues currently under investigation or requests pending before the Board. If you wish to be called upon, please sign up on the sheet at the podium in advance for inclusion.

Adjourn



Oregon Board of Pharmacy

800 NE Oregon Street, Suite 150 Portland, OR 97232 Phone: 971 / 673-0001

Fax: 971 / 673-0002

E-mail: pharmacy.board@state.or.us
Web: www.pharmacy.state.or.us

Date: May 22, 2019

To: Oregon Board of Pharmacy

From: Karen MacLean

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: May 22, 2019

Hearing Location: Portland State Office Building, Room 1E

Title of Proposed Rules:

2019-2021 Legislatively approved fee increases in Division 110 (2019 SB 5529A)

The rulemaking hearing on the proposed rules was convened at 9:37 a.m. No one appeared to provide comment on these rules. The hearing was closed at 9:43 a.m. The hearing was recorded.

Copies of the proposed rules were available for attendees.

Attendance included 1 public, 3 OBOP Staff, 4 OBOP Board members

Summary of Comments

There were no oral comments.

Summary of Written Comments

Four written comments were received in the Board office prior to the public comment deadline of 5/22/19, 4:30pm deadline are summarized as follows, the full text of comments as received by OBOP are attached:

- Brainard Brauer Owner/Member Redland Station, LLC, Oregon City.
 A small gas station owner that sells a few packs of convenience items, suggests that if a business sells less than \$5000 or 10,000 per year in pharmacy type products they should be exempt from paying a fee for licensure. Requests the Board remove small business from the pharmacy program and not to increase fees since it will hurt customers.
- 2. Jennifer Irby doesn't agree with the proposed fee increases.

3. Mike Letsky (pharmacist)

Suggests that proposed pharmacist's fees are unacceptable and that manufacturers who make millions, if not billions on profits, should be billed for more than the proposed 25% increase they are receiving.

4. Lawrence LaJoie, Director of Enterprise Services Linn-Benton Community College Asking for consideration in eliminating or "freeze" of the renewal fee structure for government institutions only and non-profits for small over the counter outlets.

Eight comments were received in response to the November 13, 2018 <u>Notice of Proposed Fee Increases</u> message (sent via email, USPS mailed to all licensees without email address on record, posted on the Board's website). They are summarized as follows, the full text of comments are attached:

5. Bill Booth - MedStar NW

Reimbursement rates and agency fees – he recommends laying off staff, take salary and pension cuts to make agency budget work.

6. Leonard Leis, RPh

He will not be renewing when the \$250 renewal fee becomes effective.

7. Karen Nguyen, CPhT

Protests the possible rate increase; citing techs are paid so little and are charged for all CE's anymore.

8. Mary Beth Luehrs, RPh

Asked if there was any break for a retired pharmacist.

9. Rebecca Black, RPh

Doubling the fee is ridiculous!

10. Sean Branigan, CPhT

From \$50 to 100 for a technician, that's a steep increase.

11. Todd Gregory, CPhT

No vote to all proposed increases

12. Meredyth Warren, CPhT

Questions doubling technician fee

From: <u>Brainard Brauer</u>

To: PHARMACY RULEMAKING * BOP

Cc: Redland Station

Subject: Oregon Board of Pharmacy Rule Making Date: Monday, April 29, 2019 3:01:30 PM

To Whom It May Concern,

I am a small gas station that sells a few packs of convenience items and find the existing Fee to be to much and in appropriate for a small establishment like myself.

Please consider that if a business sells less than lets say \$5,000 or perhaps \$10,000 per year in pharmacy type products that they should be exempt. I do so propose if there is any question.

Costs should be for services and this is a TAX without services. This year I also pay a state wide transit tax that costs me more to prepare then the tax itself so do we raise the tax simply to justify for a small/micro business like myself.

Oregon State Government needs to consider the burden on business. There is a place for regulation like in the case of OLCC which likely undercharges and due to the structure is the fundamental reason for our craft brewing industry and diversity in hard spirit companies plus winery distribution. OLCC provides a foundation for a huge part of our economy and convenience of citizens and tourists for Oregon.

I do believe in a place for agencies but YOUR reach to the small or micro business is disturbing at best. Thank you for informing us of the rule making.

Please remove small business from the pharmacy program and definitely do not increase fees since it will hurt consumers. We likely do not even sell enough per year to make a profit enough to offset the cost of your existing fee plus overhead. We do it due to a sense of service to our community. Should someone need to drive another 6 miles to get a simple over the counter medicine and then for that matter a small dosage.

Sincerely,

Brainard Brauer Owner/Member Redland Station, LLC 18150 S. Redland Rd. Oregon City, OR 97045 (503) 238-1414
 From:
 PHARMACY BOARD * BOP

 To:
 MACLEAN Karen S * BOP

Subject: FW: Notice of Proposed Fee Increases

Date: Tuesday, November 13, 2018 4:02:49 PM

From: Jennifer Irby <wadejen99@gmail.com> **Sent:** Tuesday, November 13, 2018 3:59 PM

To: PHARMACY BOARD * BOP < PHARMACY.BOARD@oregon.gov>

Subject: Re: Notice of Proposed Fee Increases

I don't agree.

On Tue, Nov 13, 2018 at 2:46 PM PHARMACY BOARD * BOP < PHARMACY.BOARD@oregon.gov > wrote:

NOTICE TO LICENSEES - PROPOSED FEE INCREASES

The Oregon Board of Pharmacy has prepared its 2019-2021 Agency Budget Request for the Governor and Legislative approval during the 2019 Legislative Session. This is available on the Board's website. Proposed fee increases are necessary to allow the Board to continue current and anticipated operations to carry out the Board's mission.

Please see the attached. This message is being sent to all licensees via email.



From: <u>Michael Letsky</u>

To: PHARMACY RULEMAKING * BOP

Subject: Division 110 - Fees

Date: Tuesday, April 30, 2019 8:49:39 PM

The fees registered pharmacists will need to pay every 2 years is proposed to be more than double what is currently active. This is unacceptable as drug manufacturers who make millions, if not billions of dollars every year on profits do not see their increases >25%. Registered pharmacists should not be burdened with funding the board more than current and the manufacturers should be billed this difference.

Thank you.

Mike

From: <u>Lawrence LaJoie</u>

To: PHARMACY RULEMAKING * BOP
Subject: Div 110 Fees testimony

Date: Tuesday, April 23, 2019 1:02:11 PM

I'm writing for consideration regarding the fee structure proposed:

As a college store institutionally owned, I'm asking for consideration in eliminating the renewal fee structure for government institutions only. We supply a small amount of over the counter medicines for resale like Tylenol, Advil, etc. to help serve the students and staff who are in need, and really only see this as a necessary service to the college. Increasing an already high fee structure jeopardizes our ability to recoup those fees through resale and impacts the future service we can provide. The nature of the fee structure is intended for larger volume "true" retail outlets, which can easily be absorbed in the profitability of the store, but for a non-profit institution, it impacts us dramatically. I'm requesting a fee "freeze" or elimination of the fee altogether for non-profit and government institutions. Thank you for your consideration.

--

Lawrence LaJoie
Director of Enterprise Services
Linn-Benton Community College
lajoiel@linnbenton.edu
(541) 917-4953 Office
(541) 917-4954 Fax

 From:
 PHARMACY BOARD * BOP

 To:
 MACLEAN Karen S * BOP

Subject: FW: Notice of Proposed Fee Increases

Date: Tuesday, November 13, 2018 4:20:13 PM

From: Bill Booth bbooth@medstarnw.com Sent: Tuesday, November 13, 2018 4:10 PM

To: PHARMACY BOARD * BOP < PHARMACY.BOARD@oregon.gov>

Subject: RE: Notice of Proposed Fee Increases

In a time when our reimbursement is dropping by over 30% you choose to charge a 30% increase. Only the government would think like that. Lay some people off, take salary and pension cuts. Do what you have to do to make your budget work. That is what we do.

Bill Booth -MedStar NW 503-616-8427 Mobile 503-427-1665 Fax

From: PHARMACY BOARD * BOP < PHARMACY.BOARD@oregon.gov >

Sent: Tuesday, November 13, 2018 2:47 PM

To: PHARMACY BOARD * BOP < PHARMACY.BOARD@oregon.gov >

Subject: Notice of Proposed Fee Increases

NOTICE TO LICENSEES - PROPOSED FEE INCREASES

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From: <u>Leonard Leis</u>

To: <u>obop-rph@listsmart.osl.state.or.us</u>

Subject: RE: [Obop-rph] Notice of Proposed Fee Increases

Date: Tuesday, November 13, 2018 6:51:57 PM

Good grief!

An increase for pharmacy license from \$120 to \$250 is ridiculous – over 100% increase! For what?

Count me out! When the next license renewal of \$250 comes into effect, I'll be turning in my license.

Leonard Leis

From: Obop-rph [mailto:obop-rph-bounces@listsmart.osl.state.or.us] On Behalf Of obop-

rph@listsmart.osl.state.or.us

Sent: Tuesday, November 13, 2018 3:53 PM **To:** obop-rph@listsmart.osl.state.or.us

Subject: [Obop-rph] Notice of Proposed Fee Increases

NOTICE TO LICENSEES - PROPOSED FEE INCREASES

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From: <u>Karen Nguyen</u>

To: obop-cpt@listsmart.osl.state.or.us

Subject: Re: Notice of Proposed Fee Increases

Date: Tuesday, November 13, 2018 6:03:28 PM

Dear OBOP

I protest this possible rate increase. Us techs are paid so little, and are charged for all of our CE's anymore. Where I am employed I have to be licensed by the state and nationally. Thanks to President Trump we cant even use these fee's as a tax deduction next year. We very rarely get a raise in our pay. Yet the price of everything just keeps going up. I just cant make more money appear! I understand you have operational needs, but is it really necessary to take it out on the pharmacy techs? How about charging the pharmacists for there CE's they have mostly free ones? My property taxes went up \$300 this year thanks to a local school bond passing. Gas has gone up, but not my wages. I no I am not the only one in this situation. Us tech's are hurting. Please dont do this to us!

Karen Nguyen Cpht Oregon State Hospital Pharmacy Department.

From: Obop-CPT <obop-cpt-bounces@listsmart.osl.state.or.us> on behalf of Oregon Board of

Pharmacy <obop-cpt@listsmart.osl.state.or.us>

Sent: Tuesday, November 13, 2018 2:32 PM

To: Obop-rph; obop-pics@listsmart.osl.state.or.us; obop-interns@listsmart.osl.state.or.us; obop-

 $\verb|cpt@| listsmart.osl. state.or. us; obop-techs@| listsmart.osl. state.or. us \\$

Subject: [Obop-CPTs] Notice of Proposed Fee Increases

NOTICE TO LICENSEES – PROPOSED FEE INCREASES

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From: <u>MaryBeth Luehrs</u>

To: <u>obop-rph@listsmart.osl.state.or.us</u>

Subject: Re: [Obop-rph] Notice of Proposed Fee Increases

Date: Wednesday, November 14, 2018 4:54:53 PM

Any fee break for retired pharmacist??

Mary Beth retired RPh

> On Nov 13, 2018, at 3:52 PM, obop-rph@listsmart.osl.state.or.us wrote:

>

> <2019 Proposed Fee Notice to Licensees.pdf>

From: Rebecca Black

To: <u>obop-rph@listsmart.osl.state.or.us</u>

Subject: Re: [Obop-rph] Notice of Proposed Fee Increases

Date: Sunday, November 18, 2018 12:54:56 PM

Doubling the fee is ridiculous!

Sent from my iPhone

On Nov 13, 2018, at 3:52 PM, obop-rph@listsmart.osl.state.or.us wrote:

NOTICE TO LICENSEES - PROPOSED FEE INCREASES

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We respect, reflect and respond to the diverse people we serve.

<image001.jpg>

<2019 Proposed Fee Notice to Licensees.pdf>

Obop-rph mailing list

Obop-rph@listsmart.osl.state.or.us

http://listsmart.osl.state.or.us/mailman/listinfo/obop-rph

Hosted by the State Library of Oregon. The Library is not responsible for content.

From: Sean Branigan

To: <u>obop-cpt@listsmart.osl.state.or.us</u>

 Subject:
 RE: [Obop-CPTs] Notice of Proposed Fee Increases

 Date:
 Wednesday, November 14, 2018 1:33:22 PM

 Attachments:
 81ACBA594B3D4AC6BB269D8C2914B941.png

From \$50 to \$100 for a technician? Most technicians barely make above minimum wage. That's a pretty steep increase

Sean Branigan, CPhT

Sent from Mail for Windows 10

From: Oregon Board of Pharmacy

Sent: Tuesday, November 13, 2018 3:51 PM

To: Obop-rph; obop-pics@listsmart.osl.state.or.us; obop-interns@listsmart.osl.state.or.us; obop-

cpt@listsmart.osl.state.or.us; obop-techs@listsmart.osl.state.or.us

Subject: [Obop-CPTs] Notice of Proposed Fee Increases

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From: <u>ToddElla Gregory</u>

To: <u>Oregon Board of Pharmacy</u>

Subject: Re: [Obop-CPTs] Notice of Proposed Fee Increases

Date: Wednesday, November 14, 2018 5:10:41 PM

A NO vote to all proposed increases. I could write a 2-volume text/email/book about why, but it won't be read or considered by the undemocratic "Board" in any way. No, and no. Board needs to tighten its belt like people living in the real world who don't have their lives subsidized by others.

On Tuesday, November 13, 2018 02:33:36 PM PST, Oregon Board of Pharmacy <obopcpt@listsmart.osl.state.or.us> wrote:

NOTICE TO LICENSEES – PROPOSED FEE INCREASES

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 From:
 PHARMACY BOARD * BOP

 To:
 MACLEAN Karen S * BOP

Subject: FW: Notice of Proposed Fee Increases

Date: Wednesday, November 14, 2018 10:24:43 AM

From: Suzanne R <suzanner@communitycmpd.com> **Sent:** Wednesday, November 14, 2018 9:57 AM

To: PHARMACY BOARD * BOP < PHARMACY.BOARD@oregon.gov>

Subject: RE: Notice of Proposed Fee Increases

Doubling pharmacy technician licenses? Double? Many techs make barely above minimum wage. I notice nearly no other license is being doubled. That's just not right.

I will be asking every pharmacy technician I know to call the governor and legislator to oppose this unfair increase.

Sincerely, Meredyth Warren

From: PHARMACY BOARD * BOP < PHARMACY.BOARD@oregon.gov >

Sent: Tuesday, November 13, 2018 2:47 PM

To: PHARMACY BOARD * BOP < PHARMACY.BOARD@oregon.gov >

Subject: Notice of Proposed Fee Increases

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Please see the attached. This message is being sent to all licensees via email.

OFFICE OF THE SECRETARY OF STATE

BEV CLARNO SECRETARY OF STATE



JUNE 2019 / A1

ARCHIVES DIVISION

MARY BETH HERKERT

DIRECTOR

800 SUMMER STREET NE SALEM, OR 97310 503-373-0701

NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855 BOARD OF PHARMACY **FILED**

04/18/2019 4:28 PM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Legislatively approved fee increases in Division 110

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2019 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Karen MacLean 800 NE Oregon St. Suite 150 Filed By:

971-673-0001 Portland,OR 97232 Karen MacLean

Pharmacy.Rulemaking@oregon.gov Rules Coordinator

HEARING(S)

Auxilary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/22/2019 TIME: 9:30 AM

OFFICER: Karen MacLean

ADDRESS: Portland State Office

Building

800 NE Oregon St. Conference Room 1E Portland, OR 97232

NEED FOR THE RULE(S):

Implements fee increases included in the Board of Pharmacy Legislatively Approved Budget for 2019-21.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

2019 SB 5529 - https://olis.leg.state.or.us/liz/2019R1/Downloads/MeasureDocument/SB5529/Enrolled Notice to Licensee - Proposed Fee Increases - November 13, 2018

Email sent to all licensees and registrants with email address on file 11/13/18 or sent via USPS and posted to the agency website home page at

https://www.oregon.gov/pharmacy/Imports/Memos/2019ProposedFeeIncreaseNoticeToLicensees.pdf All new licensees or registrants since 11/13/18 received this notice with license/registration.

FISCAL AND ECONOMIC IMPACT:

These rules reflect fee increases in 24 license/registration categories that generate \$2,411,800 of Other Fund revenue. Note, approximately \$1,350,670 of this increase is related to the adjustment for biennial licensure for pharmacists and certified pharmacy technicians.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

Fee increases for various drug outlet registrations and personnel licensure include some county health departments, correctional facilities and state run institutional facilities. There are currently 899 facilities that have identified as small businesses. These rules do not generate any minimal reporting, recordkeeping and other administrative activities required for compliance for small businesses.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S): None.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Fees were legislatively adopted.

RULES PROPOSED:

855-110-0005, 855-110-0007, 855-110-0010

AMEND: 855-110-0005

RULE SUMMARY: Legislatively approved fee updates to be effective 7/1/19 for new applicants. The Board of Pharmacy's operating budget is largely dependent on licensing fees. Note: Pharmacist and Certified Oregon Pharmacy Technician fees now reflect a biennial fee for a two year license. New fees for these categories will not impact current licensees until their next renewal in 2020 (for CPTs) or 2021 (for RPHs).

CHANGES TO RULE:

855-110-0005

Licensing Fees ¶

- (1) Pharmacist license examination (NAPLEX) and re-examination fee \$50.¶
- (2) Pharmacist jurisprudence (MPJE) re-examination fee \$25.¶
- (3) Pharmacist licensing by reciprocity fee \$200*. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.¶
- (4) Pharmacist licensing by score transfer fee \$200*. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).50. ¶
- (4) Pharmacist licensing by score transfer fee \$250. ¶
- (5) Intern license fee. Expires November 30 every two years \$5100.¶
- (6) Pharmacist:¶
- (a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is $$42\underline{5}0$. Delinquent renewal fee; (postmarked after May 31) 50.¶
- (b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially- \$50. (This is a mandatory fee, required by ORS 431.972 that must be paid with the pharmacist license renewal fee).¶
- (c) Workforce Data Collection fee. Due by June 30 biennially \$4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacist license renewal fee.)¶
- (7) Certification of approved provider of continuing education course fee, none at this time.
- (8) Pharmacy Technician license fee \$50.¶
- (a) A Pharmacy Technician license initially issued prior to January 1, 2015 to a person under 18 years of age

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expires June 30 in odd numbered years - \$50. Delinquent renewal fee, (postmarked after May 31) - $\$2\underline{10}$ 0. \P

- (9) Certified Oregon Pharmacy Technician: ¶
- (a) Biennial license fee. Expires June 30 each even numbered year $$5\underline{10}$ 0. Delinquent renewal fee, (postmarked after AugustMay 31) \$20.¶
- (b) Workforce Data Collection fee. Due by June 30 biennially \$4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy Technician license renewal fee.) Statutory/Other Authority: ORS 689.205, 291.055, 183.705

Statutes/Other Implemented: ORS 689.135, 431.972, 676.410

AMEND: 855-110-0007

RULE SUMMARY: Legislatively approved fee updates to be effective 7/1/19. The Board of Pharmacy's operating budget is largely dependent on licensing fees.

CHANGES TO RULE:

855-110-0007

Fees for Registration, Renewal, and Reinspection of Drug Outlets ¶

- (1) Community Health Clinic. Expires March 31 annually \$75*100. Delinquent renewal fee (postmarked after February 28) \$25. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.
- (2) Drug Distribution Agent. Expires September 30 annually \$400. Delinquent renewal fee (postmarked after August 31) $$100.\P$
- (3) Drug Room (including correctional facility). Expires March 31 annually $$75^*100$. Delinquent renewal fee (postmarked after February 28) \$75. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013. ¶
- (4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually \$400525. Delinquent renewal fee (postmarked after August 31) \$100.
- (5) Medical Device, Equipment & Gas Class C. Expires January 31 annually $$\underline{7}5\theta$. Delinquent renewal fee (postmarked after December 31) \$25.¶
- (6) Nonprescription Class A. Expires January 31 annually $$\underline{7}50$. Delinquent renewal fee (postmarked after December 31) \$25.¶
- (7) Nonprescription Class B. Expires January 31 annually $$\underline{7}50$. Delinquent renewal fee (postmarked after December 31) \$25.¶
- (8) Nonprescription Class D. Expires January 31 annually \$100. Delinquent renewal fee (postmarked after December 31) $$25.\P$
- (9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer \$50*. Expires December 31 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013. ¶
- (10) Re-inspection fee \$100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.
- (11) Retail-or, Institutional, or Consulting/"Drugless" Pharmacy Drug Outlet. Expires March 31 annually \$175* 225. Delinquent renewal fee (postmarked after February 28) \$75. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.
- (12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually \$400525. Delinquent renewal fee (postmarked after August 31) \$100.
- (13) Remote Dispensing Machine or Remote Distribution Facility. Expires March 31 annually \$1020. Due by February 28 annually.¶
- (14) Charitable Pharmacy. Expires March 31 annually \$75. Delinquent renewal fee (postmarked after February 28) \$25.¶
- (15) Home Dialysis. Expires March 31 annually $$175^{*}225$. Delinquent renewal fee (postmarked after February 28) 75. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.
- (16) Supervising Physician Dispensing Outlet. Expires March 31 annually \$175*. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Delinquent renewal fee (postmarked after February 28) \$75. ¶

 (17) Dispensing Practitioner Drug Outlet. Expires March 31 annually --- \$100*. Delinquent renewal fee

 (postmarked after February 28) --- \$25*. (*This fee will be waived until the 2019 renewal cycle that begins January 1, 2019.).

Statutory/Other Authority: ORS 689.205, 291.055

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Statutes/Other Implemented: ORS 689.135, 689.774, 689.305

AMEND: 855-110-0010

RULE SUMMARY: Legislatively approved fee updates to be effective 7/1/19. The Board of Pharmacy's operating budget is largely dependent on licensing fees.

CHANGES TO RULE:

855-110-0010

Fees for Registration for Controlled Substances under ORS 475.095 ¶

- (1) Animal Euthanasia controlled substance registration fee \$750 annually.
- (2) Drug Distribution Agent controlled substance registration fee \$50*100 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). ¶
- (3) Drug Room (including correctional facility) controlled substance registration fee \$50*100 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). ¶
- (4) Manufacturer controlled substance registration fee \$50*100 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). ¶
- (5) Retail or Institutional Drug Outlet controlled substance registration fee \$50*100 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). ¶
- (6) Schedule II Precursor registration fee $$\underline{7}50^*$ annually. $$(*Temporary\ revenue\ surplus\ fee\ reduction\ pursuant\ to\ ORS\ 291.055(3)).}$
- (7) Wholesaler controlled substance registration fee \$50*100 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). ¶
- (8) Remote Distribution Facility controlled substance registration fee \$50*100 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

Statutory/Other Authority: ORS 689.205, 291.055

Statutes/Other Implemented: ORS 689.135

Minutes

Oregon Board of Pharmacy – Rules Advisory Committee Drug Compounding – Division 045 May 8, 2019; I-4pm in Room IB 800 NE Oregon Street Portland OR, 97232

Items	Desired Outcome			
Welcome	Committee Members:			
Introductions and Discussion	Dianne Armstrong, Board Member/Kaiser Kathryn Arnone, Portland VA Medical Center Aaron Bohn, Community Compounding Pharmacy Shannon Buxell, Franz Infusion Pharmacy, Providence Cancer Institute Fernando Camacho, Walgreens Compounding Center Derek Deforest, Salem Hospital (absent) Luke Eilers, Northwest Compounders Forrest Fentress, NW Pharmaceutical Compounding Natalie Gustafson, Lloyd Central Compounding Pharmacy Anne Harthman, Broadway Apothecary Amy Johnson, Red Cross Institutional Pharmacy Judy Lim, Kaiser Permanente NW Tabitha Norris, Asante Carrie Reedy, Samaritan Health Services Mike Shaver, PeaceHealth Riverbend Jeff Wassouf, OHSU			
	Board Staff: Joe Schnabel, Executive Director Fiona Karbowicz, Pharmacist Consultant Karen MacLean, Administrative Director			
	❖ Committee Introductions, Overview/Background, and Purpose The Drug Compounding – Division 045 Rules Advisory Committee (RAC) was			
	selected to discuss the impacts of the Board's draft rules. This RAC provides the structure for stakeholder and industry insights.			
	Pharmacist Consultant Fiona Karbowicz presented an informational set of slides, defining a rule, providing background of agency promulgation of rules, and outlining the purpose of a RAC, in alignment with the Board's mission. The presentation described the objectives of the revisions to the compounding rules, as well as the context and considerations for the RAC. (see pg of this document for slides)			
	■ The current revisions to Division 045 – Drug Compounding include:			
	 Articulation of the Board's intent for full compliance with USP Chapter standards (versus "in the spirit of") for patient and personnel safety. All drug compounding must adhere to guidelines of the current edition of the USP Chapters 795, 797 and 800, as well as all Chapters related to the compounding practices at a location; and 			

- Expression of the Board's expectations for:
 - Registration requirements, including accreditation. A 503B Outsourcing Facility must register as an Oregon Manufacturer. All compounding pharmacies must either pass an inspection by a Board approved entity or must receive accreditation by a Board approved entity every 3 years at a minimum, in order to distribute or dispense compounding preparations into and within Oregon.
 - Personnel responsibilities, including required P&P. The PIC and drug outlet shall establish, maintain and enforce policies and procedures in accordance with the standards in USP Chapters for all aspects and categories of the compounding operation of non-sterile, sterile and parenteral product preparation. Items are outlined in rule by a list of required P&P, which must be aligned with applicable USP directives.
 - Labeling and documentation requirements. All compounding records, including training documents, master formulation records, compounded preparation records, individual prescription records, and dispensing or transfer of all compounded preparations must be maintained electronically or manually, stored in an organized manner, retained for a minimum of 3 years and be made readily available for inspection by the Board. Items are outlined in rule by a list of required documentation of processes related to drug compounding.
- The existing rules no longer meet the acceptable minimum standards for safety. The federal landscape for compounding has been informing this rules revision for a number of years, particularly as a result of the major safety implications exhibited by the New England Compounding Center (NECC) tragedy. Major stakeholders include Federal legislators (authors of the DQSA), the FDA, NABP, USP, other regulators, healthcare professionals, and, of course, patients.

Committee Dialogue

Committee Members shared concerns, opinions and personal insights related to this topic, addressing compliance challenges, timeframes, and the fiscal impact to various stakeholders. As a way to invoke as much dialogue as possible, Members took additional turns to speak, as often the sharing by one member inspired another's thoughts. Overall, Members were supportive of the rule changes, to ensure patient and worker safety.

Broad topic points shared by committee dialogue included:

- FDA: Years' worth of regulatory guidance, many items such as guidance documents and regulations are still under development; FDA agents are performing proactive inspections and issuing 483s, which provide insight to their compliance and enforcement initiatives and policy prerogatives. FDA activities are having a major impact to the compounding industry.
- USP: All stakeholders (including the Board) are awaiting the release of the final revisions to the compounding Chapters; major concern among most stakeholders is that the time to comply with the "Intended Official Date" of 12/1/2019 gives the pharmacies only 6 months to align all P&Ps, staff training,

facility updates, etc. for compliance; Members seeking insights related to the Board's expectations for compliance in Oregon. Staff anticipates this may be similar to other rule/policy changes in the past – the Board allows a reasonable timeframe for a pharmacy to achieve compliance with new rules and plans to create an updated Self-Inspection Form for compounding to help with understanding and compliance expectations.

- Oregon Shared Services: General understanding related to the historic and current role that shared services for compounded products services (compounding batches of non-patient specific drug products), and the need to phase out shared service for human compounded drug products however, Members shared concerns related to ongoing confusion among some Oregon pharmacies and Oregon clinicians; agreement that streamlined Board processes for shared services allowance is needed, as well as a necessity for a consistent communication to impacted clinicians; current overall landscape permits the use of Oregon shared services for veterinary compounding for batches of non-patient specific drug products
- Patient Impacts: It is anticipated that compliance with USP standards will have a positive impact on the safety and quality of the drugs compounded for patients. It is assumed that at least some of the increased costs of doing business in the compounding realm may ultimately passed along to patients, estimated increase of 25%, though hospitals cannot pass along increases to patients due to primarily fixed reimbursements. Additionally, patients and clinicians may notice that certain drugs will have shorter expiration dates (BUDs) depending on the final language put forth by USP for dating standards. Some pharmacies may choose to stop compounding all together, though there may be an increase in FDA-approved kits to replace some frequently compounded items (i.e. magic mouthwash).
- Fiscal Impacts: The majority of the Committee's discussion directly or indirectly related to the costs to comply with USP Standards (and therefore also with Board rule). Compliance costs can be placed into two major categories: initial costs, such as facility remodels and ongoing costs, such as gowning/garbing items needed for daily compounding activities. It is anticipated that the costs to comply are high, ranging anywhere from an estimated \$50,000 to more than \$2,000,000 per location, depending on the current facility specifications and the type of compounding being performed. The Committee had a robust discussion related to the Board's proposed requirement to for a compounding pharmacy to be accredited by a Board approved entity, every three years at a minimum, and the related costs; not all accreditors are 'created equally' and the Board may not ultimately get the safety assurances they seek from this policy directive.

Good of the Order

The meeting concluded with general consensus related to the overall high fiscal realities of compliance with USP standards, and therefore with the Board's proposed rules. General agreement that Committee Members are willing to meet again, particularly if the USP standards published in June include unanticipated additional costs. Otherwise, the group may continue to meet, not as a RAC, but rather as a formal stakeholder group, to continue providing ongoing expertise and professional insights to the Board.

DIVISION 045-DRUG COMPOUNDING

OREGON BOARD OF PHARMACY RULES ADVISORY COMMITTEE (RAC) MEETING - MAY 8, 2019



OVERVIEW

- Purpose / RAC responsibilities
- Historical context for Oregon compounding regulations
- Committee Member dialogue and discussion

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.

OBOP MISSION STATEMENT

May be established and used for rules in which there are issues that may substantially impact the interests of persons or entities ("stakeholders"), who will likely be affected by the proposed rulemaking.

RULES ADVISORY COMMITTEE (RAC)

RULES ADVISORY COMMITTEE - PURPOSE

- Involve the public in the development of public policy
- Estimate financial impact on interested persons/entities, including small businesses, as well as the fiscal impact on the public
- Members must represent interests of persons likely to be affected by the rule

A RAC's role is advisory only.

WHAT IS A RULE?

- Any agency directive, standard, regulation or statement
- 2. Of general applicability
- That implements, interprets or prescribes law or policy, or
- That describes the procedure or practice requirements of any agency

ORS 183.310(9)

WHEN IS A RULE REQUIRED?

- · When required / written in statute
- To interpret broad statutory authority
- · To amend, suspend, or repeal existing rule

Tip: Statute mandates what, and the rule mandates how (implementation)

WHERE ARE RULES FOUND?

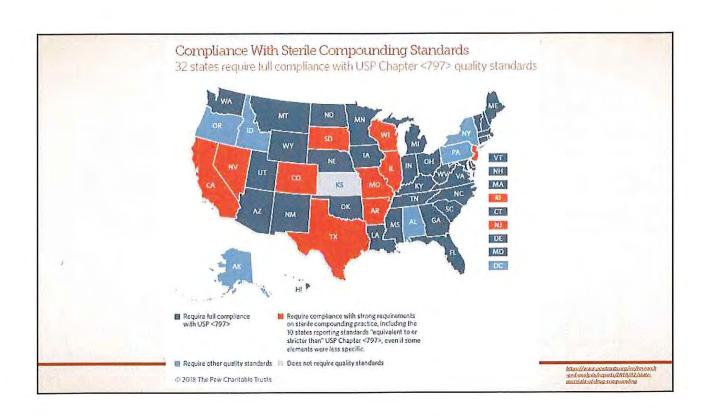
- Oregon Administrative Rules (OAR)-official compilation of rules & regulations having the force of law in Oregon
 - http://sos.oregon.gov/archives/Pages/oregon administrative rules.aspx

PROPOSED RULES - OBJECTIVES

- Current revisions to Division 045 Drug Compounding include:
 - Articulate the Board's intent for full compliance with USP Chapter standards (versus "in the spirit of") for patient and personnel safety
 - Express the Board's:
 - 。Registration requirements, including accreditation
 - Personnel responsibilities, including required P&P
 - Labeling and documentation requirements
- · Existing rules no longer meet the acceptable minimum standards for safety

HISTORICAL CONTEXT/CONSIDERATIONS

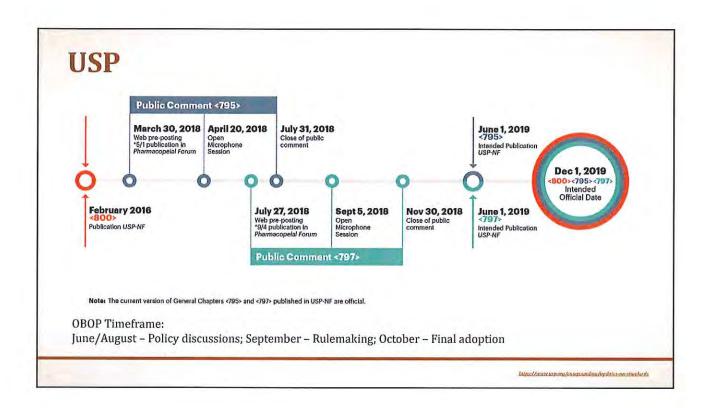
- Current Division 045 February 2008
- NECC (2012)
 - DQSA (November 2013)
 - FDA ongoing 50-State Meetings, guidance documents, proactive inspections and 483s
 - USP aligning re-written Chapters
- Contemporary OBOP Division 045 re-writes and revisions
 - Workgroup and SME input for current draft (2.2019)



POLICY ITEM - SHARED SERVICES

- FDA
 - · Guidance Documents
 - · Bulk Drug compounding
 - · Statement on Veterinary Compounding
 - MOU
- · OBOP Policy changes, in response to FDA actions and guidances:
 - Rule edited in 2016: "Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon for Oregon outlets and practitioners located in Oregon only"
 - · Required for all "office use", not just for clinician "sales"; denied when commercially available
 - Reduced from 5 year → 2 year → 1 year (human)
 - · OBOP Clarifying Statements

https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding https://www.fda.gov/animal-veterinary/resources-you/fda-regulation-animal-drugs



COMPLIANCE

- Current "State of the State"
- Realities / Challenges
 - Accreditation
 - Facility remodel
 - o Other
- Patient Safety elements

COMMITTEE
MEMBER
SHARING
& DIALOGUE

IMPACTS

- Identify any state agencies, units of local government and members of the public likely to be economically affected by the rule
- Effect on small businesses
 - o Estimate number and type(s) impacted
 - Estimate costs to comply
 - Reporting, recordkeeping, admin activities
 - Professional services, equipment supplies, labor and increased admin

COMMITTEE MEMBER DISCUSSION:

FISCAL IMPACT

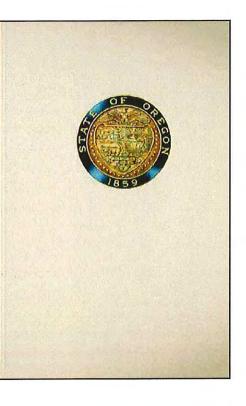
FISCAL IMPACT STATEMENT - MAY 2018

- Agency cost specific to inspector training
- Potentially significant costs to stakeholders, depending on their current levels of compliance with national standards. Costs include:
 - o Construction of or modification of sterile compounding/clean rooms
 - Ventilation and power costs
 - o Materials, equipment and supplies necessary for compliance
 - o Ongoing accreditation
- Range of costs of compliance is dependent on the type of compounding an outlet performs and current readiness. Could cost less than \$100,000 or more than \$1,000,000

FINAL THOUGHTS

THANK YOU VERY MUCH

We appreciate your participation in this important work!



- 1 Updates to Division 045 Drug Compounding are provided. This is a rules revision; this is not a
- 2 re-write.
- 3 Current regulations (adopted in February 2008) are written in "the spirit" of USP Chapters 795
- 4 and 797. They were drafted prior to the publication of USP <800> (February 2016). On
- 5 2/26/2018, the Pew Charitable Trusts published their research on State Oversight of Drug
- 6 Compounding. For safety assurances aligned with national standards, in 2013 the Board stated
- 7 that the rules needed to be updated to full compliance with USP (Resources available: USP
- 8 <u>website</u>). Efforts to strengthen compounding rules are needed due to the critical safety
- 9 implications for patients.
- 10 Changes to these rules include: (1) Expectation of full compliance with all USP Chapter
- standards commensurate with the compounding performed; (2) Registration, including the
- requirement for compounding pharmacies to be accredited by a Board approved entity every 3
- years at a minimum; this does not replace the Board's annual inspections; (3) Personnel
- responsibilities, including required policies and procedures (P&Ps); (4) Labeling; and (5)
- 15 Documentation.
- Note: There is a distinction between compliance with safety standards and compliance with
- 17 law/rule. The Oregon Board of Pharmacy is committed to Compliance Through Education and
- one way that is achieved is through clear rules that articulate compliance expectations.
- 19 Therefore, these rules provide for the broad directive to "Comply with all USP Chapters" as well
- as provide structure and clarity to licensees who compound drugs by specifying required P&Ps
- 21 and documentation.
- 22
- 23 Division 45
- 24 STERILE AND NON-STERILE DRUG COMPOUNDING
- 25 855-045-0200
- 26 Application
- 27 (1) These rules (OAR 855-045-0200 to 855-045-0270) apply to any person, including any
- business entity, located in <u>or outside</u> Oregon that engages in the practice of compounding <u>a</u>
- 29 drugs, for use or distribution in Oregon. or any person, including any business entity, located
- 30 in any other state that compounds drugs for the use of patients located in Oregon. Compounding
- 31 of radiopharmaceuticals is specifically exempted from these rules where these rules are in
- 32 conflict with the rules or guidelines established by the Nuclear Regulatory Commission, the
- 33 Radiation Protection Services of the Oregon Department of Human Services or any other
- 34 applicable agency. Any person located outside Oregon that compounds drugs for the use of
- patients located in Oregon is expected to follow the compounding rules of their home state or
- 36 these rules, whichever are more stringent.
- 37 (2) These rules apply to sterile and non-sterile compounding of a drug medications that are
- 38 prepared for a specific patient and that are prescribed or ordered subject to a valid practitioner
- 39 patient relationship.

- (3) All drug compounding must adhere to standards of the current edition of the United 40
- States Pharmacopeia Chapters 795 (USP <795>), 797 (USP <797>) and 800 (USP <800>), 41
- as well as all Chapters of USP and USP-NF related to the compounding practices at any 42
- location. This includes, but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 825, 43
- 1072, 1116, 1160, 1163, 1211 and 1229.5. Whilst the Board does not insist on rigid application 44
- 45 of, or adherence to, all the guidelines of the current edition of the United States Pharmacopeia
- Chapters 795 (USP 795) and 797 (USP 797), it expects pharmacists engaging in compounding to 46
- adhere to those guidelines that apply to their practice setting and in all situations to comply with 47
- the spirit of USP 795 and USP 797. 48
- 49 (4) Any compounding activity that is not pursuant to a valid prescription or an order to prepare
- 50 for administration and for a specific patient is considered to be manufacturing, and any person
- engaged in manufacturing must be registered in accordance with OAR 855-060-0001, with the 51
- following exceptions: 52
- 53 (a) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in
- Oregon that is covered by a Shared Pharmacy Services agreement as defined in OAR 855-006-54
- 55 0005;
- 56 (b) Compounding in anticipation of a prescription drug order or an order to prepare for
- 57 administration, based on a routine, regularly observed pattern;
- 58 (c) Notwithstanding any other provisions of this rule, the preparation of a patient specific product
- 59 utilizing all non-sterile commercial components, as defined in these rules as Category 1
- compounding, is not considered compounding under these rules provided that: 60
- (A) Preparation of these products is an infrequent occurrence; 61
- (B) Quantity of product prepared does not exceed the requirements of a single prescription 62
- except that small quantities can be prepared upon request for in-office use by licensed 63
- practitioners. 64
- Statutory/Other Authority: ORS 689.205 65
- Statutes/Other Implemented: ORS 689.155 66
- 855-045-0210 68

67

- **Definitions** Registration 69
- (1) A pharmacy that compounds a drug and dispenses a patient specific drug must register 70
- with the Board as a retail drug outlet or an institutional drug outlet or both if dispensing to 71
- both an ambulatory and residential patient. This applies to resident and non-resident 72
- pharmacies. 73
- 75
- (2) In addition to obtaining an Oregon drug outlet registration, all compounding
- pharmacies must either pass an inspection by a Board approved entity or must receive 76
- accreditation by a Board approved entity, every 3 years at a minimum, in order to 77
- distribute or dispense compounded preparations into and within Oregon. 78

79	
80	(3) A non-resident facility distributing non-patient specific drugs into Oregon must be
81	registered with the FDA as a 503B Outsourcing Facility and must register with the Board
82	as a manufacturer drug outlet.
83	(4) A regident feelity distributing non-nations greatly during within and autaids of Oregon
84 85	(4) A resident facility distributing non-patient specific drugs within and outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the
86	Board as a manufacturer drug outlet.
87	Dou't us a manaracturer arag outles.
88	What about Oregon shared services?
89	
90	
91	Stat. Auth.: ORS 689.205
92	Stats Implemented: ORS 689.155
93	
94	As used in this division of administrative rules:
95	(1) "Airborne Particulate Cleanliness Classification" means the level of cleanliness defined by
96	the maximum allowable number of particles per cubic meter of air as specified in the
97	International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-
98	1). The levels used in these rules are:
99	(a) ISO Class 5 is an atmospheric environment that contains less than 3,520 particles 0.5 microns
100	in diameter per cubic meter of air.
101	(b) ISO Class 7 is an atmospheric environment that contains less than 352,000 particles 0.5
101	microns in diameter per cubic meter of air.
102	interons in diameter per cubic meter or an:
103	(c) ISO Class 8 is an atmospheric environment that contains less than 3,520,000 particles 0.5
104	microns in diameter per cubic meter of air.
105	(2) "Beyond Use Date" (BUD) means the date after which the preparation may not be dispensed
106	or administered to a patient. BUD has the same meaning as "Expiration Date".
107	(3) "Biological Safety Cabinet" (BSC) means a ventilated cabinet with an inward airflow for
108	personnel protection, a downward, High Efficiency Particulate Arresting (HEPA) filtered,
109	laminar airflow for product protection, and a HEPA filtered exhaust system for environmental
110	protection.
111	(4) Categories of compounding: In these rules, compounding is defined as:
112	(a) Category 1: Nonsterile — Simple: Generally, the mixing of two or more commercial
113	products. In these rules, this is not considered to be compounding.
114	(b) Category 2: Nonsterile — Complex: Generally, compounding with bulk drug substances or
115	when calculations are required.

(c) Category 3: Sterile Risk Level 1: Low Risk, as defined in OAR 855-045-0250.

- 117 (d) Category 4: Sterile Risk Level II: Medium-Risk, as defined in OAR 855-045-0250.
- 118 (e) Category 5: Sterile Risk Level III: High Risk, as defined in OAR 855-045-0250.
- 119 (5) "Compounding Aseptic Isolator" (CAI) means a glove box isolator with a microbially
- 120 retentive HEPA air filter that maintains an aseptic compounding environment within the isolator
- 121 throughout the compounding and material transfer process.
- 122 (6) "Compounded Sterile Preparation" (CSP) means:
- 123 (a) A preparation prepared according to the manufacturer's labeled instructions and other
- manipulations when preparing sterile products that expose the original contents to potential
- 125 contamination, and includes all preparations compounded in IV rooms; or
- 126 (b) A preparation containing nonsterile ingredients, or employing nonsterile components and
- 127 devices, that must be sterilized before administration; or
- 128 (c) Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the
- 129 above two characteristics, and which include, but are not limited to, baths and soaks for live
- organs and tissues, implants, inhalations, injections, powders for injections, irrigations, metered
- 131 sprays, and ophthalmic and otic preparations.
- 132 (7) "Compounding pharmacy" means any pharmacy where sterile or non-sterile compounding
- 133 occurs on a regular basis.
- 134 (8) "Parenteral Admixture" means a sterile preparation that is the combination of one or more
- 135 sterile products with an appropriate admixture vehicle.
- 136 (9) "Laminar Airflow Hood" (LAF) means a workspace where the work surface is subjected to a
- 137 constant, HEPA filtered airflow that is directed towards the user.
- 138 Statutory/Other Authority: ORS 689.205
- 139 Statutes/Other Implemented: ORS 689.155

- 141 855-045-0220
- 142 Personnel and Responsibilities
- All drug compounding must adhere to guidelines of the current edition of the United States
- 144 Pharmacopeia Chapters 795 (USP <795>), 797 (USP <797>) and 800 (USP <800>), as well
- as all Chapters of USP and USP-NF related to the compounding practices at any location.
- 146 This includes, but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 1072, 1116, 1160,
- 147 1163, 1211 and 1229.5.
- 148 (1) <u>All Ppersonnel who prepare</u> and supervise the preparation of compounded
- pharmaceuticals, both sterile and non-sterile, shall must complete be provided with appropriate
- training and be capable and qualified to perform assigned duties. before they begin to prepare
- such products including for CSPs, training in the theoretical principles and practical skills of
- 152 aseptic manipulations.

153	(2) The pharmacist in charge Pharmacist-in-Charge (PIC) and the drug outlet shall establish.
154	maintain and enforce pharmacy Ppolicies and Pprocedures that contain protocols in accordance
155	with the guidelines in USP Chapters 797, for all aspects and categories of the compounding
156	operation of non-sterile, sterile and parenteral product preparation that include written
157	procedures for: the initial training and testing of all personnel and for annual retesting in aseptic
158	manipulative skills for those personnel involved in low and medium risk compounding.
159	(a) Personnel Qualifications, to include training, evaluation and requalification;
160	(b) Hand hygiene;
161	(c) Garbing;
162 163	(d) Engineering and environmental controls, addressing but not limited to equipment certification and calibration, air and surface sampling, and viable particles;
164	(e) Cleaning activities, addressing but not limited to sanitizing and disinfecting;
165	(f) Components, addressing but not limited to selection, handling, and storage;
166	(g) Creating Master Formulation Records;
167	(h) Creating Compounding Records;
168	(i) Establishing BUDs;
169	(j) Continuous quality assurance program and quality controls, addressing but not limited
170	to release testing, end-product evaluation, quantitative/qualitative testing;
171	(k) Completed compounded preparations, to include handling, packaging, storage and
172	transport;
173	(1) Adverse event reporting process and recall procedure. The recall procedure must
174	include notification to the Board within 10 working days in the event of a patient-level
175	recall of a compounded drug.
176	
177	(3) Personnel involved in high-risk compounding must be retested in aseptic manipulative skills
178	at least semi-annually.
	·
179	(4) The PIC shall ensure that training protocols are followed and records are kept for the training
180	of all new personnel and for all continuing education and periodic testing that is completed.
181	(5) The PIC is responsible for the procedures and the overall operation of all activities within the
182	pharmacy and must:
183	(a) Ensure all pharmacy personnel involved in preparing compounded products are trained and
184	have demonstrated skills commensurate with the complexity of the procedures they are

performing;

(b) Establish a procedure for verification by a pharmacist of the preparation of each completed 186 187 compounded product. This verification shall be accomplished by a review of each compounded 188 product that includes but is not limited to: (A) Ensuring that the drug, dose and dosage form ordered are appropriate for the patient; 189 (B) Verifying that the correct drugs and components were selected; 190 (C) Confirming that the calculation and quantity of each drug and component is correct; 191 (D) Verifying the label is correct and where appropriate contains all the information specified in 192 OAR 855-041-0065 and these rules. 193 194 (c) Document verification by the pharmacist responsible for the review. Statutory/Other Authority: ORS 689.205 195 Statutes/Other Implemented: ORS 689.155 196 197 855-045-0230 198 199 **General Requirements** 200 A person licensed to practice pharmacy by the Oregon Board of Pharmacy who is working in a compounding pharmacy, including a pharmacy that only prepares sterile parenteral products, has 201 202 the duty to exercise that degree of care, skill, diligence and professional judgment that is used by ordinarily competent, careful pharmacists in the same or similar circumstances in the community 203 of the pharmacist or a similar community. 204 205 (1) A pharmacist engaged in compounding shall: (a) Conform to all relevant federal laws and rules; 206 207 (b) Dispense a compounded product only subject to a valid prescription except as provided in OAR 855-045-0200(4), and only when, in their professional judgment, it results from a valid 208 209 prescriber-patient relationship; 210 (c) Compound only products that are not commercially available except as allowed in OAR 855-211 045-0240(2), and, except that with the prior approval of the Board, a commercial product that is temporarily in short supply or otherwise unavailable, may be compounded subject to OAR 855-212 045-0200(4)(c); 213 (d) Maintain all records in accordance with OAR 855-045-0270; 214 215 (e) Perform final product verification. (2) The pharmacist in charge of a compounding pharmacy including a pharmacy that only 216 prepares sterile parenteral products shall ensure that policies and procedures for that pharmacy 217 are reviewed not less than annually, are available for all staff to refer to, and are complied with 218 by all staff. The policies and procedures for a compounding pharmacy shall include but are not 219

limited to, the following:

- 221 (a) An organized index;
- 222 (b) Product formula information;
- 223 (c) Specifications for a compounding log book in compliance with OAR 855 045 0270;
- 224 (d) Conditions and surveillance of the compounding environment;
- 225 (e) Compounding procedures including requirements for use of gowns, shoe covers or dedicated
- 226 shoes, hair covers, gloves and masks;
- 227 (f) Cleaning and equipment maintenance procedures;
- 228 (g) QA plan and documentation;
- 229 (h) Shipping and delivery procedures;
- 230 (I) Product labeling;
- 231 (j) Procedures for final product verification by the pharmacist;
- 232 (k) Compounded product quality procedures including procedures for establishing BUD;
- 233 (1) Training requirements for all staff;
- 234 (m) Safety procedures and training for personnel handling hazardous materials including:
- 235 (A) Use of personal protective equipment;
- 236 (B) Availability of Manufacturers' Safety Data Sheets;
- 237 (C) Emergency procedures related to spills, fire, or exposure to hazardous materials.
- 238 (n) Requirements for availability of reference materials.
- 239 (3) Pharmacies that compound sterile products including parenteral products shall, when
- 240 appropriate, also include in their policies and procedures:
- 241 (a) Establishment of BUD;
- 242 (b) End Product Testing;
- 243 (c) Random sampling of both the environment and CSPs.
- 244 (4) The pharmacist in charge of a compounding pharmacy shall ensure that a quality assurance
- 245 plan is written for that pharmacy and that:
- 246 (a) It includes record keeping requirements for cleaning, testing and calibration of all equipment
- 247 and devices;
- 248 (b) Pharmacies that compound sterile products shall additionally include:
- 249 (A) Schedules and protocols for End Product Testing. Pharmacies mixing High Risk Level CSPs
- 250 or extending Beyond Use Dating (BUD), must establish an End Product Testing schedule that

251 includes random sampling. End Product Testing of a mixing process must show an acceptable 252 sampling of the total preparations prepared annually; (B) Protocols for establishing BUDs. BUDs may not exceed those in USP 797 guidelines unless 253 254 a quality assurance program is established that verifies End Product Testing beyond the dating established by USP 797. Records to verify sterility and pyrogenicity must be maintained and 255 256 available for review for three years. 257 (5) Bulk chemicals require a certificate of analysis. (6) The labeling of bulk chemical containers shall contain: 258 259 (a) The date obtained; (b) The BUD, which shall be established as specified in the pharmacy policies and procedures 260 but not more than five years after opening unless additional testing is conducted to extend that 261 BUD by not more than one year. 262 263 Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.155 264 265 266 855-045-0240 267 **Sterile Parenteral Products** Labeling (1) In addition to the labeling requirements specified in Division 041, the label of a 268 compounded drug or medication order dispensed or distributed must contain the 269 following, at a minimum: complying with all the other rules in this chapter of rules that are 270 appropriate to their practice setting, pharmacists compounding sterile parenteral products must 271 272 comply with the following specific rules. (a) The generic or official name of each active ingredient; Establish, maintain and enforce 273 written policies and procedures associated with the pharmacy's preparation and dispensing of 274 parenteral products. Policies and procedures shall be available for inspection at the pharmacy. 275 These policies and procedures shall include all requirements of OAR 855-045-0230 as 276 277 appropriate to the practice setting and: (b) The strength or concentration of each active ingredient, to include primary solution for 278 a sterile parenteral preparation; 279 280 (c) The name of the base, diluent, or primary excipient;

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(d) The dosage form and route of administration;

(f) The total quantity of the drug product;

(e) Rate of infusion, for a sterile parenteral preparation;

(g) A beyond-use-date (BUD), compliant with current USP guidelines;

285 286	(h) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety; and	
287 288	(i) A statement that the product is a compounded preparation (An auxiliary label may be used on the container to meet this requirement).	
289	(A) Requirements for compounding, labeling and storage of the products;	
290	(B) Requirements for administration of parenteral therapy;	
291	(C) Requirements for storage and maintenance of equipment and supplies.	
292	(b) Labeling: In addition to regular labeling requirements, the label shall include:	
293	(A) Rate of infusion, as appropriate;	
294	(B) Beyond Use Date;	
295	(C) Storage requirements or special conditions, if applicable;	
296 297	(D) Name, quantity and concentration of all ingredients contained in the products, including primary solution;	
298	$(\underline{\mathbf{j}}) \to \underline{\mathbf{Initials}} \ \underline{\mathbf{Identity}}$ of the pharmacist who verified the accuracy of the completed product.	
299 300	(c) Patient Care Services: Counseling shall be available to the patient or patient's agent concerning proper use of parenterals and related supplies furnished by the pharmacy.	
301 302	(2) In addition to complying with all the requirements in section (1) of this rule, licensed pharmacy personnel preparing parenteral admixtures as defined in OAR 855-045-0210 may:	
303	(a) Prepare multiple source commercially available premixed parenteral admixtures;	
304 305	(b) Prepare single source premix parenteral admixtures if the individual components of the premixed parenteral solution are commercially available;	
306 307 308 309	(c) Reassign a parenteral admixture to another patient if the admixture does not exceed the documented BUD for that admixture, and the parenteral admixture that was prepared and dispensed for a patient specific order, and has been stored at all times under the control of a person trained and knowledgeable in the storage and administration of drugs;	
310 311 312	(d) In the case of a patient specific parenteral admixture, the pharmacist does not need to comply with the worksheet and log requirements in these rules provided that a quality assurance process is in place to address drug recalls, and appropriate safeguards are in place.	
313 314 315	Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.155	
316 317	855-045-0250 Definitions of Risk Levels for Sterile Preparations	

- The three risk levels of CSPs recognized by USP 797 are based on the probability of
- 319 contamination by microbial, chemical or physical agents. Low-Risk and Medium-Risk Level
- 320 CSPs are determined by the potential for microbial contamination during preparation, and High-
- 321 Risk Level CSPs by the potential for not being properly sterilized before administration to
- 322 patients. These risk levels are defined, and products must be prepared and managed as follows:
- 323 (1) Low Risk Conditions:
- 324 (a) CSPs prepared using aseptic manipulation within an air quality environment that is equal to
- or better than ISO Class 5, using only sterile ingredients, products, components and devices;
- 326 (b) No more than three commercially manufactured sterile products and entries into one
- 327 container of sterile product during preparation;
- 328 (c) Manipulations limited to:
- 329 (A) Aseptically opening ampoules;
- 330 (B) Penetrating sterile stoppers on vials with sterile needles and syringes;
- 331 (C) Transferring sterile liquids in sterile syringes to sterile administration devices, package
- 332 containers of other sterile products, and sterile containers for storage and dispensing.
- 333 (d) In the absence of sterility testing, preparations must be properly stored prior to administration
- 334 as follows:
- 335 (A) BUD less than or equal to 48 hours at controlled room temperature;
- 336 (B) BUD up to 14 days: under refrigeration;
- 337 (C) BUD up to 45 days: in solid frozen state at -20 °C.
- 338 (2) Medium Risk Conditions:
- 339 (a) CSPs compounded aseptically under Low-Risk Conditions but with the addition of one or
- 340 more of the following conditions:
- 341 (A) Multiple individual or small doses of sterile products are combined or pooled to prepare a
- 342 CSP that will be administered either to multiple patients or to one patient on multiple occasions;
- 343 (B) The compounding process includes complex aseptic manipulations other than single-volume
- 344 transfer;
- 345 (C) The compounding process requires unusually long duration, such as that required to
- 346 complete dissolution or homogenous mixing.
- 347 (b) In the absence of sterility testing, preparations must be properly stored prior to administration
- 348 as follows:
- 349 (A) BUD less than or equal to 30 hours: at controlled room temperature;
- 350 (B) BUD up to 9 days: under refrigeration;

- 351 (C) BUD up to 45 days: in solid frozen state at -20 °C.
- 352 (3) High Risk Conditions:
- 353 (a) CSPs compounded from non-sterile ingredients, including products manufactured for other
- 354 routes of administration, or a non-sterile device is employed before terminal sterilization;
- 355 (b) Exposure to an air quality environment that does not meet ISO 5 or better conditions for more
- 356 than one hour for any of the following:
- 357 (A) Sterile contents of commercially manufactured products;
- 358 (B) CSPs that lack effective antimicrobial preservatives;
- 359 (C) Sterile surfaces of devices and containers for the preparation, transfer, sterilization and
- 360 packaging of CSPs.
- 361 (c) Prior to terminal sterilization:
- 362 (A) Nonsterile procedures including weighing and mixing occur in an air quality environment
- 363 that does not meet ISO 7 or better conditions;
- 364 (B) Compounding personnel are improperly gloved or garbed;
- 365 (C) Water-containing preparations are stored for more than 6 hours.
- 366 (d) In the absence of sterility testing:
- 367 (A) A preparation must be properly stored prior to administration as follows:
- 368 (i) For a BUD not to exceed 24 hours, at controlled room temperature;
- 369 (ii) For a BUD up to three days, under refrigeration;
- 370 (iii) For a BUD up to 45 days, in solid frozen state at -20 °C.
- 371 (B) All nonsterile devices must be rinsed thoroughly with sterile, pyrogen-free water then
- 372 thoroughly drained or dried immediately before use;
- 373 (C) Terminal sterilization is required as follows:
- 374 (i) CSP solutions passed through a filter with a nominal porosity not larger than 1.2 micron
- 375 preceding or during filling into their final containers to remove particulate matter;
- 376 (ii) Sterilization of high risk level CSPs by filtration must be performed with a sterile 0.22
- 377 micron porosity filter entirely within an air quality environment better than or equal to ISO 5.
- 378 (4) Immediate-use:
- 379 (a) A compounded preparation intended for immediate use may be prepared in an air quality
- 380 environment that does not meet ISO 5 or better conditions and a preparer is not required to wear
- 381 gloves or gown, provided that it is prepared using aseptic manipulation, only sterile ingredients,
- 382 products, components and devices are used, and it meets all of the following conditions:

- 383 (A) No more than three sterile ingredients, products, components and devices are used;
- 384 (B) Only simple manipulation techniques employed;
- 385 (C) The preparer completes the preparation without interruption and with no direct contact
- 386 contamination;
- 387 (D) Administration must begin within one hour of preparation;
- 388 (E) If prepared by someone other than the person who will administer the drug, labeling must
- 389 include patient name, name and quantity of ingredients, name of person who prepared it, and
- 390 exact one hour BUD.
- 391 (b) Provided that such preparations do not involve the use of hazardous materials, they are
- 392 classified as "Low Risk".
- 393 (5) "Same day use": In this rule, the term "Same day use" means that the administration of the
- 394 preparation shall commence within 24 hours from the time of preparation. A same-day-use
- 395 product that is prepared using aseptic manipulation in a controlled environment with ISO 5 or
- 396 better class air quality conditions, using only sterile, ingredients, products, components and
- 397 devices, may be classified as Low or Medium risk provided that it meets all the following
- 398 conditions:
- 399 (A) Only simple manipulation techniques employed;
- 400 (B) The environment meets or exceeds the following conditions:
- 401 (i) The mixing cabinet is located in an area that restricts airflow to prevent drafts and reduce
- 402 particle counts;
- 403 (ii) There is a partitioned area around the mixing cabinet to create a buffer zone, which must be
- 404 at least the width of the hood in front of the mixing cabinet;
- 405 (iii) The buffer zone must be clearly identified to prevent cardboard or outer packing material
- 406 intruding into the buffer zone and to prevent any intrusion during the compounding process;
- 407 (iv) The environment is cleaned daily.
- 408 (C) The preparer completes the preparation without interruption and with no direct contact
- 409 contamination;
- 410 (D) Batch preparation will not exceed eight CSPs;
- 411 (E) Administration of the preparation must begin within twenty-four hours of preparation;
- 412 (F) The preparer must use gloves, shoe covers or dedicated shoes, hair covers, gown and mask.
- 413 (6) Single dose vial.
- 414 (a) The BUD shall be no greater than one hour from time of initial entry if accessed in an
- 415 environment worse than ISO 5:

- 416 (b) The BUD may be up to 24 hours from time of initial entry if appropriately stored and
- 417 accessed only in an environment better than or equal to ISO 5;
- 418 (c) Medications in a single dose ampoule may not be reused.
- 419 (7) Multi-dose vial. The BUD may be up to one month or the manufacturer's assigned BUD
- 420 whichever is shorter, from time of initial entry, in accordance with the pharmacy policies and
- 421 procedures.
- 422 Statutory/Other Authority: ORS 689.205
- 423 Statutes/Other Implemented: ORS 689.155
- 424 History:
- 425 BP 2-2008, f. & cert. ef. 2-20-08
- 426 **855-045-0260**
- 427 **Pharmacies and Equipment**
- 428 Minimum standards for pharmacies and equipment are dependent on the risk level of the
- 429 products being prepared.
- 430 (1) Pharmacies and equipment for the preparation of immediate-use CSPs shall be in accordance
- 431 with OAR 855-045-0250(4).
- 432 (2) Effective January 1, 2009, for preparation of low-risk level CSPs, an ISO 5 certified or better
- 433 Biological Safety Cabinet (BSC), or a Compounding Aseptic Isolator (CAI), or a Laminar
- 434 Airflow Hood (LAF) shall be used.
- 435 (3) Effective January 1, 2009, for preparation of medium-risk level CSPs, an ISO 5 certified or
- 436 better BSC, CAI or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or
- 437 better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or
- 438 better anteroom or area. These areas must have positive airflow unless used to prepare hazardous
- 439 drugs. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or
- better environment, or in accordance with the manufacturer's specifications.
- 441 (4) Effective January 1, 2009, for preparation of high-risk level CSPs, an ISO 5 certified or better
- 442 BSC, CAI, or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better
- 443 buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better
- 444 anteroom or area. Unless used to prepare hazardous drugs, the buffer room or zone shall have a
- 445 positive air pressure of 0.02 to 0.05-inch water column and may not contain a sink or drain.
- Surfaces and essential furniture in buffer rooms and zones and anterooms shall be nonporous,
- smooth, nonshedding, impermeable, cleanable and resistant to disinfectants. CAIs may be placed
- 448 in an area away from traffic and in a room with ISO 8 certified or better environment, or in
- 449 accordance with the manufacturer's specifications.
- 450 (5) Hazardous drugs must be prepared in compliance with state and federal regulations.
- 451 (6) Radiopharmaceuticals must be prepared in accordance with OAR 855-042-0005 through
- 452 0025.

453 (7) Pharmacy policies and procedures must include protocols for cleaning and monitoring that 454 include: (a) A cleaning policy that requires the cleaning of all work surfaces in ISO 7 and 8 areas to be 455 performed at least daily. Floors in ISO 7 and 8 areas cleaned at least daily. Surfaces that are used 456 to prepare CSPs must be cleaned either with a high-level disinfectant or with a medium-level 457 458 disinfectant that is alternated regularly with another medium-level disinfectant. Empty shelving, walls and ceilings in anterooms and buffer rooms will be cleaned at least monthly with 459 460 appropriate disinfectant solution; 461 (b) All ISO classified areas will be checked and certified by a qualified individual no less than every 6 months and whenever the LAF, BSC, or CAI is relocated or the physical structure of the 462 buffer room or anteroom has been altered: 463 (c) Maintenance, and documentation of maintenance, of all equipment in accordance with 464 manufacturer's specifications. 465 (8) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will 466 further public health or safety. A waiver granted under this section shall only be effective when 467 issued in writing. 468 Statutory/Other Authority: ORS 689.205 469 Statutes/Other Implemented: ORS 689.155 470 471 855-045-0270 472 Records 473 (1) Except for products prepared subject to OAR 855-045-0200(4)(c), aAll appropriate 474 compounding records, including training documents, master formulation records, 475 compounded preparation records, individual prescription records, and logs, formula 476 worksheets and documentation of the preparation, verification, dispensing or transfer of all 477 compounded products preparations must be maintained electronically or manually, stored in 478 479 an organized manner, retained for a minimum of three years and be **made readily** available for inspection by the Board. Records must be stored onsite for at least one year and may be 480 stored in a secure off-site location if retrievable within three business days. Required 481 records include, but are not limited to: 482 (a) Standard operating procedures, including documented annual review; 483 484 (b) Personnel training, competency assessment, and qualification records, including corrective actions for any failures, including glove tip test and aseptic technique validation. 485 The pharmacy must maintain a training record for each person, including temporary 486 personnel, who compound preparations. At a minimum, the record must contain: 487

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(A) Name and signature of the person receiving the training;

489 490	(B) Documentation of initial and continuing competency evaluation, to include dates and results of elements in the outlet's policies and procedures; and
491	(C) Name and signature of the PIC or other pharmacist/person employed by the pharmacy
492	who is designated as responsible for validation of the completion of all training.
493 494	(c) Engineering and environmental control records, including equipment, calibration, certification, environmental air and surface monitoring procedures and results, as well as
495	documentation of any corrective actions taken;
133	
496	(d) Cleaning and disinfecting of all compounding areas and equipment;
497	(e) Engineering and environmental control records,
498	(2) Records for compounding must utilize a master formulation record. All master
499	formulation records must be approved by the pharmacist for compounded preparations,
500	and records for all preparations The formula worksheets for compounding pharmacies,
501	excluding those for patient specific IV admixture products, must contain, at a minimum include
502	but are not limited to the following:
503	Additional discussion needed – re: non-patient specific and patient specific, and in various
504	practice setting (i.e. in-patient)
505	(a) The name, strength and dosage form of the preparation;
506	
507	(b) Physical description of the final preparation;
508	
509	(c) Ingredient identities and amounts;
510	
511	(d) Complete instructions for preparing the product, including equipment, supplies, and a
512	description of the compounding steps;
513	
514	(e) Calculations needed to determine and verify quantities of components and doses of
515	ingredients;
516	(f) Compatibility and stability information including references when availables
517	(f) Compatibility and stability information, including references when available;
518	(a) Powerd use data (PLID) assignment and staying requirements, including reference
519 520	(g) Beyond-use-date (BUD) assignment and storage requirements, including reference
520 521	source;
521	(h) Sterilization method utilized, when applicable. Methods include steam, dry heat,
522 523	radiation and filtration;
523 524	<u>า สนาสมงาก สิทิน 1ทิน สินิงมา</u>
524 525	(i) Quality control procedures and expected results; and
JZJ	(1) Quanty control procedures and expected results, and
526	(j) Appropriate ancillary instructions, such as storage instructions or cautionary
527	statements, including hazardous drug warning labels where appropriate.

- 528 (3) Any compounded product must be documented and the unique compounding record
- 529 <u>must include, but is not limited to, the following:</u>
- 530 (a) Drug name, and strength, and dosage form of the preparation;
- 531 (b) Physical description of the final preparation;
- 532 (c) Master formulation record reference for the preparation;
- 533 $\frac{\text{(b)}}{\text{(d)}}$ Quantity prepared;
- 534 (e) (e) Date and time prepared;
- 535 (d) (f) Pharmacy unique lot number;
- 536 (e) (g) Name, quantity, and Mmanufacturers' lot numbers and expiration dates of for all
- ingredients used to prepare and package compounded product;
- 538 (f) (h) Beyond Use Date;
- 539 $\frac{\text{(g)}}{\text{(i)}}$ Identity of verifying pharmacist;
- 540 (h) (j) Names <u>Identity</u> of all technicians personnel involved in each step of the process;
- 541 (I) Copy of the label used for the compounded product;
- 542 (j) Mixing instructions;
- 543 (k) Physical evidence of the proper weight of each dry chemical or drug used;
- 544 (j) Documentation of the proper weight and measurement of each ingredient;
- 545 (h) Pharmacist documented verification that the correct formula, calculations, and the
- 546 correct **measurements** weights or volumes of chemical or drugs were used;
- 547 (m) Certification of completion of any additional testing, including endotoxin, required by the
- 548 pharmacy's policies and procedures
- 549 (l) Total quantity compounded;
- 550 (m) BUD assignment and storage requirements, including reference source, if differs from
- 551 master formulation record;
- (n) Description of final preparation and Product Identification Label (PIL);
- 553 (o) Documentation of any quality control issue and any adverse reaction or preparation
- problem, including those reported by the patient, caregiver, or other person, to include
- 555 corrective actions for any failure.
- 556 $\frac{\text{(n)}}{\text{(p)}}$ Any other information required by the pharmacy's policies and procedures.

557	(d) In the case of a patient specific parenteral admixture, the pharmacist does not need to compl		
558	with the worksheet and log requirements in these rules provided that a quality assurance process		
559	is in place to address drug recalls, and appropriate safeguards are in place.		
560	POLICY DISCUSSION:		
561			
562	(3) (4) Record of maintenance and certifications for all equipment must be retained for a		
563	minimum of three years and be available for inspection by the Board. Compounding activity		
564	that is not pursuant to a valid prescription or an order to prepare for administration and		
565	for a specific patient is considered to be manufacturing, and any person engaged in		
566	manufacturing must be registered in accordance with Division 060, with the following		
567	exceptions:		
568			
569	(a) Compounding in anticipation of a prescription drug order or an order to prepare for		
570	administration, based on routine, regularly observed patterns; or		
370	definition, bused on Touthie, regularly, observed patterns, or		
571	Is more clarification needed here?		
572 573	Pursuit of patient safety – we are seeing more pharmacies centralize compounding processes and "batching"		
574	Not enough 503Bs to meet all need yet. More to come on the "1 mile radius"		
575	(b) Preparing non-controlled compounded products by an Oregon pharmacy for a		
576	practitioner located in Oregon, documented by use of Board approved Shared Pharmacy		
577	Services agreement.		
578			
579	Regarding shared services:		
580	-Bring back veterinary specific rules to allow SS for vet		
581			
582	Statutory/Other Authority: ORS 689.205		
302 583	Statutes/Other Implemented: ORS 689 155		

Oregon Board of Pharmacy

585 586	855-006-0005 Definitions	
587	As used in OAR chapter 855:	
588 589 590 591	(28) "Shared Pharmacy Service" means a written agreement, that has been approved in writing by the board, that exists for the processing by a pharmacy of a request from another pharmacy or a practitioner licensed to prescribe the drug, to fill or refill a prescription or a drug order, or to perform processing functions including but not limited to:	
592	(a) Dispensing;	
593	(b) Drug utilization review;	
594	(c) Claims adjudication;	
595	(d) Refill authorizations;	
596 597	(e) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon for Oregon outlets and practitioners located in Oregon only; and	
598	(f) Therapeutic interventions.	

Minutes	Public Health and Pharmacy Formulary Advisory Committee Meeting May 3, 2019, 8:30am Portland State Office Building, 800 NE Oregon St. Portland, OR 97232 Conference Room 1E			
Committee Members □ Evon Anukam, F □ Kat Chinn, RN M □ Sean Jones, MD □ Amy Valdez, RP	Mark Helm, MD Helen Turner, DNP			
OBOP Staff to Commit ☐ Joe Schnabel, Ex ☐ Fiona Karbowics				
Agenda Item	Desired Outcome			
Welcome	Agenda review and approval Motion to approve agenda was made and unanimously carried (Motion by Turner, second by Helm). 2.1.19 Minutes review and approval Motion to approve 2/1/19 Minutes was made and unanimously carried (Motion by Jones, second by Turner).			
Committee Business	There were no high priority items to discuss. There have been no new concepts submitted for Committee review. Committee discussions: Pharmacist Consultant Fiona Karbowicz provided the Committee with a presentation to address: 1. Welcome new Executive Director Joe Schnabel, 2. Statutory and legal scope review, 3. Committee business, focusing on expectations and processes, 4. Committee business, reviewing Committee recommendations Executive Director Joe Schnabel introduced himself and thanked the Committee for their excellent and groundbreaking work so far and for work that is to come. Statutory and Legal Scope Review: ORS 689.649 states that the Committee shall recommend a formulary of drugs and devices that a pharmacist may prescribe and dispense to a patient: Items must be pursuant to a diagnosis by a health care practitioner qualified to make the diagnosis and who has prescriptive authority (ORS 689.645) The Board may adopt the recommendations by rule The Committee shall periodically review the formulary and recommend revisions to the board			

devices such as diabetic testing supplies, emergency refills of insulin, albuterol

inhalers, epinephrine autoinjectors, smoking cessation aids, discharge medications for transitions of care, rapid strep tests and spacers."ORS 679.645 states that a pharmacist may provide approved patient care services

pursuant to a statewide drug therapy management protocol:

- Developed by the Public Health and Pharmacy Formulary Advisory Committee; and;
- Adopted by rule of the Board.
- Patient care services include smoking cessation and travel health services are mentioned in statute
- Pharmacist to establish 'P&Ps/protocols' for the prescription and administration
 of vaccines and the provision of patient care services [under sub (1) which allows
 a pharmacist to provide patient care services via statewide drug therapy
 management protocols developed by the Committee]
- Note: For the purposes of the conversation and past minutes (10/26/2018), a statewide protocol consists of a standardized patient assessment process and treatment care plan under which a pharmacist may prescribe and dispense a drug or device to a patient, pursuant to legal scope articulated in ORS 689.

o Board Rules overview:

- Division 019 added a rule to establish an Oregon pharmacist's authority to prescribe pursuant to scope authorized by 2017 HB 2397
- Division 020 Codify recommendations of items added to the Formulary and Protocol Compendia; Codify the "core elements" that all prescribing processes must adhere to, including:
 - Oregon pharmacist, located and licensed in Oregon only; responsibility to recognize limits of own knowledge and experience – refer when necessary
 - Utilize drug therapy management protocol based on current clinical guidelines, including inclusion, exclusion and referral criteria
 - Collect subjective and objective info about patient's health history and clinical status
 - Evaluate and develop individualized patient care plan, within parameters (when defined)
 - Implement care plan, including treatment goals, monitoring and follow-up
 - Notify patient's care provider(s) within 5 days of issuing prescription
 - Maintain records (visit summary, dispensing files, etc.)
- Check and adjust": Rule edits need to be drafted need to align processes with statute, in particular OAR 855-020-0110(3) will need to be re-written to make it clear that a pharmacist may prescribe via post-diagnostic drugs and devices adopted by Board rules on the Formulary Compendia or via statewide drug therapy management protocols developed by the Committee and adopted by Board rules on the Protocol Compendia. The statute does not permit a pharmacist to create his/her own protocol; rather, a pharmacist may provide approved patient care services pursuant to the statewide drug therapy management protocol that is developed by the Committee and adopted by rule of the Board. A pharmacist may develop policies and procedures to implement and document the provision of patient care services pursuant to the statewide drug therapy management protocol.
- The Committee and staff had a robust discussion about what a "sample" statewide drug therapy management protocol will look like, particularly regarding the level of detail needed. Is this still considered "pharmacist prescribing"? Yes, due to scope of practice articulated by Oregon law; the scope and risk are connected to the pharmacist.

- 3. Committee Business, Expectations and Processes:
 - Pharmacist Consultant Karbowicz outlined the roles and responsibilities for Committee members, Board members and the staff that works to integrate each.
 - Committee members meet regularly to develop, recommend and review items on the formulary and statewide drug therapy management protocols. They discuss and provide unified recommendations and revisions, via formal vote, to the Board's Formulary and Protocol lists. A focus is on assessment of clinical elements and are tasked with anticipating patient safety "boundaries" such as pharmacist education, assessment details (i.e. inclusion/exclusion criteria), and required care plan elements, etc.
 - Board members focus on patient safety and legal scope by promulgation of rules and/or policy, including interpretation of laws defining Oregon pharmacist scope of practice. They review Committee recommendations and create rules for addition to the Formulary and Protocol lists. They remain aware of and help facilitate implementation, for patient access to safe provision of pharmacy services. Additionally, they direct compliance and enforcement.
 - Staff is tasked with legal scope review, as defined in statute, rules and policy, at direction from the Executive Director, Legal Counsel, etc. Staff is also tasked with general process, including monitoring and preparing concepts submitted, acquiring SMEs, meeting facilitation and creating draft agendas/minutes. Additionally, staff is to facilitate all communications between the Board, Committee and stakeholders (including pharmacists, pharmacies, the public, etc.); all communications are subject to public record which must be managed appropriately pursuant to state agency requirements.
 - Regarding expectations and processes:
 - For Committee business and communications, we must utilize the formulary email (cc'd correspondence). It is pharmacy.formulary@oregon.gov
 - Outreach is created by staff and speaker(s) determined by Executive Director; any inquiries, such as from the pharmacy associations to be directed to Executive Director
 - If Committee and Board members receive inquiries related to the regulations, implementation, etc. please pass along to Executive Director for prompt attention by appropriate staff member – legal scope is not discretionary
 - We will be scheduling an annual (or semi-annual) meeting devoted to review of prior items added for clinical appropriateness;
 - Any Committee member may make a request for an item to be reviewed for Formulary/Protocol recommendation – make request via form and cc the formulary email
- 4. Committee Business, Reviewing Recommendations
 - We are continuing development of a clear and consistent methodology for Committee to utilize for reviewing items, in order for a consistent review process which can help properly "build" each concept/recommendation. We will continue to work through the process for the management and distribution of the protocols, particularly pursuant to Board direction. Additionally, the Committee plans to utilize the 'minutes review' meetings to assess any new concepts, to essentially determine the first analysis question, "Is this a concept the Committee wants to consider?" It is anticipated the phone call may take longer by incorporating this preliminary review; this may adjust the timing of the phone call meetings – staff to evaluate and bring back for further discussion and scheduling,

though some is a "wait and see", depending on the number of concepts that continue to be submitted, or not. Analysis questions include: Is this a post-diagnostic drug or device? Or, is this suited for a statewide drug therapy management protocol? Are clinical parameters needed? This includes the development of standardized patient assessment process and treatment care plan, with defined inclusion, exclusion and referral criteria, based on current and referenced clinical guidelines, and articulating any prescribing parameters, monitoring requirements and follow-up. Is a Subject Matter Expert (SME) needed? Is there a specific clinical guideline or other mandated resource required? Does the Committee want to recommend an additional mandated education requirement? The Committee proceeded to re-review the concepts discussed at the January 11, 2019 meeting, considering them as statewide drug therapy management protocols. Fiona entered the January discussion elements in to a slide for each item, to engage Committee dialogue. The general plan is to request SMEs to return to future meeting(s) to continue work on level of depth required. Legal counsel and Board direction will be needed. Smoking Cessation - non-NRT **Pre-Travel Consult Medications** Non-Occupational Post Exposure Prophylaxis (nPEP) Additional points shared during Committee dialogue included: Updates should be made to the Concept Intake Form, to provide additional clarity to what the Committee and Board are seeking when a concept is submitted. Regarding new items received, staff will shift from a general "pass along" to a more detailed "work-up" moving forward, in attempt to bring forth solid "packages" of items for Committee and Board review. This will require additional staff resources; the 0.5FTE pharmacist position is envisioned to assist. Helpful verbiage may be found in OAR 855-019-0260, Collaborative Drug Therapy Management **Upcoming Meeting** Next meeting Schedule – subject to May 29, 2019 at 6:00pm – (brief conference call to approve minutes – note date change and time change; call to include pre-view of any new concepts) ➤ July 12, 2019 – room 1E • TBA – (brief conference call to approve minutes and pre-view new concepts) October 25, 2019 – room 1D • TBA – (brief conference call to approve minutes and pre-view new concepts)

Motion to adjourn at 12:57PM was made and unanimously carried (Motion by Turner, second by Helm)

Public Health and Pharmacy Formulary Advisory Committee

2019



Objectives

- · Statute and Legal Scope Review
- · Committee Business Expectations and Processes
- · Committee Business Review of Committee Recommendations

Statutory Directives

ORS 689.649(7) states that the Committee shall recommend a formulary of drugs and devices that a pharmacist may prescribe and dispense to a patient

- Items must be pursuant to a diagnosis by a health care practitioner qualified to make the diagnosis
- · The Board may adopt the recommendations by rule
- The Committee shall periodically review the formulary and recommend revisions to the board

Statutory Directives

ORS 689.645(1)(b) states that a pharmacist may provide approved patient care services pursuant to a statewide drug therapy management protocol

- Developed by the Public Health and Pharmacy Formulary Advisory Committee; and
- · Adopted by rule of the Board
- Patient care services include smoking cessation and travel health services

Statutory Directives

ORS 689.645(4-6) states that the Board shall adopt rules:

- Requiring pharmacists to establish protocols for the prescription and administration of vaccines... and the provision of patient care services [under subsection (1) – which allows a pharmacist to administer vaccines, and provide patient care services via statewide drug therapy management protocols developed by the Committee]
- To establish the formulary of drugs and devices, that a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis
- The formulary may include post-diagnostic drugs and devices such as diabetic testing supplies, emergency refills of insulin, epinephrine autoinjectors, smoking cessation aids, discharge medications for transitions of care, rapid strep tests and spacers

Board Rules – Divisions 019 and 020

- Division 019
 - Establish an Oregon pharmacist's authority to prescribe pursuant to scope authorized by 2017 HB 2397 (located and licensed in Oregon)
- Division 020
 - · Codify the "core elements" that all prescribing processes must adhere to, including:
 - · RPH responsibility to recognize limits of own knowledge and experience refer when necessary
 - Utilize drug therapy management protocol based on current clinical guidelines, including inclusion, exclusion and referral criteria
 - · Collect subjective and objective info about patient's health history and clinical status
 - · Evaluate and develop individualized patient care plan, within parameters (when defined)
 - · Implement care plan, including treatment goals, monitoring and follow-up
 - · Notify patient's care provider(s) within 5 days of issuing prescription
 - · Maintain records (visit summary, dispensing files, etc.)
 - Codify recommendations of items added to Compendia
- · We will be drafting rule edits needed to align processes with statute
 - · OAR 855-020-0110(3)

Roles and Responsibilities

PHPFAC Members

- Meet regularly to develop, recommend and review;
 - · Formulary; and
 - Statewide Drug Therapy Management Protocols
- Discuss and provide unified recommendations and revisions (via formal vote) to the Board's Formulary and Protocol lists
 - · Assess clinical elements
 - Anticipate patient safety "boundaries", such as RPH education, inclusion/ exclusion criteria, required care plan elements, etc.

Staff

- Legal scope defined by statute, rules and policy (direction from Executive Director, Legal Counsel, etc.)
- All communications between Board, Committee and stakeholders (pharmacists, pharmacies, public, etc.)
- General process, including monitoring/preparing concepts submitted, acquiring SMEs, meeting facilitation, agendas/minutes
- Communications subject to public record (to be managed appropriately by state agency requirements)

Board Members

- Legal Scope -Promulgates rules and/or policy for Oregon pharmacist scope of practice
- Reviews Committee recommendations and promulgates rules for addition to Formulary / Protocol lists
- Facilitate implementation – patient access to safe pharmacy services
- Compliance and enforcement

Expectations

- · Utilize formulary email for all communications
 - · Pharmacy.formulary@oregon.gov
- · Outreach is created by staff and speaker(s) determined by Executive Director
- If Committee and Board members receive inquiries related to the regulations, implementation, etc. please pass along to Executive Director for prompt attention by appropriate staff member – legal scope is not discretionary
- We will be scheduling an annual (or semi-annual) meeting devoted to review of prior items added for clinical appropriateness
- Any Committee member may make a request for a item to be reviewed for Formulary/ Protocol recommendation – make request via form and cc the formulary email

Review – Committee Recommendations

- · Continuing development of consistent methodology for Committee to review items
 - · Consistent review process
 - · Helps to properly "build" each recommendation
- · Analysis questions include:
 - · Is this a concept that the Committee wants to consider?
 - Is this a post-diagnostic drug or device? Or, is this suited for a statewide drug therapy management protocol?
 - Clinical parameters needed? Development of standardized patient assessment process and treatment care plan, with defined inclusion, exclusion and referral criteria, prescribing parameters, monitoring requirements, follow-up.
 - · Is a Subject Matter Expert (SME) needed?
 - · Is there a specific clinical guideline or other mandated resource required?
 - Does the Committee want to recommend an additional mandated education requirement?

- · Is this a concept that the Committee wants to consider? YES
- Is this a post-diagnostic drug or device? Or, is this suited for a statewide drug therapy management protocol? ADD TO PROTOCOL LIST — Which drugs? Bupropion and Varenicline (others?)
- Is a Subject Matter Expert (SME) needed? Yes, RPH KL provided concept and detailed background information
- · Is there a specific clinical guideline or other mandated resource required? Addressed below
- · Clinical parameters:
 - Development of standardized patient assessment process STANDARDIZED QUESTIONNAIRE (to include all elements presented, as well as PHQ2 and suicide question)
 - Defined exclusions: < 18, positive screen on PHQ2, yes on suicide question, or any other elements from questionnaire
 - Defined referrals; PER MENTAL HEALTH ASSESSMENT TOOL and PROVIDE OREGON SUICIDE HOTLINE (or similar) and ACTIVE REFERRAL TO QUIT LINE (or equivalent)
 - Prescribing: $1^{\rm st}$ RX UP TO 30 DAYS, MAX DURATION 12 WEEKS, MAX FREQUENCY 2x in ROLLING 12 MONTHS
 - · Follow-up: WITHIN 7-21 DAYS (Phone consult permitted)
- Does the Committee want to recommend an additional mandated education requirement? 1 TIME COURSE, MINIMUM 2 HOURS CE

Smoking Cessation - nonNRT

CONCEPT

Preventative travel medications including:

- 1. Malaria Prophylaxis: chloroquine, atovaquone/proguanil, mefloquine, doxycycline
- 2. Traveler's Diarrhea Prevention and Treatment: ciprofloxacin, azithromycin
- 3. Acute Mountain Sickness (Altitude Sickness) Prophylaxis: acetazolamide
- 4. Motion Sickness: Scopolamine patches, promethazine tablets/suppositories, medizine tablets
 These medications would be prescribed in accordance to the recommendations outlined in the CDC Health
 Information for International Travel guidelines (Yellow Book)

Per January 11, 2019 minutes:

- The Committee discussed a desire to provide recommendations to the Board in a format that would permit a pharmacist to utilize current guidelines and not to specify specific drug classes, drugs or devices.
- Staff stated that the law states that the Committee is to provide recommendations to the Board via drug
 or device but that there is a specific carve out to allow for protocol recommendations for travel
 medications and smoking cessation.
- · Staff stated that they would confer with counsel on this and inform the Committee on how to proceed.

Pre-Travel Consult Medications

- · Is this a concept that the Committee wants to consider? YES
- Is this a post-diagnostic drug or device? Or, is this suited for a statewide drug therapy management protocol? ADD INDIVIDUAL ITEMS TO PROTOCOL LIST
- · Is a Subject Matter Expert (SME) needed?
- · Is there a specific clinical guideline or other mandated resource required?
- · Clinical parameters:
 - Standardized patient assessment process INCL. ROUTINE VACCINATION ASSESSMENT
 - · Defined exclusions:
 - · Defined referrals:
 - · Prescribing:
 - · Follow-up:
- · Does the Committee want to recommend an additional mandated education requirement? YES:
 - COMPLETE APhA IMMUNIZATION TRAINING (or equivalent) PLUS 4 HOUR TRAVEL VACCINATION CLASS (or equivalent)
 - o COMPLETE 1 HOUR TRAVEL MEDICATION-RELATED CE EVERY 2 YEARS

Pre-Travel Consult Medications

CONCEPT

Time-sensitive access to non-occupational post-exposure prophylaxis (nPEP) treatment

- Tenofovir disoproxil fumurate 300 mg/emtricitabine 200 mg (Truvada) one tablet by mouth daily, plus either raltegravir 400 mg (Isentress) one tablet by mouth twice daily; OR
- · Dolutegravir 50 mg (Tivicay) one tablet by mouth daily for 28 days

Per January 11, 2019 minutes:

- The Committee discussed a desire to say "Follow per nPEP clinical guideline and chose appropriate drug and durations". If not, then they would like to recommend by drug class.
- · Discussion to be continued at next meeting

Non-Occupational Post Exposure Prophylaxis (nPEP)

- · Is this a concept that the Committee wants to consider? YES
- Is this a post-diagnostic drug or device? Or, is this suited for a statewide drug therapy management protocol? ADD INDIVIDUAL ITEMS TO PROTOCOL LIST
- · Is a Subject Matter Expert (SME) needed?
- Is there a specific clinical guideline or other mandated resource required?
- · Clinical parameters:
 - · Standardized patient assessment process
 - · Defined exclusions:
 - · Defined referrals: MANDATORY REPORT OF ABUSE of MINORS
 - · Prescribing:
 - Follow-up:
- · Does the Committee want to recommend an additional mandated education requirement?

Non-Occupational Post Exposure Prophylaxis (nPEP)

Suzanne McClelland (RPH-0013479): Waiver Request

S

Situation: Waiver Request – PIC of multiple pharmacy drug outlets

• RPH Suzanne McClelland (PIC-0013479) seeks approval to be the PIC at Bay Area Hospital to oversee three pharmacies.

B

Background:

- Regulations:
 - OAR 855-019-0300(3) A pharmacist may not be designated PIC of more than two pharmacies without prior written approval by the Board. If such approval is given, the pharmacist must comply with the requirements in sub-section (4)(e) of this rule.
 - OAR 855-019-0300(4)(e) The PIC must perform the following the duties and responsibilities: A pharmacist designated as PIC for more than one pharmacy shall personally conduct and document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC Compliance Audit Form provided by the Board

Description, as provided by PIC Suzanne McClelland:

- Nothing has changed in the hospital's course of business, however, we have been notified that our Cancer Center registration will need to change from a drug room over to retail drug outlet because we have a pharmacist at the center from open to close (7:00-17:30). We understand that if the Board gives Bay Area Hospital PIC a waiver that a quarterly compliance audit must be conducted at both locations on the form provided by Board.
- The Cancer Center registration is changing from a drug room registration to a pharmacy registration and will need a PIC.
- PIC McClelland currently conducts daily huddle meetings to discuss operations/patient care and physically is present several time a month to oversee processes and general communication with the Cancer Center.
- Contact information:

Suzanne McClelland, BS, PharmD, PhD, Bay Area Hospital Interim Directory of Pharmacy 1775 Thompson Rd Phone: 541-269-8490 Coos Bay, OR 97420



- Drug outlet registrations impacted are:
 - o IP-0000616 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay)
 - o RP-0000822 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay)
 - DR-0000050 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay-transitioning to RP)

R

Recommendations:

Staff recommendation for approval: Grant (5 year; traditional language)

Inquiry Date: 4/10/2019

Board review: June 2019 meeting

Diabetes Community Care Team Charitable Pharmacy (CP-000015): Waiver Requests (2) and Rule Clarification inquiry

S

Situation: Waiver Requests (2) related to donations and distribution/dispensing of insulin

- Diabetes Community Care Team (DCCT)(CP-000015) is seeking waiver to 2 rules in Div 044-Charitable Pharmacies
 - OAR 855-044-0050(1)(d)
 - o OAR 855-044-0050(1)(j)
- DCCT is requesting clarification of OAR 855-044-0030(5)(a)

3

Background:

- Regulations: ORS 689.770 through 689.780 and Division 044 Charitable Pharmacies
 - OAR 855-044-0050(1)(d)
 - OAR 855-044-0050(1)(j)
 - o OAR 855-044-0030(5)(a)
 - OAR 855-041-1045 (Returned Drugs and Devices)

Description, as provided by RPH Julie Dewsnup:

- DCCT's request is for a permanent waiver of these requirements, as they would be unduly burdensome to the goals of DCCT and detrimental to the health of the community, as documented (see pg. 3-4)
- DCCT's contact information:

Julie Dewsnup, RPh, CDE, AAHIVP

DCCT Executive Director

2101 Bailey Hill Rd., Suite D

Fax: 541-600-8149

Eugene, OR 97405



Regarding the requested waivers, the following items are provided for the Board: Rule History

Division 044 – Charitable Pharmacies rules were originally adopted in June 2010. There were amendments made in 2014 and 2017, to add waiver language to certain regulations as implementation realities created challenges for some charitable pharmacies.

Waiver History

Over the years, the Board has approved waiver requests for a number of different charitable pharmacies (including Central City Concern, Outside In, Providence Charitable and Volunteers in Medicine) particularly for the following rules:

OAR 855-044-0030(2)(a) \rightarrow lot numbers

OAR 855-044-0050(1)(a), (1)(d) and (1)(j) \rightarrow general, exp date <9mo, refrigeration OAR 855-044-0070(1)(b) and (2)(d) \rightarrow lot numbers

Regarding the requested rule clarification, the following items are provided for the Board: Related FAQs:

Q: Who can bring in drugs for donation?

A: Anyone, but donated drugs must meet the criteria laid out in the rules and the pharmacist may always use their discretion as to whether or not the drug is safe and appropriate for redispensing.

Q: Will prescription drugs that were dispensed in a standard prescription vial, to an individual patient who manages their own medications, be accepted for re-dispensing? A: No.

<u>NABP's Position Statement</u> on the Return and Reuse of Prescription Medications in the Community Pharmacy Setting. Highlights include:

- Returned and reused medications refer to those medications that have been removed from the pharmacy for delivery by pharmacy staff, a pharmacy contracted delivery service, or an approved common carrier and returned because the product is not deliverable or the patient refuses delivery and such medications have not left the control of the pharmacy staff, pharmacy contracted delivery service, or approved common carrier. Medications that have been delivered to the patient cannot be returned and reused.
- The return and reuse of prescription drugs in institutional pharmacy settings is legal in most, if not all, states and is a very common and safe practice. In the community pharmacy setting, however, this has not been the case. In recent years, a number of states began legalizing and even implementing a charitable form of return and reuse "prescription drug repository" or "prescription drug donation" programs.
- These programs, however, are contrary to most state pharmacy practice acts and regulations, as well as laws, regulations, and policies enacted at the federal level. In fact, FDA's Compliance Policy Guide on the Return of Unused Prescription Drugs to Pharmacy Stock directly states that "[a] pharmacist should not return drug products to his stock once they have been out of his possession" because of the inability to assure drug "strength, quality, purity or identity."
- In an attempt to determine consensus on this issue, NABP convened the Task Force on Medication Collection Programs in December 2008. The charge of the task force was to evaluate the status of medication collection programs throughout the country; review state and federal laws and regulations, including those administered by the United States Drug Enforcement Administration, applicable to medication collection programs; suggest possible medication collection program protocols compliant with current, applicable state and federal laws and regulations; and recommend revisions, if necessary, to the Model Act
- Task force members acknowledged that medications dispensed in institutional settings within a closed distribution system may be appropriate for reuse; however, members concluded that, because the medications leave the closed distribution system, programs based in the community pharmacy setting necessitate different requirements to ensure patient safety. Members concurred that any medication reuse program must comply with all state and federal regulations, including standards of the USP

Recommendations:

Staff recommendation for waiver requests: Grant (5 year; traditional language) Staff recommendation for rule clarification: Board discussion

Inquiry Date: 4/19/2019

Board review: June 2019 meeting

Date: 4/19/2019

Waiver Request:

The Diabetes Community Care Team (DCCT), a recently opened charitable pharmacy (CP-000015, issued 3/19/2019) specializing in treating individuals with diabetes in Eugene and the surrounding areas, is requesting waiver of several of the Oregon Administrative Rules regarding the acceptance and distribution of certain drugs by charitable pharmacies.

Specifically, DCCT is requesting waiver of the requirements in OAR 855-044-0050(1)(d) and (j) stating that: A charitable pharmacy may not distribute a donated prescription drug that:

- (d) Bears an expiration date that is less than nine months from the date the drug is donated; [or]
- (j) Requires refrigeration.

DCCT is also requesting clarification on 855-044-0030 (5)(a). DCCT was told on licensure that they could not accept donations from individuals. The OAR(s) currently state:

- (5) A charitable pharmacy may accept a drug from:
- (a) An individual;

DCCT's request is for a permanent waiver of these requirements, as they would be unduly burdensome to the goals of DCCT and detrimental to the health of the community, as documented below.

• Related OARs: 855-044-0050(1)(d); 855-044-0050(1)(j); 855-044-0030(5)(a)

Background:

(Include need, how this will further public health, scale of impact on patients, impact on staff)

DCCT requires the wavier of these requirements in order to achieve its goals of providing assistance and medication to the diabetic community of Eugene and the surrounding area. The primary medication required to treat diabetes is insulin. One of the main purposes of DCCT obtaining a license to act as a charitable pharmacy is to provide a means for diabetics to obtain the insulin they need, even if they do not have access to insurance or sufficient financial resources to purchase the insulin themselves. As shown by the recent surge in news stories, congressional hearings and other well-publicized events, there is a great deal of concern regarding the high price of insulin. For diabetics, access to insulin is a matter of life and death, in a very literal sense. Unfortunately, even with the high level of interest in the subject of insulin prices, there are still many people who do not have access to the insulin they need to live. As noted before, addressing this issue is one of the primary purposes of DCCT.

The regulations at issue here prohibit DCCT from distributing insulin entirely, since 855-044-0050(1)(j) specifically prohibits distribution of drugs requiring refrigeration. Although there are still a few other things DCCT could do through its charitable pharmacy work, the inability to distribute insulin is a severe impediment to DCCT's work. Since nearly all forms of insulin require refrigeration, this requirement effectively prohibits DCCT from providing the one thing its patients need most. The scale of the impact

on the patients who cannot receive the insulin they need is difficult to overstate. Complications from high blood sugar can include loss of eyesight, loss of limbs, brain damage and even death if left untreated. DCCT's goal is to provide a way for individuals who need insulin but cannot afford it to get it, but that goal is not possible without a waiver of the refrigeration requirement. DCCT is requesting waiver for all diabetes medications that require refrigeration, with insulin being the top priority.

OAR 855-044-0050(1)(d) prohibits distribution of drugs that were donated less than nine months from their listed expiration date. This requirement would also create a substantial hardship for DCCT to fulfill its goal of providing life-saving insulin to those who need it. As with all medications, insulin has a limited shelf-life. If stored properly in the refrigerator, it can last many months. Once it is removed from the refrigerator, it must be used within a few weeks. For most diabetics, using one vial or pen of insulin within a few weeks is not a problem, as they will often require multiple vials or pens per month to properly manage their blood sugars. Assuming these waivers are granted, DCCT expects to cycle through the insulin it receives very quickly—far more quickly than that nine-month window. And for the individuals receiving the insulin, they will use it almost immediately. Insulin is not the type of drug that sits around on the shelf and rarely gets used. Most diabetics use it multiple times a day, every single day. The risk of the insulin not being used prior to its expiration date is very small and DCCT will carefully monitor expiration dates to ensure it stays that way.

If DCCT is required to abide by the requirements of 855-044-0050(1)(d), it will greatly reduce the amount of insulin DCCT is able to accept from donors and distribute to its patients. Most individuals or entities who would have insulin available to donate will do so either with no regard to the expiration date or with the thought that they should donate because it will expire soon and it should be used by someone. DCCT will likely have to refuse or destroy a significant amount of insulin because of this rule, which would be detrimental to the health of the community. It is difficult to estimate exactly how much insulin would be unavailable to the community and the impact that would have, but if even one person cannot get the insulin he or she needs because of this rule, that is one too many. Of course, if the rule is waived, DCCT will implement procedures to ensure that any insulin it receives is distributed with sufficient time to allow the patient to use the insulin well before the expiration date.

If DCCT does not receive a waiver of these rules, it will have a real and significant impact on the health of the diabetic community in and around Eugene. Under the current rules, DCCT cannot distribute insulin through its charitable pharmacy program. There are many people out there struggling to pay for their insulin and DCCT could offer a way for them to get the medication they desperately need. In order to make that happen, however, DCCT needs to be able to receive and distribute insulin through its charitable pharmacy operations, which requires a waiver of the rules.

Author's Contact Info:

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- **689.770 Definitions for ORS 689.770 to 689.780.** As used in ORS 689.770 to 689.780, "the Charitable Prescription Drug Program" means a drug outlet that has:
 - (1) A valid certificate of registration issued by the State Board of Pharmacy;
 - (2) Volunteered to participate in the Charitable Prescription Drug Program; and
- (3) Been approved by the board to accept and distribute to needy individuals donated prescription drugs through the program. [2009 c. 300 \$2]
- **689.772** Establishment of program; immunity from liability; rules; fee. (1) There is created in the State Board of Pharmacy the Charitable Prescription Drug Program. The purpose of the program is to distribute donated prescription drugs to needy or uninsured individuals. Participation in the program is voluntary.
 - (2) The program may accept and distribute within this state:
- (a) Prescription drugs received as donations in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug;
 - (b) Sealed single unit dose packages received in opened packages containing multiple single unit doses; and
- (c) Prescription drugs received as donations and repackaged by another charitable prescription drug program.
- (3)(a) Except as provided in paragraph (b) of this subsection, the Charitable Prescription Drug Program may not distribute donated prescription drugs that:
 - (A) Fail to meet the requirements of this section;
 - (B) Bear an expiration date that is less than nine months from the date the drugs are donated;
 - (C) Are adulterated or misbranded; or
- (D) Belong to a category of controlled substances that may not be distributed under the program as adopted by the board by rule pursuant to ORS 689.774.
- (b) The board may waive a requirement of this subsection if the board determines that the waiver is in the interest of public health and safety. A waiver under this subsection must be issued in writing in accordance with rules adopted by the board.
 - (4) The program shall:
- (a) Require a donor of a prescription drug to complete and sign a donor form, adopted by rule by the board, releasing the prescription drug to the program for distribution under the program and certifying that the donated prescription drug has been properly stored and has never been opened, used, adulterated or misbranded;
- (b) Require that the pharmacist will use professional judgment, based on a visual inspection, to verify compliance with this section and rules adopted by the board under ORS 689.774;
- (c) Properly dispose of all prescription drugs received as donations that do not meet the requirements of this section and rules adopted by the board under ORS 689.774;
- (d) Maintain separate confidential files for individuals receiving donated prescription drugs through the program;
 - (e) Eliminate personal information from the labels of donated prescription drugs;
- (f) Maintain a separate inventory of donated prescription drugs received by the program and transferred to another charitable prescription drug program;
 - (g) Store donated prescription drugs in a secure location to be used exclusively for the program;
 - (h) Report to the board on the activities of the program in the form and manner required by the board; and
- (i) Require a recipient of a donated prescription drug to sign a form, as adopted by the board by rule, attesting that the recipient has been notified by the program that:
 - (A) The prescription drug distributed to the recipient was donated to the program;
- (B) A visual inspection was conducted by a pharmacist to ensure that the donated prescription drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging or has been repackaged by another charitable prescription drug program;
- (C) A pharmacist has determined that the donated prescription drug is safe to distribute based on the accuracy of the donor's form and the visual inspection by the pharmacist; and
 - (D) Participants in the program are immune from liability as provided in ORS 689.780.
- (5) The program may not charge a fee for accepting a donation but may charge a fee established by the board by rule for distributing a donated prescription drug.

- (6) The program may not sell any prescription drugs received as a donation through the program.
- (7) The program may distribute donated prescription drugs that it received from another charitable prescription drug program only to an individual with a new prescription for prescription drugs who meets the requirements of ORS 689.778.
- (8) The program may refuse to accept from a donor a prescription drug that, upon visual inspection, appears not to qualify for distribution under this section or rules adopted by the board under ORS 689.774.
 - (9) The program may distribute donated prescription drugs to:
 - (a) Another charitable prescription drug program, subject to subsection (7) of this section; or
- (b) An individual with a new prescription for prescription drugs who meets the requirements of ORS 689.778. [2009 c.300 §3; 2013 c.95 §1; 2016 c.14 §1]
- **689.774 Rules.** The State Board of Pharmacy shall adopt rules to carry out ORS 689.770 to 689.780, including but not limited to:
- (1) Specifying categories of prescription drugs that the Charitable Prescription Drug Program may not distribute under the program;
 - (2) Prescribing the forms described in ORS 689.772;
 - (3) Establishing the criteria for licensure and regulation under the program;
- (4) Establishing standards and procedures for accepting, storing, repackaging, distributing, shipping and disposing of donated prescription drugs under the program;
- (5) Establishing standards and procedures for inspecting donated prescription drugs to ensure that the drugs comply with the requirements of this section and ORS 689.772; and
 - (6) Establishing record keeping and reporting requirements for the program. [2009 c.300 §4; 2016 c.14 §2]
- **689.776 Inspection; audit.** The State Board of Pharmacy shall ensure compliance with ORS 689.770 to 689.780 by:
 - (1) Inspecting the Charitable Prescription Drug Program on a regular basis; and
- (2) Auditing records required to be maintained by a pharmacy in connection with the program. [2009 c.300 §5]
- **689.778 Eligibility.** An individual is eligible to obtain donated prescription drugs through the Charitable Prescription Drug Program created in ORS 689.772 if the individual:
 - (1) Is a resident of this state; and
 - (2)(a) Does not have health insurance coverage for the prescription drug requested;
- (b) Is enrolled in a program of public assistance, as defined in ORS 411.010, or medical assistance, as defined in ORS 414.025; or
- (c) Meets other requirements adopted by rule by the State Board of Pharmacy that identify needy individuals with barriers to accessing prescription drugs. [2009 c.300 §6; 2013 c.688 §92]
 - **689.780 Immunity.** (1) As used in this section, "participant" means:
 - (a) A person who donates a prescription drug to the Charitable Prescription Drug Program;
 - (b) The Charitable Prescription Drug Program;
 - (c) The State Board of Pharmacy;
 - (d) A pharmacist;
 - (e) A drug manufacturer; or
 - (f) A health practitioner.
- (2) A participant who accepts or distributes donated prescription drugs through the Charitable Prescription Drug Program is not subject to criminal prosecution or civil liability for any injury, death or loss of or damage to person or property that results from the acceptance or distribution of the donated prescription drugs if the participant accepts or distributes the donated prescription drugs in good faith. [2009 c.300 §7]

Division 44 CHARITABLE PHARMACIES

855-044-0001

Purpose

The purpose of the program is to provide a process to make donated prescription drugs available to needy or uninsured individuals and those with limited access to pharmaceuticals. Under the rules in this Division, a Charitable Pharmacy that is registered with the Oregon Board of Pharmacy (Board) may accept drugs for donation and distribution within this state when the pharmacist can reasonably be assured of the purity and integrity of the drug. The program may not include categories of drugs specified by the Board as excluded from the program.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.772 & 689.774

History:

BP 1-2017, f. & cert. ef. 2-23-17 BP 6-2010, f. & cert. ef. 6-29-10

855-044-0005

Definitions

- (1) "Charitable Pharmacy" means a facility registered with the Oregon Board of Pharmacy for the purpose of receiving and distributing donated drugs.
- (2) "Point-of-Contact" means an individual designated by a charitable pharmacy who serves as the primary contact person for the charitable pharmacy and who is responsible for managing the charitable pharmacy at that location.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.772 & 689.774

History:

BP 6-2010, f. & cert. ef. 6-29-10

855-044-0010

Registration

- (1) A facility may not operate as a charitable pharmacy unless it is registered as such with the Board and has paid the fee specified in Division 110 of these rules.
- (2) The application for registration must be on a form provided by the Board and must include proposed policies and procedures and a description of the organization.
- (3) Each location must be registered separately.
- (4) An applicant for registration as a charitable pharmacy must name a point-of-contact for each registered location.

Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.774

History:

BP 6-2010, f. & cert. ef. 6-29-10

855-044-0020

Personnel

- (1) A charitable pharmacy must have a licensed pharmacist. The pharmacist may also be the Point-of-Contact.
- (2) A charitable pharmacy that is co-located with an existing registered pharmacy may name a pharmacist employed by the existing pharmacy as its pharmacist.
- (3) A charitable pharmacy that is not co-located with an existing registered pharmacy and does not have a pharmacist on staff must employ a consultant pharmacist.
- (4) The pharmacist must develop policies and procedures for:
- (a) Receiving donated drugs;
- (b) Security;
- (c) Drug storage;
- (d) Distribution of drugs;
- (e) Record keeping;
- (f) Disposal of unusable drugs; and
- (g) Staff training.
- (5) The pharmacist must conduct a visual inspection of each donated drug to ensure that the drug has not expired, been adulterated or misbranded and is in its original, sealed packaging, and that based on this inspection and on the accuracy of the Donor's Form, the drug is safe to distribute.

Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.774

History:

BP 6-2010, f. & cert. ef. 6-29-10

855-044-0030

Drug Donation

- (1) A charitable pharmacy may not accept:
- (a) Any controlled substance or any kit, package or blister pack that contains any controlled substance;
- (b) A non-prescription drug;
- (c) A drug in a container or package that does not contain a product identification label (PIL), except that a drug in a manufacturer's original container or a manufacturer's blister pack does not need to bear a PIL;
- (d) An FDA REMS (Risk Evaluation and Mitigation Strategy) drug;
- (e) A drug donated from another state.
- (2) A charitable pharmacy may accept:
- (a) A prescription drug received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; and

- (b) Sealed single unit dose packages received in opened packages containing multiple single unit doses.
- (3) The following are examples of acceptable packaging:
- (a) Manufacturer's original container;
- (b) Single-dose blister packs in sealed outer package;
- (c) Single-dose blister packs in opened outer package;
- (d) Tamper-evident hospice kit containing manufacturer's original containers.
- (4) Donated drugs that do not meet the above criteria or are judged by the pharmacist to be unsafe for redispensing must be stored separately from the drug supply until they can be destroyed.
- (5) A charitable pharmacy may accept a drug from:
- (a) An individual;
- (b) A long-term care facility;
- (c) A pharmacy;
- (d) A practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice;
- (e) Another registered charitable pharmacy;
- (f) A medical clinic;
- (g) A drug manufacturer or wholesaler;
- (h) A Medication Assistance Program (MAP) such as those supported by drug manufacturers.
- (6) The donor must certify on a Donor Form provided by the Board that the donated drug has been properly stored, in accordance with manufacturer's recommendations, and has never been opened, used, adulterated or misbranded.
- (7) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.772 & 689.774

History:

BP 1-2017, f. & cert. ef. 2-23-17 BP 6-2010, f. & cert. ef. 6-29-10

855-044-0040

Storage and Security

(1) A charitable pharmacy must store all donated drugs securely and physically separate from any existing inventory.

- (2) All charitable pharmacy records must be secured to comply with HIPAA and all state and federal regulations.
- (3) Outdated and unusable drugs intended for destruction must be quarantined and stored securely.
- (4) A charitable pharmacy co-located with an existing pharmacy must use storage and record keeping procedures that maintain separation of charitable pharmacy records and drugs from other pharmacy records and inventory.

Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.774

History:

BP 6-2010, f. & cert. ef. 6-29-10

855-044-0050

Drug Distribution

- (1) A charitable pharmacy may not distribute a donated prescription drug that:
- (a) Fails to meet the requirements of the program;
- (b) Has not been stored in accordance with manufacturer's recommendations;
- (c) Has been repackaged, except that a drug that has been repackaged for a long-term care pharmacy may be distributed:
- (d) Bears an expiration date that is less than nine months from the date the drug is donated:
- (e) Is adulterated or misbranded;
- (f) Is a controlled substance;
- (g) Is a drug that requires a special registration for dispensing;
- (h) Is an over-the-counter drug;
- (i) Requires specialty storage or handling;
- (j) Requires refrigeration;
- (k) Is a compounded drug; or
- (L) In the pharmacist's professional judgment, may be unfit for dispensing.
- (2) A charitable pharmacy may only dispense a drug to a person who:
- (a) Has a valid prescription for the drug; and
- (b) Is a resident of Oregon; and
- (c) Is underinsured or does not have adequate health insurance coverage for the prescription drug requested; or
- (d) Is enrolled in a program of public assistance as defined in ORS 411.010;

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- (3) A drug may only be dispensed by a pharmacist or by a practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice, or by a registered nurse subject to the following:
- (a) A registered nurse who is an employee of a charitable pharmacy may dispense a drug to a client of the charitable pharmacy; and
- (b) Such dispensing by a registered nurse shall be pursuant to the order of a person authorized to prescribe the drug.
- (4) The dispensing practitioner must provide the patient with appropriate counseling on the use of the drug and any potential side effects, and may provide written drug information;
- (5) A recipient of a drug under this program must sign a Recipient Form, provided by the Board, that attests that the recipient has been notified that:
- (a) The prescription drug was donated to the program;
- (b) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging;
- (c) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the Donor's Form and the visual inspection by the pharmacist;
- (d) Participants in the program are immune from liability as provided in ORS 689.780; and
- (e) That they are qualified to receive the drug as specified in section (2) of this rule.
- (6) Upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.772 & 689.774

History:

BP 6-2010, f. & cert. ef. 6-29-10

855-044-0060

Labeling

- (1) The label on a drug dispensed or distributed from a charitable pharmacy must meet all federal rules and laws and must contain:
- (a) The name, address and telephone number of the pharmacy;
- (b) The name of the prescribing practitioner;
- (c) The initials of the dispensing practitioner;
- (d) Date dispensed;
- (e) The name of the patient;
- (f) Name and manufacturer of drug, drug strength, the quantity dispensed;

(g) Direction for use;
(i) The expiration date;
(j) A unique identifier; and
(k) Any further cautionary information required for patient safety.
(2) All original patient identification must be removed.
Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.774 History: BP 6-2010, f. & cert. ef. 6-29-10
855-044-0070 Records
(1) A charitable pharmacy must maintain a donation record of all drugs received that includes:
(a) Donor's name and address;
(b) Drug manufacturer, lot number, name and strength;
(c) Drug quantity;
(d) Expiration date of the drug;
(e) Date donated; and
(f) The unique identifier.
(2) A charitable pharmacy must maintain a distribution and dispensing record that includes:
(a) Drug name and strength;
(b) Quantity distributed;
(c) Name of manufacturer;
(d) Lot number and expiration date;
(e) Date of distribution or dispensing;
(f) Name and address of recipient.
(3) A charitable pharmacy must maintain a record of all drugs that are destroyed.
(4) In addition to the above records, a charitable pharmacy must cross-reference the donation record and the distribution and dispensing record with the appropriate donor and recipient forms.
(5) A charitable pharmacy must make an annual report to the Board by completing a form provided by the Board

and submitting it with their application for renewal of registration.

- (6) All records required by these rules must be retained for three years and made available to the Board upon request.
- (7) Upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Statutory/Other Authority: ORS 689.205 **Statutes/Other Implemented:** ORS 689.774

History:

BP 9-2014, f. & cert. ef. 12-4-14 BP 6-2010, f. & cert. ef. 6-29-10

855-044-0080

Fees

- (1) A charitable pharmacy may not charge a fee for accepting a donation.
- (2) A charitable pharmacy may not sell a donated drug.
- (3) A charitable pharmacy may charge a dispensing fee that does not exceed two and a half times Oregon's current Medicaid dispensing fee.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.772 & 689.774

History:

BP 6-2010, f. & cert. ef. 6-29-10

855-044-0090

Liability

In accordance with ORS 689.780, a person who accepts or distributes donated prescription drugs through the charitable pharmacy program is not subject to criminal prosecution or civil liability for any injury, death or loss of or damage to person or property that results from the acceptance or distribution of the donated prescription drugs if the participant accepts or distributes the donated prescription drugs in good faith.

Providence Specialty Pharmacy Services - LTC Pharmacy (IP-0001899): Auto Refill Policy Discussion

S

Situation: Inquiry

- Providence Specialty Pharmacy Services LTC (IP-0001899) is asking the Board to review their processes with regard to the Board's auto-refill rule OAR 855-041-1120(6) for their Independent ElderPlace program participants.
- Per the regulation, a pharmacy is required to have the patient/caregiver authorize automatic fill with each new medication start.
- Nurses with the program are questioning this requirement (and are resistant) and consider this an unnecessary barrier for their provision of patient care.

B

Background:

- Rules: OAR 855-041-1120(6) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may use a program that automatically refills non-controlled prescription medications, that have existing refills available and are consistent with the patient's current medication therapy only when the following conditions are met:
- (a) A patient or patient's agent must enroll each prescription medication in an auto-refill program before a pharmacy can include the prescription medication as part of the auto-refill program; and
- (b) The prescription is not a controlled substance; and
- (c) The pharmacy must discontinue auto-refill program enrollment when requested by the patient or patient's agent; and
- (d) Pick-up notification to a patient or patient's agent may be generated upon completion of a prescription refill; and
- (e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription medication is removed from the auto-refill program for that patient.

Description, as provided by PIC Breier:

- ElderPlace is a PACE (Program of All-inclusive Care for the Elderly) recognized by CMS as one of the most robust models of care for seniors with significant comorbidities. ElderPlace serves patients age 55 or older certified by individual state to need nursing home care. Based on its status as a PACE program and the nature of care provided by PACE, ElderPlace is a closed system which naturally contains all of our participants in a medical bubble under close scrutiny of an interdisciplinary team. ElderPlace and other PACE programs are able to provide the same level of care in the community by offering adult day center services, home healthcare visits, social services, and medical care that is provided by a medical team that includes MD/NP, RN, SW, RD, PharmD, PT/OT, SLP, CNA/CMA, PMHNP and drivers. Most ElderPlace patients live in licensed facilities and less than 10% live independently at home or with families. The oversight of the independently living participants is significantly different from a typical community based patient who receives their medications from a typical retail pharmacy.
- Our Pharmacy is the only dispensing pharmacy that is used for and by ElderPlace patients. Participants are unable to receive prescription orders from outside providers or pharmacies because Providence ElderPlace is also their Medicare Part D coverage. Also, given that our pharmacy is a related party under the same parent organization, Providence Health & Services, we have complete access to the EPIC EHR system. All medication orders and changes

are sent to the pharmacy both as a standard E-Script for filling and as an internally routed message in the EHR. This means that our pharmacy is in the unique position of having a real-time picture of every independently living participant's medication list. This allows the dispensing pharmacist to reach out more effectively to the medical team to reconcile discrepancies and ensure that no unnecessary or old medications are being sent to our participants.

• The intention of our pharmacy is to fill routine, non-control medications in synchronization each month for these Independent participants per ElderPlace request. We want to ensure that the residents do not miss necessary medication fills and maintain adherence to their medication regimen. Upon enrollment in the ElderPlace program, each independent patient, their caregiver and their family is made aware of our automated, synchronized monthly fill and medication delivery system. Given the PACE program's care model and closed system of medication management, we believe requesting authorization at each medication start would not be needed.

A

Assessment:

- Waiver assessment: There is no waiver provision in this rule set; rather, the Board is asked to review the scenario/model described and make a determination whether it is permitted (rule interpretation)
- Rule language assessment: The pharmacy's program is not exactly "cycle-fill"; They are a
 long term care pharmacy but the 10% of the patients they are serving from PACE program
 are home bound- and don't meet care facility definition for LTC. Trend in healthcare is to
 keep the aging population at home to receive care, as it is a lower cost and systems are in
 place to provide safe patient care and positive outcomes
- Considerations:
 - This could meet the intent of the rule, but the languages does not reflect- meaning this is the cycle fill for LTC language being to prescriptive and unintentionally prohibitive
 - The intent of the auto-refill regulation is to prevent the excessive automated processes from inundating patients with medications they do not need or that have been discontinued. This model works to ensure intentional dispensing to align with patient safety and has safeguards in place to prevent abuse of auto refills by the pharmacy for a financial gain. The pharmacy proactively monitors the medication profile.
 - These patients are under routine medical care, with coordinated care oversight by a team of healthcare providers, including visiting nurses.
 - Uniquely situated federal designation According to <u>CMS</u>: The PACE program is a
 unique capitated managed care benefit for the frail elderly provided by a not-forprofit or public entity. The PACE program features a comprehensive medical and
 social service delivery system using an interdisciplinary team approach in an adult day
 health center that is supplemented by in-home and referral services in accordance
 with participants' needs.



Recommendation:

Patient safety assessment: Meets Board criteria for "as safe, or safer"

Staff recommendation: Based on the rules intent, this process meets the criteria to be 'excepted' per the long term care cycle-fill component.

As described, ongoing proactive oversight by pharmacy staff and collaborative care team ensures that the patient is receiving the correct medications. Therefore a patient or patient's agent does not have to enroll each prescription into the Providence Specialty – LTC Pharmacy prescription filling and dispensing program.

Inquiry Date: 4/25/19

Author: RPH Chris Breier

Prepared by OBOP staff

Board review: June 2019 meeting

SBAR: e-Verification

Situation:

There will be a new e-Verification system which will be implemented in the fall. The Board has the opportunity to take advantage of a one time import into the new MyLicense Office database and import all available public documents.

B

Background:

In 2007, public documents became available via the Board's license verification. All public documents associated with actions for 2007 to present are available online. All public documents prior to 2007 continue to be available by written request to the Board of Pharmacy.



Assessment:

Currently, there are an additional 439 public records that are formatted for the web and are available to be imported during the one time import into the e-Verification system by System Automation.

	Records
Year	Available
1983	1
1988	3
1989	1
1990	0
1991	2

	Records
Year	Available
1992	3
1993	7
1994	4
1995	5
1996	3

Year	Records Available	Year	Records Available
1997	10	2002	34
1998	29	2003	47
1999	44	2004	45
2000	44	2005	57
2001	41	2006	59

The majority, if not all, of the public records were prepared and formatted for previous written records requests.

By importing the 439 public records, the Board increases transparency and reduces staff resources spent providing public records.

Because the records prior to 2007 are not available online, staff resources are used to provide credentialing agencies the same records annually.



Recommendations:

The staff recommends the importing of the additional available records into the new eVerification system.

Date: 5/17/19

Author: Chrisy Hennigan

Oregon Retail Sale of Cannabidiol (CBD) Products FAQ

BACKGROUND

In the U.S., the 2018 Farm Bill removed industrial hemp (and its extracts) from the Controlled Substances Act and legalized hemp to be considered as an agricultural product. It has had a wide range of practical uses including the production of fibers, textiles, cosmetics, foods, beverages, oils and more.

Like marijuana, hemp is a variety of the *Cannabis sativa* plant species. However, it is typically distinguished by its lower concentration of tetrahydrocannabinol (THC) which is the main psychoactive component of cannabinoids (i.e. marijuana, hemp). Legally, industrial hemp cannot contain >0.3% THC on a dry weight basis. With its fast-growing popularity, hemp has also become a primary source of CBD which like THC is a major component of cannabinoids but has no psychoactive ("high") effects.

In Oregon, cannabis is divided into 2 categories: industrial hemp and marijuana. If hemp-made, a license or registration is <u>not</u> required for a business to sell CBD products under the state's Hemp Program as long as the product has <0.3% THC and is not advertised as a dietary supplement. Testing requirements are implemented and enforced by the Oregon Department of Agriculture (ODA) to ensure growers and handlers are in compliance prior to sale or transfer to consumers. Overall, there is no legal prohibition against the sale of CBD products to individuals who are <21 years of age (unless it is used for the sale of inhalant delivery systems and their components) or limitations on purchases from retail locations.

Per the Oregon Board of Pharmacy, CBD products can be sold at the pharmacy register by any staff, but all questions related to CBD products must be directed to the pharmacist. CBD products should <u>not</u> be stored in the pharmacy or ordered through the pharmacy. (source: April 2019 Board meeting minutes)

FAQs

The following FAQs are provided to address pharmacy involvement in the sales of CBD products. The Oregon Board of Pharmacy does not have jurisdictional oversight over the regulation of industrial hemp and CBD products in Oregon.

- Q. Are pharmacy locations permitted to sell CBD products at the retail (front-end) of the store and if so does this require registration with a regulatory body?
- A. Per the 2018 Farm Bill, which legalized industrial hemp (including its extracted products such as CBD), it is legal to sell hemp derived CBD products at a retail location as long as they are: 1) not advertised as a dietary supplement, and 2) provided that their THC concentration is <0.3%.
 - Currently, there is no requirement for a license or registration for a business to sell CBD products under ODA's Hemp Program.
- Q. Who regulates CBD products and verifies that the amount of THC is within legal concentrations, per 2018 Farm Bill, THC level <0.3%?
- A. In Oregon, testing requirements are implemented and enforced by the <u>ODA</u> to ensure growers and processors of industrial hemp are in compliance prior to sale or transfer to consumers.
- Q. Are there any restrictions to sale; age restriction, limit in quantity, delivery mechanism?
- A. No, as long as the CBD product is derived from <u>industrial hemp</u> and meets federal requirements.
- Q. Can CBD be sold as a dietary supplement?
- A. No. According to the FDA, under the FD&C Act, it is illegal to market CBD as a dietary supplement.

- Q. Can CBD products be sold at the pharmacy register?
- A. Yes.
- Q. Who can answer health-related questions about CBD?
- A. Pharmacists, when the pharmacy is open.
- Q. Can a CBD product user test positive for a marijuana drug screen?
- A. Yes, it is possible. The test does not distinguish between THC derived from hemp product or marijuana product. The test may be dependent on how much individuals take, when they use it and the frequency in which they consume it. (Note: Drug tests do not test for CBD, but do detect THC. The test cannot distinguish whether detectable THC metabolites is the result of CBD use or the use of marijuana.)

OREGON LAWS AND RULES

The laws and rules applicable to the retail sales of CBD in Oregon include:

<u>2018 OR SB 1544</u>. Requires that products sold in an Oregon Liquor Control Commission (OLCC) retailer (recreational marijuana) must have a label that clearly identifies the source of the CBD – hemp vs marijuana.

ORS 571.303. Industrial hemp is an agricultural product that is subject to regulation by ODA.

ORS 571.333. ODA may enter an agreement with the Oregon Health Authority (OHA) to ensure that hemp crops contain THC concentrations <0.3% on a dry weight basis and are tested by a laboratory licensed by OLCC and accredited by OHA.

REGULATORY OVERSIGHT

	Medical Marijuana	Recreational Marijuana	Industrial Hemp
Product	Marijuana	Marijuana products and	CBD products derived
		CBD products derived	from industrial hemp
		from marijuana or	containing <0.3% THC.
		industrial hemp.	
Location of Sales	Designated growers or	Licensed OLCC	Any retail location.
	medical marijuana	recreational marijuana	
	dispensaries.	dispensaries.	
Restriction on Sales	Must have a medical	Must be ≥21 years of age	None.
	marijuana card.	or older.	
			Unless the product is used
	Individuals with	Source of CBD must be	for the sale of inhalant
	a qualifying medical	labeled – hemp or	delivery systems and their
	condition and a	marijuana.	components, then must
	recommendation for		be ≥21 years of age or
	medical marijuana from		older.
	an attending		
	physician may apply for a		
	medical marijuana card.		
Regulatory Body	ОНА	OLCC	ODA

Board and Other Pharmacist Appointments

Appointed to	Appointee	Date	Term	Appointed by	Notes
		appointed	expires		
Public Health and Pharmacy Formulary Advisory Committee Effective 1/1/2018, pursuant to 2017 HB 2397.	Evon Anukam RPh Amy Baker, RPh Amy Valdez, RPh Mark Helm, MD Sean Jones, MD Kat Chin, APRN Helen Turner, APRN	12/1/17	11/30/19	Recommended by the Board and appointed by the Governor.	Two year terms. 2017 Oregon Laws Chapter 106.
Council on Naturopathic Physicians Formulary	Justin Bednar Natalie Gustafson John Block	Jun 2013 Aug 2011 Jun 2006	Jun 2019 Jun 2019 Dec 2018	Board of Pharmacy Board of Pharmacy Naturopathic Formulary Council	Two year terms (no limit) ORS 685.145
Rural Health Coordinating Council	Leanne Yantis	June 2016	Jun 2020	Board of Pharmacy	Two year terms (no limit) ORS 442.490
Council on Optometric Non- topical Formulary	Christopher de Guzman	June 2017	June 2018	Board of Pharmacy	Two year terms (no limit) ORS 683.240
Oregon Patient Safety Commission Board of Directors	Amy Baker	10/1/18	9/30/2022	Governor (Subject to Senate confirmation)	Four year term, two term limit ORS 442.830
Pain Management Commission	Michele Koder	6/6/13	5/31/21	Director of the Oregon Health Authority	Four year terms, two term limit ORS 409.520
Immunization Policy Advisory Team	Fiona Karbowicz	6/7/2018	6/1/2020	DHS Immunization Program Manager	Two year terms (no limit) (OBOP Staff Member)

 From:
 MACLEAN Karen S * BOP

 To:
 MACLEAN Karen S * BOP

Subject: Council on Naturopathic Physicians Formulary

Date: Friday, May 10, 2019 2:07:13 PM

Attachments: McClatchey cv 2019.pdf

From: Will McClatchey <will.mcclatchey@gmail.com>

Sent: Wednesday, February 27, 2019 3:21 PM

To: MACLEAN Karen S * BOP < Karen.S. MACLEAN@oregon.gov>

Subject: Fwd: [Obop-rph] Oregon Board of Pharmacy Opportunities - Apply Now!

Dear Karen,

I am interested in applying to serve on the Naturopathic Formulary Council. For the last 3 years I have worked part-time as a clinical pharmacist for BHS pharmacy, a long-term care pharmacy in Eugene that services facilities all over Oregon and Washington. During the rest of my time I manage a small fruit farm south of Eugene near Lorane.

Although my professional career began in pharmacy in Oregon, I have conducted formal and informal research on a variety of traditional herbal and natural medicine practices in several different countries (my cv has more details). My interest in herbal products began with training as a teenager from my grandmother who was an herbalist in Arizona, and continued at OSU with training by Marine Natural Product chemist, Bill Gerwick and natural product pharmacognosist, George Constantine. As a graduate student I studied traditional medicine with healers on the island of Rotuma, Fiji. For 15 years I was a professor with the University of Hawaii at Manoa with appointments in several departments, primarily Botany, and the Cancer Research Center, Natural Products Program. During this time I taught courses on plant-based medicines for graduate students, pre-medical, and medical students. Throughout most of my career I have been a very active member and leader in the Society for Economic Botany which is the world's largest eclectic collection of people interested in how plants and humans interact. For over 20 years I have also participated in the American Botanical Council and currently am a member of the Advisory Board. In 2010, I moved to Texas to lead the research program transition of the Botanical Research Institute of Texas (BRIT) from a smallscale program to a program with a wide range of research projects in 10 countries and a large permanent, temporary, and adjunct staff of scientists and educators. In 2015, my wife's health began to fail, I resigned as head of research, and we moved home to Oregon to be close to family and to set up a small farm to grow fruit trees and berries. I plan to live out my days in Oregon and therefore hope to be able to contribute what I can to see our community develop.

Please find attached my cv and consider the message above as my letter. I am happy to address any questions you may have and look forward to being of service to Oregon in this or some other fashion.

Thank you,

Will McClatchey 28281 Hamm Road Eugene, OR 97405 **Will McClatchey**, Woodland Valley Meadows Farm, 28281 Hamm Road, Eugene, Oregon 97405 Cell: (541) 579-8827 (or 458-210-8146); will-mcclatchey@gmail.com

CAREER BRIEF

Farmer in Practice	2001-present
Oregon Pharmacist	2015-present
Director of Research	2010-2015
Professor of Botany	1997-2012
Florida Pharmacist	1993-1997
Utah Pharmacist	1990-1993
Oregon Pharmacist	1988-1989
University Student	1984-1996
Oregon Timber & Agriculture Worker	1981-1988
EDUCATION	
University of Florida (UF), Gainesville, Florida, Ph.D (Evolutionary Biology/Botany) Brigham Young University (BYU), Provo, Utah, MS (Botany & Range Science) Oregon State University (OSU), Corvallis, Oregon, BS (Pharmacy) Oregon State University, Corvallis, Oregon, BS (Anthropology)	1996 1993 1989 1989
5 /////// -	

ACCOMPLISHMENT BRIEF

Mentored almost 2 graduate students per year through competition of PhD/MS degrees.

Development of world's first formal degrees in Ethnobotany/Ethnobiology at three institutions in USA.

Developed & implemented botanical garden plans in Hawaii and Palau.

Synthesized social and biological science theories to generate new ideas about humans as ecological managers.

Organized and hosted in 2001 the world's largest conference on ethnobiology and ethnomedicine.

Honored as 2013 Economic Botanist of the year by Society for Economic Botany.

Consistently brought in enough funding through grants and contracts to keep 15+ people/year working on science.

Completed 10+ years of research on 6 types of traditional European orchards as artificial ecosystems and now am applying it as a set of long-term experimental plots in Oregon.

PHARMACY EXPERIENCE

Pharmacy License Oregon RPH-0007847 Not current: Florida 29553, Hawaii 1639, Utah 90152152-1701

For each of the following I worked as both a floating/relief pharmacist and regular staff pharmacist. Several times I worked relief for small outpatient facilities. For two extended periods, I was a pharmacy manager until a permanent person could be hired. The locations listed are primary bases and in each case I also worked in MANY other stores. Currently, I am working about 3 days per week for BHS Pharmacy.

Oregon	
BHS Pharmacy, Clinical Pharmacist (Long-term care), Eugene, Oregon, (541) 868-1490	current (2015+)
Safeway Pharmacy, Float Pharmacist (Retail), Western Oregon region, mostly Eugene	2015-2016
<u>Payless Drug Stores</u> , Staff Pharmacist/Manager (Retail), Portland/Woodburn, OR, (503) 982-1340 Internships/Externships	1988-1989
Syncore International, (Nuclear pharmacy), Portland, Oregon, (503) 223-8785	1989
 All coursework (OSU) and internships were completed for nuclear pharmacy cert <u>United States Veterans Medical Center</u>, (Nuclear pharmacy), Portland, Oregon, (503) 222-9221 <u>Oregon Health Sciences University</u>, (Psychiatric pharmacy), Psychiatric Pharmacy, Portland, 	1989
Oregon, (503) 279-8007	1988
Emmanuel Hospital Pharmacy, (Hospital pharmacy), Portland, Oregon, (503) 280-4176	1988
Professional Plaza 102 Pharmacy, (Retail pharmacy), Portland, Oregon, (503) 254-7383	1988
Utah	1003 1004
Payless Drug Stores, Float Pharmacist (Retail), Provo, Utah & Salt Lake City, Utah, (801) 374-2015	
Payless Drug Stores, Rx Manager (Retail), Park City, Utah, (801) 649-9621	1989-1993
Florida	
Eckerd Drugs, Float Pharmacist (Retail), Gainesville, Florida, (352) 371-1223	1995-1997
Wises Pharmacy, Relief Pharmacist (Independent Retail), Gainesville, Florida, (352) 376-8286	1996-1997
K-Mart Pharmacy, Relief Pharmacist (Retail), Leesburg, Florida, (352) 787-0557	1994-1995
Specialized Training (most recent for each)	
Basic Life Support and CPR	2018
Adult Immunization Training	2018
Prescribing Medroxyprogesterone Injection	2017
Comprehensive Contraception Education and Training for the Prescribing Pharmacist	2016
CPR Adult and Children Training, American Red Cross	2016
Medication Therapy Management, Postgraduate Healthcare	2015
Human Research Subjects Training, National Institute of Health	2014
Industrial Climbing and Rigging Safety Certification, Texas	2012
Laboratory Health and Safety Training/Hazardous Waste Training, University of Hawaii	2010
Advanced SCUBA certification (+ Navigation, Night Diving, First Aid), SSI Diving	1992
Nuclear Pharmaceutical Labeling and Administration, Syncore International	1989
Wilderness Survival Training, OSU, School of Forestry	1985

ACADEMIC & RESEARCH EXPERIENCE

Botanical Research Institute of Texas

Vice President and Director of Research

2010 - 2015

Economic Botanist of Year (2013), Society for Economic Botany

Research Associate 2008 - 2010

As the administrative head of research, I managed a permanent team of 6-8 researchers and 6 research support staff. 5-12 additional researchers worked on specific project contracts. I oversaw budgeting, with staff assigned to purchases, local and international logistics, and grants management. The organizational budget annually is approximately 5 million with ~2 million from endowments, <2 million from donors, and >1 million from grants and contracts. During the five years I worked with BRIT the endowment was tripled to about 45 million based primarily on our expanding research and educational reputations, and the diversity and increase of competitive federal and private funding sources received. In particular, I worked with ranchers in Texas and Brazil to both produce new research on their lands and to address general conservation issues that impact their production efforts. The most important lasting success in this regard was a change in members of our non-profit board of directors to include several ranchers with strong conservation values and abilities to help raise funding for local and international research on human interactions with environments. The research director's role has been one of facilitating communication between staff and a wide range of constituents, funding agencies, donors, and community members. I strongly believe that effective communication is the key to successful project and program management, and is critical for pharmacist interactions with patients and other professionals. Effective communication involves thoughtful development of substantive plans and actions that are shared in ways that can empower people to get their primary jobs done with a minimum of interruption.

Texas Christian University

Affiliate Professor, Institute for Environmental Studies

2011 - 2015

Although I more or less left academia when I moved to Texas, TCU offered the opportunity to continue to mentor graduate students and to help teach courses in conservation of natural resources.

University of North Texas, Health Science Center

Affiliate Graduate Faculty, Biomedical Sciences

2012 - 2015

2002 - 2007

When the decision was made to move to Texas, I still was supervising several students from UH and working collaboratively with graduate students from Thailand. UNT provided laboratory space and collaboration opportunities through a prior agreement with BRIT so my students were able to continue their work.

University of Hawai'i, Mānoa

Associate Professor of Botany

Affiliate Professor, Department of Botany	2012 - 2014
Professor of Botany	2007 - 2012
Graduato Eaculty in SE Asian Studios	

Graduate Faculty in SE Asian Studies

• Graduate Faculty in Ecology, Evolution and Conservation Biology Program

- Graduate Faculty in Pacific Studies Program
- Adjunct Researcher in Cancer Research Center of Hawai'i, Natural Products Program

Associate Director, Lyon Arboretum	2002 - 2005
Assistant Professor, Department of Botany	1997 – 2002

Although I was based within the Botany Department, collaborations and interdisciplinary research projects created opportunities to work in several different programs in Hawai'i. I was hired to produce the world's first undergraduate degree in Ethnobotany, which happened in 2002. Since then the program has been copied in variations at five other U.S. universities. I supervised more than 30 graduate students, hundreds of undergraduates in botany and biology, and at times up to 5 staff members and multiple federal grants and private contracts for research. I am vested in the state of Hawaii retirement system so will retire as a full professor in the future.

William L. Brown Center, Missouri Botanical Garden Research Associate	2007 - 2014
 Khon Kaen University, Thailand Visiting Professor, Department of Pharmaceutical Botany and Pharmacognosy Fulbright Fellowship Researcher and Instructor 	2005 - 2006
 University of Florida Post-Doctoral Instructor, Department of Botany Presidential Recognition Award for Teaching, University of Florida Fulling Award, Society for Economic Botany 	1996 - 1997
Instructor, College of Tropical Agriculture Graduate Researcher, Florida State Museum, Herbarium	1996 1994-1996
 McGinty Research Fellowship, University of Florida Systematic Field Researcher, Fairchild Tropical Garden Graduate Teaching Assistant, Department of Botany 	1995-1996 1995
Brigham Young University Special Faculty, Department of Botany & Range Science Graduate Teaching Assistant, Department of Botany & Range Science Graduate Researcher, Department of Botany & Range Science	1994 1991-1993 1991-1994
Oregon State University Courtesy Faculty, College of Pharmacy Undergraduate Research Assistant, College of Pharmacy • Dow Chemical Research Award for studies of Marine Biochemistry	2017-present 1984-1988
Assistant to Health Physicist, Radiation Center and TRIGA Reactor Facility • Laboratory, environmental and reactor radiation surveys, fabrication of source fixtures.	
 Archival Assistant/Microfilm Technician, Archives Organization and documentation of past University Presidents archival deposits, microf 	1984-1986 iche filming,

Languages

During several periods of international research, it has been important to learn and use local languages to complete the work being done. With few exceptions, I have avoided using translators when working in a community for more than a few months. While I have usually easily picked up languages (Thai being a notable exception that was very difficult), I have also made little effort to maintain them so do not feel I am currently fluent in any other languages. The following are languages that I have used for completing work and in formal publications: Babatana, Fijian, German, Rotuman, Spanish, Thai. I am also familiar with geographical, mythical, and biological terms that are common to many Polynesian languages such as Hawaiian, Samoan, and Tongan. Languages and linguistics are something I have long enjoyed dabbling in and therefore look forward to new opportunities to learn and practice.

I have been working to relearn Spanish, particularly for communication with pharmacy patients.

maintaining legal files, use of a high speed document camera, assisting researchers

COMMUNITY DEVELOPMENT and APPLIED ETHNOBOTANY EXPERIENCE

During my PhD research, I was fortunate to receive funding for a series of small field research projects in several Pacific island countries. In the second one of these, in Samoa, we worked quite closely within the traditional community structure. The research took less time than we had planned, and produced results that could not have been achieved without the community participation. This lesson was then carried over in subsequent projects where I specifically engaged local communities and spent growing amounts of time and energy working toward their objectives without any degradation of the primary research mission. After beginning as a faculty member at University of Hawai'i, that work history began to pay off as people from different island groups began to approach me and my department for work based on the good reputation developed with prior projects. The net result was that most of my work during 15 years at University of Hawai'i was conducted with communities and there was never a shortage of opportunities to address interesting research questions and for high quality student projects. Because of these relationships the only resource we really lacked was time.

E.U. (France, Germany, Italy, Spain, & United Kingdom)

 <u>Various small-scale orchards</u>. Studies with local apple orchard managers and cider producers focusing on two aspects: 1) How is knowledge developed and passed-on, and how can this be used to develop practical instructional curriculum in science, and 2) What are the elements of orchards as artificial ecosystems that have been engineered to produce cider, and are these resilient in the face of climate change?

Federated States of Micronesia

<u>Pohnpei</u>. Studies of traditional house construction techniques and Kapingamarangi carving of *Metroxylon* seeds.

French Polynesia

• <u>Mo`orea</u>. Evaluation of developing ethnobotanical garden at the Gump Research Station. Training in oral history documentation of traditions. Supervision of graduate students working on documentation of traditional farming practices and impacts on lowland forest ecosystems.

Madagascar

Analalava. Training workshop on ethnobotany field methods for Malagasy conservation researchers.
 Conducted studies with two communities on the intensity and sustainability of their interactions with forest, marsh, and grassland resources.

Malaysia

• Sarawak. Studies of traditional sago starch extraction by Malay and Dayak cultural groups near Kuching.

Palau

<u>Babeldaub</u>. Evaluation of five potential sites for a National Botanical Garden on behalf of the Palau
Tourists Authority. Each site was evaluated for conservation potential, botanical diversity, and economic
potential as an asset for tourism. Development of a Botanical Garden Rough Layout, Business Plan, and
Grant Proposals.

Republic of Fiji

- <u>Vanua Levu</u>. Studies of economically important palms: Clinostigma, Veitchia, Balaka, Metroxylon,
 Calamus, Cocos, and Pritchardia. For each palm, the uses, cultural impact on plant populations and
 resource availability/sustainability was analyzed.
- <u>Rotuma</u>. Studies of Polynesian traditional house construction techniques and materials. Technical
 terminology used in construction was compared with four other Polynesian cultures using a cladisticlinguistic analysis in order to determine cultural relationships. Studies of traditional medicine. Each
 species used was collected for chemical analysis and taxonomic identification. In addition to identifying

medicinal plants, the Rotuman perspectives of disease causation, human anatomy, health and wellness, and the development of traditional remedies were documented. Studies of traditional uses of palms: *Cocos, Pritchardia*, and *Metroxylon*.

Republic of Marshall Islands

- Rongelap Atoll. Evaluation of potential eco-tourism sites and development of grants and programs for
 resettlement of the people of the atoll back after their generation absence due to nuclear testing in
 nearby Bikini atoll. Also conducted an independent evaluation of the "clean-up" that has been conducted
 by the Department of Energy with particular emphasis upon potential environmental exposure to residual
 radioisotopes during the practice of traditional activities such as harvest of medicine and growing crops.
- <u>Ailinginae Atoll</u>. Terrestrial biodiversity evaluation as part of preparation for an application for World
 Heritage Site status. Data generated from the initial site review was used to propose and then legislate
 the atoll as the first national park in the Marshall Islands. The site is now a biodiversity preserve and
 tourist destination managed by the community of Rongelap atoll while it awaits consideration as a World
 Heritage Site.

Samoa

<u>Tutuila and Sawai'i</u>. Studies of plants used in the production of traditional fish traps. Each species was
collected and evaluated based upon cultural impact and resource sustainability. Community development
workshops conducted with Trish Flaster focusing upon culturally appropriate herbal products and
marketing of products in ways that are legal in the United States.

Solomon Islands

- <u>Lauru (Choiseul)</u>. Ethnobotanical studies of Babatana and Ririo traditional medicine and uses of nut crops including *Canarium* spp. Establishment of two research stations in the villages of Susuka and Sasamuqa.
- <u>Guadalcanal</u>. Development of a joint biodiversity research program with the Solomon Islands Ministry of Environment, Conservation, and Forestry for ethnobotanical research studies in Choiseul Island. Biodiversity research initially focused upon ethnobotanical analysis of medicinal plants with future plans to expand into floristic and ethnobotanical studies. Studies of traditional housing materials, material supplies, sustainability of traditional housing, and environmental impact of maintaining traditional housing standards. Studies of the Ririo language and Ririo/Babatana taxonomy of biota, diseases, and land usage zones.

Thailand

• Khon Kaen and Sakon Nakon. Ethnobotanical studies of distributions of traditional knowledge of plant diversity, classification systems, plant and ecosystem nomenclature in Phuthai communities.

United States of America

- <u>Florida, Big Cyprus Reservation</u>. Consultation with Florida Seminole Tribe on development of a Native American based natural product business and creating a botanical garden at the tribal headquarters.
- <u>Hawai'i</u>. Development of long-term management plan for Lyon Arboretum with special emphasis upon development of resources for the Manoa valley community and Native Hawaiian educational programs. This has included participation in development of the Hawai'i and Pacific Island 'awa Festival.
- <u>Hawai'i</u>. Development of resources for 'ahupua'a o Kahana community including: a plant inventory toward a flora of the valley; Nakoa trail signs, maps and brochures; artifact recreations, panorama photographs for a visitor interpretive center, and a 3 dimensional watershed map.
- <u>Texas</u>. Biodiversity documentation, educational curriculum generation and testing, and conservation plan development for ecosystems on ranches and in urban areas.

SYSTEMATIC BOTANY FIELD EXPERIENCE

Indo-Malesia

• <u>Sarawak, Malaysia</u>. Studies of Calamoideae genera: *Metroxylon, Korthalsia, Eugeissona, Calamus*, and *Salacca*. Morphological characters were recorded for each genus for phylogenetic studies of the Calamoideae.

Melanesia

- <u>Viti Levu, Vanua Levu and Taveuni, Fiji</u>. Studies of endemic and naturalized palm genera: *Balaka*,
 Clinostigma, *Veitchia*, *Metroxylon*, *Pelagodoxa*, *Areca*, *Neoveitchia*, *Ptychosperma*, *Calamus*, *Pritchardia*,
 Physokentia, and *Cocos*. Each genus was evaluated distributionally and ecologically with living and
 preserved collections from representative populations transported to Florida for further study.
- <u>Guadalcanal and New Georgia, Solomon Islands</u>. Studies of endemic palm genera: *Ptychosperma, Areca, Calamus*, and *Metroxylon*. Each genus was evaluated distributionally and ecologically with living and preserved collections from representative populations transported to Florida for further study.

Micronesia

- <u>Palau</u>. Studies of endemic palm genera: Gulubia, Heterospathe, Nypa, and Ptychosperma. Studies of
 introduced palm genera: Veitchia, Metroxylon, and Calamus. Each genus was evaluated distributionally
 and ecologically with living and preserved collections from each population transported to Florida for
 further study.
- Pohnpei and Chuuk, Federated States of Micronesia. Studies of endemic palm genera: Clinostigma,
 Metroxylon, Nypa, and Heterospathe. Each genus was evaluated distributionally and ecologically with
 living and preserved collections from each population transported to Florida for further study. Collections
 of Metroxylon were measured for morphological, phylogenetic studies.

United States

- <u>Utah and Arizona</u>. Studies of desert species of *Asclepias, Ephedra, Aquilegia, Garrya, Eriogonum, Opuntia, Krameria*, and *Moertonia*. Specimens were collected and analyzed for biochemical activity.
- <u>Florida</u>. Studies of *Sabal*, *Serenoa*, and *Ilex*. Distributions and morphologies evaluated for phylogenetic analysis.
- <u>Hawaii</u>. Studies of genetic and morphological diversity of Pacific Basin *Piperaceae* with special emphasis upon *Piper methysticum* traditional varieties in Hawaiian culture.
- <u>Texas</u>. Collection and analysis of floristic components of cross-timbers walnut glade ecosystems. Testing
 of restoration and conservation plans using three ranching areas.

Western Polynesia

- <u>Savai`i and `upolu, Western Samoa</u>. Studies of endemic palm genera: *Clinostigma, Metroxylon, Veitchia,* and *Balaka*. Each genus was evaluated distributionally and ecologically with living and preserved collections from each population transported to Florida for further study. Through this work a new species of *Metroxylon* was identified. Additionally, specimens of medicinal plant genera were collected for taxonomic identification.
- <u>Rotuma, Fiji</u>. Collection and identification of the flora of the eight islands of the Rotuma group. Herbarium collections of each species were prepared and distributed to four herbaria. The distribution and conservation status of each species was determined as baseline data for future ecological/impact studies following the current rapid cultural and land use changes.

ETHNOPHARMACOLOGY and NATURAL PRODUCT CHEMISTRY EXPERIENCE

Research conducted in this category has typically been done under confidentiality agreements and in participation with corporate and local community groups. Very little of this research has been published but rather appears within private reports to communities and as part of larger governmental projects. This research has largely served as a funding source to indirectly support field ethnobiology research that has been published.

Hawai`i

- O`ahu. Evaluation of secondary metabolites of terrestrial invasive and ornamental species of plants using Cancer Research Center of Hawai'i and Hawai'i Biotech, Inc. assays.
- <u>O`ahu</u>. Development of novel extraction techniques that preserve evolved chemical diversity and activity of traditional medicines that is typically lost using standard pharmacognosy methods.
- <u>Kaua`i</u>. Studies of traditional Hawaiian logic for disease diagnosis and selection of plant remedies.

Micronesia

- Kosrae. In conjunction with the University of Hawaii Sea Grant Program and Greg Patterson of the UH
 Department of Chemistry, Organization and development of an Intellectual Property Rights Agreement
 with the Kosrae Government, to conduct natural product chemistry research on Kosrae. Submission of
 collaborative grant proposals for pharmacological evaluation of the flora.
- Rongelap Atoll. Collection and evaluation of the flora of Rongelap and Ailinginae atolls for biological
 activity in a range of cyto-toxic and cytoremediation assays. Further research has involved study of the
 same collections as treatments for Anthrax and/or Botulism.

Solomon Islands

• <u>Lauru (Choiseul)</u>. Documentation of traditional disease diagnosis system of Ririo and Babatana healers with subsequent evaluation of some of the remedies used for treatment of cancer-like illnesses.

Thailand

<u>Sakon Nakon</u>. In conjunction with Khon Kaen University, Faculty of Pharmacy, Department of
Pharmaceutical Botany and Pharmacognosy, documentation of changing pharmacopoeia of Thai language
groups who have relocated south of the Mekong from Laos in the last 200 years.

PUBLICATIONS (peer-reviewed*)

In Prep/Review

- Farjado, J., A. Verde, D. Reedy & W.C. McClatchey. Climate change observations by elderly farmers growing apple trees in Cuenca and La Mancha, Spain.
- McClatchey, W.C. & D. Reedy. n.d. *Cider World: From orchards as artificial ecosystems addressing climate change to classification of fermented apple products.*
- Vougioukalou, S.A., D. Reedy, & W. McClatchey. 'Thinking with apples': using local cultural keystone species, online tools and community engagement in ethnobiological education in Hawai`i and Kent. Chapter in *Project-Based Learning and New Approaches in Teaching Botany and Applied Botany*. Edited by Valentina Savo, Universiti Tre Roma Press, Rome.
- Tongco, D. & W.C. McClatchey. Proximate and carbohydrate analysis of wild yam (*Dioscorea divaricata*Blanco), a culturally important species to the Magbukún Ayta of Kanawan, Morong, Bataan, Philippines.
 Food Chemistry in review.

2018

McClatchey, W.C. Finding Reciprocal Value in Language for Botanists and Linguists. Chapter in *The Oxford Handbook of Endangered Languages*. Oxford University Press, Oxford, U.K. Edited by K. Rehg and L. Campbell.

2017

• Ehara, H., T. Yamamoto, T. Tsuchiya, H. Naito, J.L. Dowe, W.C. McClatchey, T. Mishima, A. Itaya, C. Mizota, Y.B. Pasolon, P. Ala, M. Tuiwawa, A. Naikatini, I.A. Rounds, T. Foliga, S. Lui & S. Kwan. 2017. Phylogenetic Study of *Metroxylon* Palms in Southeast Asia and Oceania Based on 5S nrDNA Spacer Sequence Data. *Sago Palm* 25(1):xx-xx. (in press)

2015

- *McClatchey, W.C. & K.W. Bridges. 2015. Lessons learned in a conservation ethnobiology field school.
 Chapter in *Project-Based Learning and New Approaches in Teaching Botany and Applied Botany*. Edited by Valentina Savo, Universiti Tre Roma Press, Rome.
- *Savo, V., G. Caneva & W.C. McClatchey. 2015. Plant Selection for Ethnobotanical uses on the Amalfi Coast (Southern Italy). Journal of Ethnobiology and Ethnomedicine 11:58. DOI:10.1186/s13002-015-0038-y

2014

- *Tongco, M.D., W.C. McClatchey, E. Malicsi, M. Quitain, A. Malunic, M. Cayetano, J. Alejo, B. Restum, E. Restum & Magbukun Ayta Community. 2014. Traditional ecological knowledge of the wild yam buloy (*Dioscorea divaricata*) and its value to the Magbukún Ayta Community. *AghamTao* 23:45-79.
- *McClatchey, W.C., D. Reedy, V. Savo, A. Verde & J.F. Rodríguez. 2014. The Long-term Investment Strategy: Orchardists Observing and Reacting to Change. *Journal of Ethnobiology* 34(3):335-358.
- *Brown, A., W.C. McClatchey & K.W. Bridges. 2014. Traditional Botanical Knowledge of the Plain Mennonites: Time, Change, and Knowledge Transitions. *Ethnobotany Research & Applications* 13:571-596.
- *Savo, V., G. Caneva, W. McClatchey, D. Reedy & L. Salvati. 2014. Combining environmental factors and agriculturalists' observations of environmental changes in the traditional terrace system of the Amalfi Coast (Southern Italy). AMBIO: A Journal of the Human Environment DOI: 10.1007/s13280-013-0433-3

- *Reedy, D., V. Savo & W.C. McClatchey. 2013. Traditional Climatic Knowledge: Orchardists' perceptions of, and adaptations to, climate change in the Campania region (Southern Italy). *Plant Biosystems* DOI:10.1080/11263504.2013.793753.
- *McClatchey, W.C. & K.W. Bridges. 2013. Curating ethnobotanical photographs. Chapter 14 in *Curating Biocultural Collections*. Edited by J. Salick and K. Kincher. Kew Publishing, Royal Botanical Gardens, Kew, U.K. [2015 Book received the "Postgraduate Textbook Prize" by The Royal Society of Biology (England)]
- *McClatchey, W.C. & K.W. Bridges. 2013. Lessons learned in development of an interdisciplinary science curriculum support organization. Chapter in *Innovative Strategies for Teaching in the Plant Sciences*.
 Edited by C.L. Quave. Springer, New York.

• *McClatchey, W.C., G.E. Wagner, K Hall & P.D. Harrison. 2013. Editors of *Vision and Change for Undergraduate Ethnobiology Education in the U.S.A. Recommended curriculum assessment guidelines*. Open Science Network, Botanical Research Institute of Texas Press, Fort Worth.

2012

- *McClatchey, W.C. 2012. Wild food plants of Remote Oceania. Acta Societatis Botanicorum Poloniae 81(4):371-380.
- *McClatchey, W. 2012. Ethnobiology Basic methods used to document dynamic relationships between peoples, biota and environments, and ways in which this knowledge is represented in languages. Pp. 281-297 in *The Oxford Handbook of Linguistic Fieldwork*. Edited by Nick Thieberger. Oxford University Press, Oxford.

2011

- *Stevens-Releford, J. & W. McClatchey. 2011. Survivor Rongelap: Health issues and use of traditional medicine among women of Rongelap atoll. *Ethnobotany Research and Applications* 9:287-305.
- *Reedy, D., W.C. McClatchey, V. Savo, Y.H. Lau, C. Smith & K.W. Bridges. 2011. Cider house learning; Education based on taste and smell. Chapter 5 in *The Sense of Taste*. Edited by E.J. Lunch & A.P. Petrov. Nova Science Publishers, Inc., Hauppauge, New York. ISBN: 978-1-61209-748-0.
- *Savo, V., S. Bisceglie, G. Caneva, A. Kumbaric, W.C. McClatchey, D. Reedy. 2011. "Modern Linnaeus": A class exercise on plant nomenclature and taxonomy in comparison with a previous experiment.

 Ethnobotany Research and Applications 9:217-233.

2010

- *McClatchey, W. & D. Reedy. 2010. A Mouthful of Water: Do cider producers recognize the clean water
 potential of their products? Pp151-163 in *Tradiciones y Transformaciones en Etnobotánica*/Traditions and
 Transformations in Ethnobotany. Edited by Pochettino M.L., A. Ladio y P. Arenas. Edición Cyted (Programa
 Iberoamericano Ciencia y Técnica para el Desarrollo), San Salvador de Jujuy. ISBN 978-84-96023-95-6
- *Bauerle, C., A. DePass, D. Lynn, C. O'Conner, S. Singer, M. Whithers, C.A. Anderson, S. Donovan, S. Drew, D. Ebert-May, L. Gross, S. Hopkins, J. Labov, D. Lopatto, W. McClatchey, P. Varma-Nelson, N. Pelaez, M. Poston, K. Tanner, D. Wessner, H. White, W. Wood & D. Wubah. 2010. Vision and Change in Undergraduate Biology Education: A call to action. Edited by C. Brewer & D. Smith. American Association for Advancement of Science, Washington, DC.
- *McClatchey, W. 2010. Exorcising misleading terms from ethnobotany. Pp. 59-66 in Recent Developments and Case Studies in Ethnobotany. Edited by U.P. Albuquerque & N. Hanazaki. Brazilian Society of Ethnobiology and Ethnobotany (SBEE/Publication Group of Ecology and Applied Ethnobotany (NUPEEA), Ecife, Brazil.
- *McClatchey, W. 2010. Improving the quality of international ethnobotany research and publications. Pp. 143-152 in *Recent Developments and Case Studies in Ethnobotany*. Edited by U.P. Albuquerque & N. Hanazaki. Brazilian Society of Ethnobiology and Ethnoecology (SBEE/Publication Group of Ecology and Applied Ethnobotany (NUPEEA), Ecife, Brazil.
- *Amend, A., Z. Fang, C. Yi & W.C. McClatchey. 2010. Local perceptions of Matsutake mushroom management, in NW Yunnan China. *Biological Conservation*. 143:165-172.

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- *Winter, K. & W.C. McClatchey. Quantifying Evolution of Cultural Interactions with Plants: Implications for Managing Diversity for Resilience in Social-Ecological Systems. *Functional Ecosystems & Communities* 2 Special Issue 1:1-10.

2007

- *McClatchey, W. & K.W. Bridges. 2007. The Importance of Scale in Determination of Human Population Distributions in the Marshall Islands. Pp. 25-37 in *Recent Trends in Ethnopharmacology and Ethnobotany*. Edited by U.P. Albuquerque. Research Signpost Press, Kerela.
- *Prance, G.T., K. Aiona, M.J. Balick, B.C. Bennett, K. Bridges, D.A. Burney, L. Pigott Burney, R.A. Bye, L. Dunn, E. Emshwiller, M. Eubanks, T. Flaster, S. Kauka, D.L. Lentz, E. Linares, D.H. Lorence, W. McClatchey, H. McMillen, M. Merlin, J.S. Miller, D.E. Moerman, A.E. Prance, D. Ragone, J.H. Rashford, P. Raven, P.H. Raven, D. Reedy, J.R. Stepp, N.G. Tavana, R. Thaman, M.B. Thomas, T. Ticktin, T. Urban, P. Van Dyke, W. Wagner, W.A. Whistler, C.R. Wichman Jr., H. Wichman, K. Winter, J. Wiseman, M. Wysong & B. Yamamoto. 2007. Ethnobotany, the Science of survival: A declaration from Kaua'i. *Economic Botany* 61:1-2.
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- *Bridges, K.W. & W. McClatchey. 2006. Expecting the Unexpected: Safety Considerations for Ethnobotany Field Research. *Ethnobotany Research and Applications* 4:41-50.

- *McClatchey, W. & Lisa X. Gollin. 2005. An Ethnobotany Research Training Workshop in Madagascar. Ethnobotany Research and Applications 3:309-327.
- *Rakotonandrasana, Stéphan Richard, Lisa X. Gollin& W. McClatchey. 2005. Ethnobotanical Research at Analalava, Madagascar: A Photo Essay. Ethnobotany Research and Applications 3:391-403.
- *McClatchey, W. & K. Winter. 2005. Publication of Ethnobotanical Research in Local Languages. Ethnobotany Research and Applications 3:279-282.
- *McClatchey, W. 2005. Bioprospecting and Ethnobotany Research. *Ethnobotany Research and Applications* 3:189-190.
- McClatchey, W. 2005. What is Real Community Based Conservation? Ravintsara 3(2):3-4.
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- *McClatchey, W. 2005. Exorcizing Misleading Terms from Ethnobotany. *Ethnobotany Research and Applications* 3:1-4.

- *Bridges, K. & W. McClatchey. 2005. Complementing PABITRA High-Island Studies by Examining Terrestrial Plant Diversity in Atolls. *Pacific Science* 59:261-272.
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- *McClatchey, W, Harley Manner & Craig R. Elevitch. 2004. Metroxylon amicarium, M. paulcoxii, M. sagu, M. salomonense, M. vitiense, and M. warburgii (sago palms). Pp 1-23 in Species Profiles for Pacific Island Agroforestry. November 2004. www.traditionaltree.org Permanent Agricultural Resources, Honolulu, Hawai'i.
- *McClatchey, W., Randy Thaman & Sonia Juvik. 2004. Ethnobiodiversity Surveys of Human/Ecosystem
 Relationships. Pp. 159-196 in *Biodiversity Assessment of Tropical Island Ecosystems*. Edited by Dieter
 Mueller Dombois, Kim Bridges, and Curt Daehler, University of Hawaii, Honolulu.
- McClatchey, W. 2004. Techniques for Collection of Plants Specimens and Associated Records. In PABITRA
 Research Protocol Manual edited by Dieter Mueller Dombois, Kim Bridges, and Curt Daehler, University of
 Hawaii, Honolulu.
- *McClatchey, W. 2004. Cultural Interactions with Palms in the Tropical Pacific Region. Palms & Cycads 85:26-30.

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- Salick, J., J. Alcorn, E. Anderson, C. Asa, W. Balee, M. Balick, S. Beckerman, B. Bennett, J. Caballero, G. Camilo, A.B. Cunningham, E. Elisabetsky, L. Emperaire, G. Estabrook, G. Fritz, L. Gross, E. Hunn, T. Johns, E. Luoga, G. Martin, W. McClatchey, J. Miller, P. Minnis, D. Moerman, M. Paletti, D. Pearsall, C. Ramirez-Sosa, J. Rashford, B. Schaal, D. Spooner, J. Stepp, M. Thomas, T. Ticktin, N. Turner, J. Xu. 2003. *Intellectual Imperatives in Ethnobiology* NSF Biocomplexity Workshop Report. Missouri Botanical Gardens, St. Louis.
- *McClatchey, W. & M. Thomas. 2003. Why Launch a New Journal? Editorial in *Ethnobotany Research and Applications* 1:1-3.
- *McClatchey, W. 2003. Diversity of Growth Forms and Uses in the Morinda citrifolia L. Complex. Pp. 5-10 in Proceedings of the 2002 Hawai'i Noni Conference. Edited by Scot C. Nelson, University of Hawai'i College of Tropical Agriculture, Honolulu.

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- *McClatchey, W. 2002. Biogeographical Observation of Metroxylon Section Coelococcus. Pp. 119-126 in New Frontiers of Sago Palm Studies Proceedings of the International Symposium on SAGO (SAGO 2001) A New Bridge Linking South and North, Frontiers in Science Series No. 37 Edited by K. Kainuma, M. Okazaki, Y. Toyoda, & John E. Cecil. Universal Academy Press, Inc. Tokyo.
- *McClatchey, W. 2002. From Polynesian Healers to Health Food Stores: Changing Ethnopharmacology of *Morinda citrifolia*. *Journal of Integrative Cancer Therapy*. 1(2): 110-120.

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- McClatchey, W. & Valerie McClatchey. 2001. One-way bridges: Ethical dilemmas faced by Polynesian healers who share their knowledge. In *Building Bridges with Traditional Knowledge: An Exploration of Issues Involving Indigenous peoples, Conservation, Development and Ethnoscience*. Edited by Alexandra Paul and Charles Peters. New York Botanical Garden, Bronx, NY.
- *McClatchey, W. & Jodi Stevens. 2001. An Overview of Recent Developments in Bioprospecting and Pharmaceutical Development. Pp 17-45 in *Development of Plant-Based Medicines: Conservation, Efficacy and Safety* Edited by Praveen K. Saxena, Kluwer Academic Publishers, Dordroht, The Netherlands.
- McClatchey, W. 2001. Legal "Fireworks": A Botanical Celebration. *The Kukui Leaf* 28(3):1-2.

- *McClatchey, W. 2000. The History of Bananas and Plantains. Pp 175-180 in *The Cambridge World History of Food* Vol. I edited by K.F. Kiple & K.C. Ornelas,. Cambridge University Press, Cambridge, UK.
- McClatchey W., Jon Mozena, Myknee Sirikolo, Jodi Stevens, Michael Wysong, & Piet Lincoln. 2000. Editors
 of Ririo English Dictionary with Babatana equivalents, ethnobiological terminologies, and scientific
 names by Harry Truman Boe, Edison Biliki, Edwin Kaboke, Martin Love, Ester Nalatüti, Isaiah Poloso,
 Monica Qilazuka, Jonathan Takubala, & Frederick Vot'boc. University of New South Wales, Sydney.

- *McClatchey, W., Randy Thaman & Saula Vodonaivalu. 2000. A Preliminary Checklist of the Flora of Rotuma with Rotuman Names. *Pacific Science* 54:345-363.
- McClatchey, W. & Jodi Stevens. 2000. How a Seacology Project is Born: Tales from the Solomon Islands. Seacology Fall 2000.

- *Mueller-Dombois, D., R.R. Thaman, J.O. Juvik, W.C. McClatchey & K. Kitayama. 1999. The Pacific-Asia Biodiversity Transect (PABITRA): A new conservation biology initiative. Pp. 13-20 in *Biodiversity and allelopathy: From organisms to ecosystems in the Pacific*. Edited by C.-H. Chou, G.R. Waller & C. Reinhardt. Academia Sinica, Taipei.
- *McClatchey, W., Alexandra Paul, Trish Flaster, & Valerie McClatchey. 1999. An Evaluation of Educational Trends in Economic Botany. *Centre for International Ethnomedicinal Education and Research: Ethnobotany Educational Publication Series* 1:1-21
- McClatchey, W. 1999. Introductory Ethnobotany. Kendall-Hunt Publishing, Dubuque, Iowa, 98 pp.
- McClatchey, W. 1999. *Introductory Ethnobotany Laboratory Manual*. Kendall-Hunt Publishing, Dubuque, Iowa, 86 pp.
- McClatchey, W. 1999. In the classroom: suggested elements of economic and ethnobotany courses and programs of study. *Society for Economic Botany Newsletter* 13:5-7.
- McClatchey, W., M. Q. Sirikolo, H. Boe, M. Biliki, E. Biliki, & F. Votboc. 1999. A Proposed Pacific-Asia Biodiversity Transect (PABITRA) Terrestrial Research Site on Lauru in the Western Solomon Islands. Web published on the PABITRA web site, University of Hawaii, Department of Botany.

1998

- *McClatchey, W. 1998. Phylogenetic Analysis of Morphological Characters of *Metroxylon* Section *Coelococcus* (Palmae) and Resulting Implications for Studies of Other Calamoideae Genera. Pp. 285-306 in *Evolution, Variation, and Classification of Palms*. Edited by Andrew Henderson. Memoirs of the New York Botanical Garden.
- *McClatchey, Will. 1998. A New Species of the Genus Metroxylon (Arecaceae) from Western Samoa.
 Novon 8:252-258.

1996

- *McClatchey, W. 1996. The Ethnopharmacopoeia of Rotuma. Journal of Ethnopharmacology 50:147-156.
- McClatchey, W.1996. *A revision of the genus Metroxylon section Coelococcus (Arecaceae)*. Ph.D. Dissertation, University of Florida, Gainesville, Florida.
- N'Yeurt, Antoine D.R., Will McClatchey, & Hans Schmidt. *A Bibliography of the Island of Rotuma*. South Pacific Marine Studies Technical Publication, Suva, Fiji.

1993

- McClatchey, W. 1993. *The Traditional Medicinal System and Ethnopharmacopoeia of Rotuma*. Masters Thesis. Brigham Young University, Provo, Utah.
- *McClatchey, W. 1993. Traditional use of *Curcuma longa* (Zingiberaceae) in Rotuma. *Economic Botany* 47:291-296.

- *McClatchey, W. & P.A. Cox. 1992. Use of the Sago Palm *Metroxylon warburgii* in the Polynesian Island, Rotuma. *Economic Botany* 46:305-309.
- *Nagle, D.G., W. McClatchey & W.H. Gerwick. 1992. New Glycosphingolipids from the Marine Sponge, Halichondria panicea. Journal of Natural Products 55:1013-1017.

PEER-REVIEWED JOURNAL EDITOR

- Ethnobotany Research and Applications (Editor-in-chief 2003-2015)
- Economic Botany (Editorial board 2006-2010)
- Ethnobiology and Ethnomedicine (Editorial board 2008-2012)

PEER PUBLICATION REVIEWER (Examples)

Ethnobiological Journals

- EcoHealth
- Economic Botany
- Ethnobiology
- Ethnobiology and Ethnomedicine
- Ethnobotany Research and Applications
- Ethnopharmacology
- Human Ecology
- Journal of Ethnobiology

Medical Journals

- Hawaiian Medical Review
- Health Policy
- Pharmaceutical Biology

Taxonomic Journals

• American Journal of Botany

- Novon
- Palms

Regional Journals

- Journal of the Polynesian Society
- Oceanic Linguistics
- Pacific Science
- Pacific Studies
- Sago Research Journal
- ScienceAsia
- The Contemporary Pacific

Multi-disciplinary Journals

- Science
- Proceed of the National Academy of Science

PEER GRANT PROPOSAL REVIEWER (Examples)

U.S. National Institute of Health

U.S. National Science Foundation

U.S. Fulbright Program

American Association for Advancement of Science International Foundation for Science National Geographic Society

INTERNATIONAL COMMITTEE MEMBERSHIP

- American Botanical Council, Advisory Board Member (2002-2019)
- Society for Economic Botany, Education Committee (1995-2005)
- U.S. National Committee for the International Union of Biological Sciences (USNC/IUBS) (2005-2012)
- William L. Brown Center for Plant Genetic Diversity, Board Member (2008-2014)

SCIENTIFIC SOCIETY MEMBERSHIP AND SERVICE

- American Association for Advancement of Science (1990-2014)
- Linnean Society of London (elected 2010)
- Oregon Flora Project <u>www.oregonflora.org</u>
 - Advisory Committee (since 2015)
- Pacific-Asia Biodiversity Transect Network (PABITRA) (Pacific Science Association Section)
 - Workshop co-organizer (2000, 2003)
 - Organizational development (1998-2005)

- Co-founding member
- Pacific Science Association (1998-2010)
- Society for Economic Botany (SEB)
 - Economic Botanist of Year, 2013
 - o President, 2006-2007
 - o Secretary, 2002-2005
 - o Council Member-at-large, 1998-2001
 - Member since 1989, now lifetime
- Society of Ethnopharmacology
 - o Co-founding member 1990

EDUCATIONAL VIDEOS PRODUCED

(most available at https://sites.google.com/site/introtoethnobotanyvideos/) 2007

- McClatchey, W., M. Ostraff, T. Ticktin & C. Davenport. Maintaining the Beat. In four episodes.
 - Why are Plants Useful to Us? Filmed at University of Hawai'i, Manoa.
 - Hula Plants (27 minutes) Filmed at various locations on Maui.
 - o Felted Bark: Kapa/Tapa (in production) filmed at Makapu'u and Bishop Museum, O'ahu.
 - o Kuo Hina E Hiapo (27 minutes) M. Ostraff filmed in Tonga. Provided for series.

2006

- McClatchey, W. T. Ticktin, M. Merlin & K. Winter. I'll Drink to That! In five episodes.
 - o Stimulating Beverages (34 minutes) Filmed at University of Hawai'i, Manoa.
 - Alcoholic Beverages (40 minutes) Filmed at Murphies Bar, O'ahu.
 - o 'Awa and Cultural Conservation (52 minutes) Filmed at Limahuli Botanical Garden, Kaua'i.
 - Entering Another World (22 minutes) Filmed at University of Hawai'i, Manoa.
 - Plants of the Gods (43 minutes) Filmed at St.John Garden.
- Ticktin, T., C. Trauernicht, O. Gauoe. *Conservation of Culture and Biodiversity*. In three episodes.
 - Ethnoecology and Conservation (36 minutes) Filmed at University of Hawaii, Manoa.
 - Ethnobotany and Conservation in Micronesia (16 minutes) Filmed at various locations on Pohnpei, Federated States of Micronesia.
 - Ethnobotany and Conservation in Africa (24 minutes) Filmed at University of Hawaii, Manoa.
- McClatchey, W. Science, Faith and Plant Thoughts. In four episodes.
 - o Taxonomy (44 minutes) Filmed at St.John Garden.
 - o Ethics (55 minutes) Filmed at Kapiolani Garden, O'ahu.
 - o Buddhism and Plants (30 minutes) Filmed at Honolulu Myohoji Mission.
 - o Christianity and Plants (40 minutes) Filmed at St. Elizabeth Episcopal Church.

- Discovery Channel Production Featuring W. McClatchey
 - Moringa-The Miracle Tree. (16 minutes) Filmed in Hawai`i, Mexico, and various locations in Africa.
- McClatchey, W. Ethnobotany: The Science of Interactions between People and Plants. In four episodes.
 - o Introduction to Ethnobotany (29 minutes) Filmed at Lyon Arboretum.
 - Guns, Germs and Steel (31 minutes) Filmed at University of Hawaii, Manoa.
 - o Transported Landscapes (46 minutes) Filmed at Ka'ena Point, O'ahu.
 - Origins of Plant Uses (26 minutes) Filmed at University of Hawai'i, Manoa.
- McClatchey, W. & I. A. Abbott. Evolution of Oceanic Cultures. In four episodes.
 - Evolution of Pacific Cultures (19 minutes) Filmed at University of Hawai'i, Manoa.
 - o Lapita Toolkits (36 minutes) Filmed at University of Hawai'i, Manoa.
 - o Crops in Pacific Island Cultures (24 minutes) Filmed at University of Hawai'i, Manoa.
 - o Limu (Algae) (42 minutes) Filmed at Waialae Beach Park, O'ahu.
- McClatchey, W., T. Ticktin & M. Nguyen. What's Really for Dinner. In four episodes.
 - Wild Food Plants (25 minutes) Filmed at University of Hawai'i, Manoa.
 - Origins of Agriculture (46 minutes) Filmed at Kawela and Waialee, O'ahu.
 - o World Food Crops (30 minutes) Filmed at University of Hawai'i, Manoa.
 - o Cultural Diaspora & Culinary Knowledge (16 minutes) Filmed on O'ahu.
- McClatchey, W., L.X. Gollin & T. Ticktin. So Bitter, So Strong! In four episodes.
 - o Illness and Medicine in Cultural Settings (38 minutes) Filmed at Wa'ahila State Park, O'ahu.
 - o Making Sense of Plant Medicines (39 minutes) Filmed at St.John Garden.
 - Herbal Remedies (34 minutes) Filmed at Wa'ahila State Park, O'ahu.
 - Medicinal Plant Conservation (36 minutes) Filmed at University of Hawai'i, Manoa.

- McClatchey, W. L. 'Ohai & Y.H. Lau. *Peaceful Warriors*. In four episodes.
 - o Polynesian Herbal Medicine (43 minutes) Filmed at University of Hawai'i, Manoa.
 - o Rotuman Health Care (44 minutes) Filmed at Sand Island, O'ahu.
 - o Hawaiian Health Care (34 minutes) Filmed at Limahuli, Kaua'i.
 - Chinese Traditional Medicine (21 minutes) Filmed at St.John Garden.
- McClatchey, W., D. Webb, T. Ticktin & S. Leinweber. Home is Where the Heart is. In five episodes.
 - Shelter and Cultural Identification with Nature (38 minutes) Filmed at Pu'uHonua o Honaunau,
 Hawai'i
 - What Makes Plants Waterproof? (32 minutes) Filmed at University of Hawai'i, Manoa.
 - Hawaiian Housing Materials (38 minutes) Filmed at Bishop Museum, O'ahu.
 - o Architecture and Historic Buildings (27 minutes) Filmed at 'iolani Palace, O'ahu.
 - Home Gardens (38 minutes) Filmed at University of Hawai'i, Manoa.

Not completed but available for production with funding for final editing

- McClatchey, W. Hawaiian Voices. In six episodes.
 - o The Queens Garden (in production) with Nalani Olds at various locations on O'ahu.
 - o `ahupua`a o Kahana (in production) with Sunny Greer and Dieter Mueller-Dombois at Kahana Valley on O`ahu
 - Surfing Plants (in production) with Ian Masterson at various location in the Hawaiian Islands.
 - o Chants with Plants (in production) with Sam Gon and John Lake at various locations on O'ahu.
 - Marking Time. (in production) with Keoni Nunes at various locations on O'ahu.
 - o Na Mea Kaua Hawai`i. (in production) with La`akea Suganuma at various locations on O`ahu.
- McClatchey, W. Fundamental Research Methods for Ethnobotanists: Part I. In four episodes.
 - Herbarium Specimens (in production) filmed at Bishop Museum / University of Hawaii, Manoa.
 - Market Surveys (in production) filmed at Honolulu China Town, Kalihi Filipino Market and Moilili,
 Star Market.
 - o Informed Consent and Human Subjects (in production) filmed with W. Dendle.
 - O Questionnaires (in production) filmed at various locations on O'ahu and Hawai'i.

WORKSHOPS AND CONFERENCES ORGANIZED

2017

 McClatchey, W.C. Field Methods for Collecting Biological Information. Training workshop within the 10th Conference on Oceanic Linguistics, Honiara, Solomon Islands. (July 10-15)

2015

 McClatchey, W.C. & G. Bascope. Botanical Field Collections for Non-Botanists. Training workshop organized by the Maya Research Program, Blue Creek, Belize. (July 6-9)

2014

- Hall, K. & W.C. McClatchey. *Ethnobiology Field Methods for Linguists*. Practical training in use of a variety of field methods for documentation of biological materials used in cultures and of interest to linguists. University of Texas, Arlington, Texas. (June 16-26)
- McClatchey, W.C. & K. Hall. Ethnobiology Field Methods for Linguists. Practical training in use of a variety
 of field methods for documentation of biological materials used in cultures and of interest to linguists.
 Graduate Institute of Applied Linguistics, Dallas, Texas. (May 18-19)

2013

- McClatchey, W.C. & D. Reedy. Global Cider Diversity. A practical training and research process on identification and tasting biodiversity. Hosted within the Society of Ethnobiology annual meeting, Denton, Texas. (May 16)
- McClatchey, W.C. Folk Taxonomy. Invited organizer of a Master Class Workshop at the 3rd International Conference on Language Documentation and Conservation. Honolulu, Hawaii. (March 1-2)

2012

- Harrison, P., K. McNew & W. McClatchey. Ethnobiology Curriculum Standards Workshop III. Invited
 participants workshop sponsored by the Open Science Network. National Tropical Botanical Gardens,
 Lawai, Kaua`i. (October 10-14)
- Harrison, P., K. McNew & W. McClatchey. *Ethnobiology Curriculum Standards Workshop II*. Invited participants workshop sponsored by the Open Science Network. Botanical Research Institute of Texas, Fort Worth. (February 2-5)

2011

- Harrison, P., K. McNew, S. Brosi & W. McClatchey. Ethnobiology Curriculum Standards Workshop. Invited participants workshop sponsored by the Open Science Network. Johns Hopkins University, Baltimore, Maryland. (November 17-19)
- Tongco, D.M. & W.C. McClatchey. *Flora of the Philippines project*. Workshop on organization of future collaborative research efforts. 30 participants. Held at the University of Philippines, Diliman. (June 21)

2009

McClatchey, W., H.Y. Lau & K.W. Bridges. Conservation Research in the Mekong Region. Invited minisummit meeting on culture, environment and ethnobotany in SE Asia, sponsored by the Center for SE Asian Studies, University of Hawai'i. University of Hawai'i campus. (April 11)

2007

McClatchey, W. Implementing The New Ethnobotany in the Society for Economic Botany. Invited workshop organizer, presenter and moderator, Society for Economic Botany Annual meeting, Chicago, Illinois. (June 6)

- Yee, Jonathan, Skip Bittenbender, W. McClatchey & S. Gon. *Hawai`i and Pacific Island Kava Festival*. Honolulu, Hawai`i. (October 7)
- McClatchey, W. & B. Bennett. *Curriculum Development and Ethnobotany Certification*. Invited workshop organizers and presenters, Society for Economic Botany Annual meeting, Chiang Mai, Thailand. (June 7)

McClatchey, W. Travel Medicine as a Community Pharmacy Practice. Invited organizer and presenter.
 Three-part workshop for continuing education of pharmacists in Thailand. Faculty of Pharmacy, Khon Kaen University, Khon Kaen, Thailand. (February 2-16)

2005

- McClatchey, W. & L. Gollin. *Ethnobotany Field Methods in Conservation of Biological Diversity*. Invited organizers and presenters of a 10 day intensive field workshop for Malagasy conservation biologists. Antananarivo and Analalava, Madagascar. (March22 April 4)
- McClatchey, W. Ethnopharmacology and Realistic Studies of Traditional Health Care Systems. Invited Workshop Coordinator and Speaker, University of Hawai'i, Windward, Kaneohe, Hawai'i. (January 31)

2004

• McClatchey, W., K. Bridges, A.B. Cunningham, M. Stockton, and M. Thomas. *Using Technology Effectively to address Ethnobotanical Research Questions*. Presentation and Workshop, Society for Economic Botany Annual meeting, Canterbury, England. (June 16)

2001

- McClatchey, W. & Trish Flaster. Development of Herbal Products from Traditional Samoan Medicinal Plants: Ethical, Cultural, Legal, and Commercial Aspects Two-day workshop conducted for the Land Grant College of American Samoa, PagoPago, American Samoa (October 30-31)
- McClatchey, W. Parallels between Ecological and Individual Health. Sponsored community workshop, Queen's Hospital, Healing Heart Institute, Honolulu, Hawai'i. (August 4)
- McClatchey, W., M. Faigle, V. McClatchey, et al. *Building Bridges with Traditional Knowledge: An International Summit Meeting on Ethnoscience*. Honolulu, Hawai'i. (May 28-June 3)
- McClatchey, W. & Mylien Nguyen. Herbs, Health and Happiness in the Garden of Life. Sponsored community workshop at Lyon Arboretum, Queen's Hospital, Healing Heart Institute, Honolulu, Hawai'i. (April 7)

1998

 McClatchey, W. & Myknee Sirikolo. Ethnobotanical Research Techniques for Village Based Studies in the Solomon Islands. Invited speaker. World Wildlife Fund Workshop on Ethnobotany, Honiara, Solomon Islands. (May 27)

SELECTED WORKSHOP PARTICIPATION

n15

• Ethnobotany in the Field. Remote presentation to Fairbanks, Alaska. (October 14)

2013

- Biocultural Diversity Collections. Royal Botanical Gardens, Kew. (June 27)
- Open Science Network. Royal Botanical Gardens, Kew. (June 26)

2012

- Biocultural Diversity Collections. Frostburg State University, Frostburg, Maryland. (June 8)
- CEPF Ecosystem Profile for the East Melanesian Islands Biodiversity Hotspot. Regional Stakeholder Consultation Workshop. Held by the Critical Ecosystem Partnership Fund in Honiara, Solomon Islands. (April 30)

2011

Biocultural Diversity Collections. Missouri Botanical Gardens and American Botanical Society Workshop.
 St. Louis, Missouri. (July 10) Resulted in production of a peer-reviewed book: Biocultural Collections Curation Standards. Edited by Jan Salick. Missouri Botanical Garden Press, St. Louis.

2009

• Ethnobiology in Language Documentation. International Conference on Language Documentation & Conservation Conference Workshop (March 12-14). Resulted in production of a peer-reviewed book: The Oxford Handbook of Linguistic Fieldwork. Edited by Nick Thieberger. Oxford University Press, Oxford.

• The Future of Economic Botany. Society for Economic Botany Workshop. Limahuli Botanical Garden, Kauai. (January 24-25) Resulted in production of "The Kaua'i Declaration"

2006

• *Economic Botany Publications*. Society for Economic Botany Workshop. Montgomery Foundation, Miami, Florida. (January 6)

2003

- Asian Americans and Pacific Islanders' Issues: The Challenges of Success. National Science Foundation, International Programs Workshop. Arlington, Virginia. (November 3-4)
- Intellectual Imperatives in Ethnobiology National Science Foundation Biocomplexity Workshop. Missouri Botanical Gardens, St. Louis. (March 10-11). Resulted in production of a white paper for NSF

SELECTED PRESENTATIONS

2017

- McClatchey, W.C. 2017. When Botany and Linguistics Collide. Keynote presentation in the 10th Conference on Oceanic Linguistics, Honiara, Solomon Islands. (July 10-15)
- McClatchey, W.C. 2017. Woodland Meadows and Streuobstwiese: Traditional European orchard management for Oregon. Monthly speaker for Emerald Native Plant Society meeting. (March 16)

2013

- McClatchey, W.C. 2013. Encouragement to Grow Apples & Grapes in Semi-arid Texas. Keynote
 presentation in the Botanical Research Institute of Texas Research Symposium (August 3).
- Reedy, D. & W.C. McClatchey. 2013. Learning from the Past, Adapting to the Future; Orchardists'
 Perceptions of Climatic Changes, Effects on Orchards, and Their Strategies to Cope with Change and Adapt
 to Future Climates. Poster presented in the Botanical Research Institute of Texas Research Symposium
 (August 3).
- McClatchey, W.C. 2013. A Future for Ethnobotany. Economic Botanist of the Year presentation, Society for Economic Botany annual meeting, Plymouth, U.K. (June 30).
- McClatchey, W.C. & D. Reedy. 2013. The Long-term Investment Strategy: Orchard Managers Observing and Reacting to Change. Plenary Session Speaker, Climate Change and Ethnobiology at the Society of Ethnobiology annual meeting, Denton, Texas (May 15).
- McClatchey, W.C. & D. Reedy. 2013. *Some Sacred and Practical Trees*. Keynote Speaker at the New Zealand Tree Growers Association annual meeting, Hamilton, New Zealand (April 26).
- McClatchey, W.C. & D. Reedy. 2013. *Exploring Plant Diversity through Folk Taxonomy*. Invited Speaker at the Graduate Institute for Applied Linguistics, Academic Forum. Dallas, Texas (March 26).
- McClatchey, W.C. Field Methods for Collecting Plant-related Information. Invited Speaker at the Summer Institute for Linguistics, Language Documentation Course. Dallas, Texas (March 26).
- Reedy, D., W. McClatchey, K. Barfield & R. Swadek. 2013. The World's Largest Cider Tastings and their Potential Impact on Future Orchard Diversity. Contributed poster 2nd research Symposium on the Botanical Research Institute of Texas, Fort Worth Texas (February 2).

- Boutain, J., J-C Xu, S. Keeley & W. McClatchey. 2012. On the origin of hops (Humulus, Cannabaceae): Ethnobotany, phylogeny, and next-generation hops in China. Poster presentation in EcoHealth 2012: Sustaining ecosystems, supporting health. Beijing, China (October 4).
- McClatchey, W.C. 2012. Ethnobotany of the Home and Hearth. Invited presentation to the Tarrant County chapter of the Native Plant Society of Texas. Fort Worth Botanical Garden, Fort Worth, Texas (August 2).
- Reedy, D., W.C. McClatchey, K. McNew, K.W. Bridges & M. Huddleston. 2012. Conservation Ethnobiology Field School: A transportable campus approach to Problem-Based Learning. Contributed paper 1st Research Symposium of the Botaical Research Institute of Texas, Fort Worth, Texas (July 16).

- McClatchey, W.C. K.W. Bridges, B. Yamamoto, D. Reedy & M. Huddleston. 2012. *Implementation of Vision and Change Ethnobiology 1.0 Recommendations in a Field School Setting*. Invited symposium presentation (The Future of Ethnobiology Education) at the 53rd Annual Meeting of the Society for Economic Botany, Frostburg, Maryland (June 5).
- Brown, A., W.C. McClatchey & K.W. Bridges. 2012. Time, Change and Botanical Knowledge Part 2: A historical comparison of the pharmacopeias of the Delaware tribes, Mennonites, and Amish in Eastern North America. Contributed poster at the 53rd Annual Meeting of the Society for Economic Botany, Frostburg, Maryland (June 6).
- Chock, A.K., W.C. McClatchey & T. Ticktin. 2012. Using Community Resources to Supplement Introductory Ethnobotany Courses. Contributed paper at the 53rd Annual Meeting of the Society for Economic Botany, Frostburg, Maryland (June 7).
- Reedy, D. & W.C. McClatchey. 2012. *An Evening with Cider: An interactive research event*. Research presentation within an event for top-level donors of the Botanical Research Institute of Texas, Fort Worth, Texas. (January 26).

- McClatchey, W. 2012. *Ethnobotany of the Home and Hearth*. Annual Distinguished Ethnobotanist Lecture 2011. Royal Botanic Gardens, Kew, UK (October 11).
- Reedy, D. & W.C. McClatchey. 2011. *Identification of a fiber of Typha domingensis Pers. From the Joseph Banks collection and its resulting impact on culture and artifact identification*. Invited presentation, University of Oxford, Pitt Rivers Museum, Oxford, England (October 7).
- McClatchey, W. 2011. Bitter Pills: Lessons Learned While Developing Medical Ethnobotany. Symposium
 presentation at 52nd Annual Meeting of the Society for Economic Botany, St. Louis, Missouri (July 12).
- Reedy, D. & W. McClatchey. 2011. Adopted by Invasives; The Children of Opaero (Typha domingensis Pers.) from Temae, Moorea. Contributed paper 52nd Annual Meeting of the Society for Economic Botany, St. Louis, Missouri (July 11).
- McClatchey, W. 2011. *Curating Ethnobotanical Photographs*. Workshop presentation at the 52nd Annual Meeting of the Society for Economic Botany, St. Louis, Missouri (July 10).
- McClatchey, W., P. Mokamul, W Pensuk & K. Bridges. 2011. *Lao and N.E. Thailand: A frontier of Indian plant knowledge in SE Asia*. Invited presentation, University of the Philippines Diliman (June 22).
- Reedy, D. & W. McClatchey. 2011. *Identification of a Mat Fiber From Captain Cook*"s 1st Voyage and Its Modern Cultural Impact. Invited presentation, University of the Philippines Diliman (June 22).
- Reedy, D. & W. McClatchey. 2011. *Adapting Invasives; Lessons from a Moorean Mat Fiber*. Contributed paper, 21st Pacific Science Congress, Kuala Lumpur, Malaysia. (June 14).
- McClatchey, W., D. Reedy & P. Lincoln. 2011. *Preliminary Analysis of Relationships between Solomon Island Language and Plant Distribution Data*. PABITRA Research Symposium Paper in the 21st Pacific Science Congress, Kuala Lumpur, Malaysia. (June 14).
- Reedy, D. & W. McClatchey. 2011. *Cider Knowledge, Orchard Conservation, and Adaptations to a Changing Climate*. Invited presentation at the University of North Texas (February 8).

2010

- McClatchey, W., & D. Reedy. 2010. The Tree of Life: An ecological continuum of food, medicine, and poison. Plenary lecture, 11th congress of the International Society of Ethnopharmacology, Albacete, Spain (September 23).
- McClatchey, W., D. Reedy, A. Chock, T. Ticktin. 2010. Enhancing STEM education through redesign of an entire degree curriculum: Ethnobiology. Contributed poster, Society for Economic Botany annual meeting, Xalapa, Mexico (June 7).
- McClatchey, W.C. & D. Reedy. 2010. A Mouthful of Diversity: Cider Production around the World and Conservation of Traditional Apples. Invited Spring Colloquium, East-West Center, Honolulu, Hawai'i. (March 3).

- McClatchey, W.C. & K. Winter. *Resilience in Polynesian Landscapes Addressing Climate Change Stress*. IUCN Symposium, Kirstenbosch Botanical Garden, Cape Town, South Africa. (October 8)
- McClatchey, W.C. & D. Reedy. A Mouthful of Diversity: Cider Production around the World and Conservation of Traditional Apple Cultivar Diversity. Plenary Lecture. 5th International Congress of Ethnobotany. Bariloche, Argentina. (September 22)
- McClatchey, W.C., D. Reedy, A. K. Chock, K. Bridges, H. Lau, K. Kamelamela, L. Weiss, Z. Ritchey, M.L. Nguyen, T. Ticktin, T. Gallaher & V. Savo. *Ethnobotany Segues to Science: Using Popular Classes to Increase Enrollment in STEM Courses & Degree Programs*. Poster presented at the Society for Economic Botany Annual Meeting, Charleston, South Carolina. (June 4-5)
- McClatchey, W.C., P. Mokamul, A. Pensuk and K.W. Bridges. Lao and N.E. Thailand: A frontier of Indian plant knowledge in SE Asia. Plenary Lecture. Mekong Conservation and Ethnobotany Symposium.
 University of Hawaii at Manoa, Honolulu, Hawai`i. (April 11)
- McClatchey, W., M. Sirikolo, J. Stevens & P. Lincoln. Ethnobotany Research and Documentation of the Endangered Ririo Language (Solomon Islands). First International Conference on Language
 Documentation and Conservation Supporting Small Languages Together, Honolulu, Hawai`i. (March 14)
- Winter, K. K. Bridges & W. McClatchey. The Role of Linguistics in Identifying Social-Ecological Keystones. Symposium on Linguistics and Ethnobiology: Possible synergies for research and conservation. in First International Conference on Language Documentation and Conservation Supporting Small Languages Together, Honolulu, Hawai'i. (March 14)

- McClatchey, W., Z. Ritchey & K.W. Bridges. Shifting Cultivation as an Ecologically Creative Process. Invited
 Presentation in Symposium: Rainforest as Artifact in the Sixth World Archeology Congress, Dublin, Ireland.
 (July 4)
- Reedy, D., W.C. McClatchey, C. Smith & K.W. Bridges. A Mouth Full of Diversity: Knowledge of Cider Apple Cultivars. Contributed paper in the 49th Annual Society for Economic Botany meeting, Duke University, Raleigh, North Carolina. (June 3)
- McClatchey, W. David Reedy, Han Lau, Al Chock, Kim Bridges, My Lien Nguyen, Tim Gallaher, Zak Ritchey, Pauline Chinn, Thomas Garran, Tamara Ticktin and David Webb. *Ethnobotany: Segues to Science*. Invited Symposium presentation, Society for Economic Botany annual meeting, Durham, NC. (June 1)
- McClatchey, W. Climate Change and Impacts on Plants and People of the World. Guest Lecture Series, National Tropical Botanical Garden, Kaua`i. (February 15)

- Reedy, D., M. Nguyen, K. Bridges & W. McClatchey. *Ethnobotany: Segues to Science*. Contributed paper, Society for Economic Botany annual meeting, Chicago. (June 7)
- McClatchey, W., W. Pensuk, P. Mokamul & K.W. Bridges. *A Questions of Scale: Where is Biodiversity within a Hotspot?* Contributed paper, Society for Economic Botany annual meeting, Chicago. (June 6)
- McClatchey, W. Learning from our Ancestors about the Future of Life on Earth. Invited John Dwyer Lecturer, St. Louis University, St. Louis, Missouri. (April 27)
- McClatchey, W. & K. Bridges. Ethnoecological Insights from People Living on the Margin. Invited
 Presentation in Symposium: None Like it Hot: Climate Change, Plants, and People, Environmental Change
 Institute, University of Oxford, Oxford, U.K. (April 19)
- McClatchey, W. & K. Bridges. Using Traditional Knowledge of Plants as a Measure of Local Biodiversity.
 Jean Andrews Visiting Faculty Fellow of Tropical and Economic Botany, invited speaker, Lady Bird Johnson, Wildflower Center, Austin, Texas. (March 21)
- McClatchey, W., K. Winter & K. Bridges. Ethnobotanical Basis of Plant Classification Systems in Polynesia.
 Jean Andrews Visiting Faculty Fellow of Tropical and Economic Botany, invited speaker, University of Texas, Austin. (March 20)

- McClatchey, W. & K. Bridges. Impacts of Climate Change on Atoll Cultures of the Central Pacific. Jean
 Andrews Visiting Faculty Fellow of Tropical and Economic Botany, invited speaker, University of Texas,
 Austin. (March 19)
- McClatchey, W. Biocognosy: Extracting Conservation Theory and Applications from Plant Collections.
 Invited speaker, Missouri Botanical Gardens, St. Louis. (March 15)

- McClatchey, W. & K. Bridges. *Biodiversity and Biocognosy of Phutai in N.E. Thailand*. Botany Symposium Series, University of Hawaii at Manoa, Honolulu. (December 6)
- McClatchey, W. & K. Bridges. Using Traditional Knowledge of Plants as a Measure of Local Biodiversity and Identification of Species New to Science. Anthropology Colloquium, University of Hawaii at Manoa, Honolulu. (October 25)
- McClatchey, W. Medical Ethnobotany: Wisdom of the Past for Survival in the Future. Invited presentation. University of North Texas, Health Science Center, Fort Worth. (October 6)
- McClatchey, W. Natural Products from Plants used in the Treatment of Liver Disorders. Keynote Speaker.
 Continuing Education in Natural Pharmacy, Chareonthani Hotel, Khon Kaen, Thailand. (May 18)

2005

- McClatchey, W. *Ethnobotany in Pharmacy Practice in the U.S.A.* Invited Speaker. Faculty of Pharmacy, Khon Kaen University, Khon Kaen, Thailand. (November 7)
- Bridges, K & W. McClatchey. *The Peaks and Valleys of Presenting Ethnobotanical Data*. Contributed paper, Society for Economic Botany Annual meeting, Fort Worth, Texas. (June 7)
- McClatchey, W. & K. Bridges. Quantum Ethnobotany and Survival in the Marshall Islands. Invited Symposium Speaker, Society for Economic Botany Annual meeting, Fort Worth, Texas. (June 6)

2004

- McClatchey, W. *Polynesian Healers, Plants, and Ethnopharmacology*. Invited speaker. Lady Bird Johnson, Wildflower Center, Austin, Texas. (October 14)
- McClatchey, W. *Polynesian Healers, Plants, and Ethnopharmacology*. Invited speaker. Botanical Research Institute of Texas and the Fort Worth Botanical Garden, Symposium. (October 13)
- Hansen, C., M. Ross, D. Srock, V. McClatchey & W. McClatchey. Examination of Phytochemical and Traditional Usage Diversity Across a Range of Plant Families. Poster presented at the 2004 Annual Meeting of the Society for Economic Botany, Canterbury, England (June 14).
- McClatchey, W. Some Observations on Cultural Interactions with Palms in the Western Pacific. Invited Speaker. International Palm Society annual meeting, Honolulu, Hawai'i. (May 9)
- McClatchey, W. The Importance of Scale in Determination of Human Population Distributions in the Marshall Islands. Invited Speaker. Millennium Ecosystem Assessments, Alexandria, Egypt. (March 17)
- McClatchey, W. The Pacific Island Way: Oldest Agriculture in the World to Space Age Solutions. Invited Speaker. University of Hawai'i, Hilo, Geography Department, Hilo, Hawai'i. (February 24)
- McClatchey, W. Development of a National Botanical Garden in Palau. Invited Speaker. Palau Tourists Authority and Palau Conservation Society, Koror, Palau. (January 31)

- McClatchey, W. The Pacific Island Way: Oldest Agriculture in the World to Space Age Solutions. Invited Speaker. Volcanoes National Park, After-Dark in the Park Seminar Series, Volcano, Hawai'i. (September 16)
- McClatchey, W. & K. Bridges. Emergent Theories of Human Interactions with Plants based upon 55 years
 of Economic Botany. Contributed Paper, Society for Economic Botany Annual meeting, Tucson, Arizona.
 (June 3)
- Durant, Kanani, Levon 'ohai, & W. McClatchey. Hawaiian Traditional Rationale for Selection of Medicinal Plants. Contributed paper, Society for Ethnobiology Annual meeting, Seattle Washington. (March 27)

 McClatchey, W. & Kim Bridges. Enhancing The Comparisons of PABITRA High-island Sites by Examining Terrestrial Plant Diversity on Atolls. Symposium presentation, Pacific Science Association, Bangkok, Thailand. (March 17)

2002

- McClatchey, W. & Kim Bridges. Strong Inference in Ethnobotany. Contributed Paper, Society for Economic Botany Annual meeting, New York Botanical Gardens, Bronx, New York. (June 25)
- McClatchey, W. Traditional Knowledge and Education. Invited Speaker, Brigham Young University, Hawai'i, Spring Symposium, Laie, Hawai'i. (March 13)

2001

- McClatchey, W. Phylogenetic and biogeographical analysis of Metroxylon section Coelococcus in the Western and South Pacific. Invited Speaker, International Sago Symposium, Tsukubo, Japan. (October 16)
- McClatchey, W. On Ethnobotany, Botanical Gardens and Arboreta. Invited lecture, Lyon Arboretum, Summer Internship Program, Honolulu, Hawai'i. (August 10)
- McClatchey, W. Plenary Welcoming Address: Building Bridges with Traditional Knowledge. Society for Economic Botany and International Society for Ethnopharmacology Annual Meetings held in conjunction with the Building Bridges with Traditional Knowledge Summit meetings, Honolulu, Hawai'i. (May 28)

2000

- McClatchey, W. Evolutionary Biology and Creationism. Invited representative of the University of Hawai'i, EECB program, Hawai'i Baptist Academy, Honolulu, Hawai'i. (December 7)
- McClatchey, W. & Jodi Stevens Learning Basic Ethnoecological Knowledge: Changing Patterns of Interaction with the Environment among the Ririo of Lauru, Solomon Islands. Invited presentation, International Society for Ethnobiology, Congress, Athens, Georgia. (October 25)
- McClatchey, W. Establishment of Long-term PABITRA biodiversity Monitoring and Ethnobotanical Documentation Groups in the Western Solomon Islands. International Vegetation Science Congress, Nagano, Japan. (July 24)
- McClatchey, W. *The Future of Economic and Ethnobotany*. Invited symposium speaker at the annual meetings of the Society for Economic Botany, Columbia, South Carolina. (June 22)
- McClatchey, W., Myknee Sirikolo, Jodi Stevens, Harry Boe, Fredrick Vot'boc, Edison Biliki & Michael Wysong. Interlinked Roles for Conservation of Language and Biological Diversity. Contributed paper. Annual meetings of the Society for Economic Botany, Columbia, South Carolina. (June 21)
- McClatchey, W. & Piet Lincoln. Melanesian Neighbors: 1) Ririo Plant Terms in the Context of a
 Reconstructed Proto-Oceanic Language and 2) Borrowed Landscapes: Ancient Austronesian and NonAustronesian Interactions Invited presentation for the University of Hawaii, Linguistics, Honolulu, Hawai'i.
 (April 4)
- McClatchey, W. *Polynesian Ethnobotany*. Invited Speaker for the Academy of Life Long Learning, Honolulu, Hawai'i. (February 22)

- McClatchey, W. *Ethics and Ethnobotanical Research*. Invited speaker for the Hawaii Botanical Society, Honolulu, Hawaii. (November 1)
- McClatchey, W. Botanical Sample Selection Criteria and Ethnobotany. Invited speaker for the Hawaii Biotechnology Group, Aiea, Hawai'i. (September 22)
- McClatchey, W. Development of a Cultural and Biological Field Research Station in the Solomon Islands. Ecology, Evolution, and Conservation Biology Program Lunch, Honolulu Hawai'i. (September 17)
- McClatchey, W., Myknee Sirikolo, Harry Boe, Moses Biliki, Edison Biliki, & Fredrick Votboc. A Proposed Pacific-Asia Biodiversity Transect (PABITRA) Terrestrial Research Site on Lauru in the Western Solomon Islands Pacific Science Inter-Congress, Sydney, Australia (July 8)
- McClatchey, W. *Ethnobotanical Field Methods for Non-Botanists*. Invited speaker for the Austronesian Circle, Honolulu, Hawai'i. (April 22)

- McClatchey, W. Integration of Traditional Healing Systems and Western Medicine. Invited speaker for E Ola Mau, Honolulu, Hawai'i. (April 17)
- McClatchey, W. Western Pacific Ethnobotany and Herbal Product Development Possibilities. Invited speaker for the University of Hawai'i, CASAA semi-annual meeting, Pacific Club, Honolulu, Hawai'i. (April 8)
- McClatchey, W. & Stephan Moisyadi. *Potential for yaqona crop development in Fiji*. Special consultation presentation for his excellency, Sir Ratu Mara, President of Fiji. Honolulu, Hawai'i. (March 1999)
- McClatchey, W. Andrographis paniculata and Andrographalides as potential anti-HIV natural products.
 Consultation presentation for Helishwa, Inc. Research and Development. Anaheim, California. (March 1999)
- McClatchey, W. Some implications of pre-historic cultural movements of Western Pacific plants in considerations of Pacific biodiversity transect studies. Invited symposium speaker. American Society of Geographers annual meetings, Honolulu, Hawai'i. (March 1999)
- McClatchey, W. Educational Opportunities and the Future of Ethnobotany. Invited symposium speaker.
 University of Florida Ethnobotany Society, Gainesville, Florida. (January 27)
- McClatchey, W. Rotuman Traditional Medicinal Practices and Conservation Values. Invited speaker.
 United Plant Savers Conference "The Uses, Cultivation and Conservation of Native Medicinal Plants."
 Ho'omaluhia Botanical Garden, Kaneohe, O'ahu. (January 24)
- McClatchey, W. Polynesian Healers, Diseases, and Cultural Perspectives on Medicinal Plants and Conservation. Invited symposium speaker. United Plant Savers Conference "Planting the Future." Amy Greenwell Ethnobotanical Gardens, Captain Cook, Hawai'i. (January 23)

- McClatchey, W. Results of Pacific Ethnobotanical Studies: 1) Rotuman Traditional Medicine. Cancer Research Center of Hawaii, Cancer Research Symposium Series, Honolulu (December 14)
- McClatchey, W. Biodiversity Transects (Botanical) in the Solomon Islands. Pacific Science Inter-Congress, Taipei, Taiwan (November 17)
- McClatchey, W., Amanda McQuade Crawford & Trish Flaster. *Paradigms in Ethnomedicine*. Invited symposium speakers. Natural Products Expo East, Baltimore (September 12)
- McClatchey, W. Ethnobotanical Field Techniques for Studies of Medicinal Plants. Cancer Research Center of Hawaii, Cancer Research Symposium Series, Honolulu (June 22)
- McClatchey, W. Pacific Biodiversity Transects of the Arecaceae. Pacific Biodiversity Research Seminar Series, Department of Zoology, University of Hawaii, Honolulu. (April 28)
- McClatchey, W. A Commercial Line of Topical and Internal Dietary Supplements based upon Polynesian Traditional Medicine. Consultation presentation to Helishwa, Inc., Anaheim, CA. (March 14)
- McClatchey, W. Educational Opportunities and the Future of Ethnobotany. University of Florida Ethnobotany Society, Gainesville, Florida. (February 25)
- McClatchey, W. & Trish Flaster. Establishment of an Ethnobotanical Natural Products Research and Development Program. Consultation presentation to Helishwa, Inc., Tulsa, OK. (February 1)
- Patterson, Greg & W. McClatchey. *Phylogenetic and Ethnobotanical Studies of Ponapean Plants, Federated States of Micronesia*. Seagrant Annual Research Symposium, University of Hawaii, Honolulu. (January 29)
- McClatchey, W. Hawaiian Traditional Medicine. Keynote talk at the University of Delaware, Annual Conference on Health and Nutrition, Honolulu. (January 6)

- McClatchey, W. & Trish Flaster. A Commercial Line of Internal Dietary Supplements based upon Native American Traditional Medicine. Consultation presentation to Paheoke, Inc., Denver, CO. (November 8)
- McClatchey, W. A Phylogenetic Analysis of the Useful Palms of Fiji. Hawaii Botanical Society, Honolulu. (October 6)

- McClatchey, W. A Morphological Phylogenetic Analysis of the Basal Calamoideae. Symposium Paper presented at the New York Botanical Garden conference: Evolution, Variation, and Classification of Palms, New York. (June 18-20)
- McClatchey, W. Ethnobotany Education: What will be the future role of the Society for Economic Botany.
 Round-table discussion group presentation and moderation at the annual meetings of the Society for Economic Botany, Washington University, St. Louis, Missouri. (June 4-7)
- McClatchey, W. Phylogenetic and cultural distributions of Metroxylon section Coelococcus. Paper
 presented at the University of Hawaii, Department of Botany, Honolulu, Hawaii. (May 23)
- McClatchey, W. Ethnobotany in Florida: A rich tradition. Symposium paper presented at the Florida Native Plant Conference, Gainesville, Florida. (May 16)
- McClatchey, W. On the Nature of Ethnobiological Data Sources and Collectors. Contributed Paper presented at the annual conference of the Society of Ethnobiology, University of Georgia, Athens, Georgia. (March 26-29)
- McClatchey, W. One-way Bridges: Ethical dilemmas faced by healers who share their knowledge.
 Symposium paper presented at the Building Bridges with Traditional Knowledge conference, University of Florida, Gainesville, Florida. (February 13-15)

- McClatchey, W. A Role for Linguistic Data in Determination of Phylogentic Relationships of Western Pacific Species of Metroxylon (Arecaceae). Contributed Paper at the annual meeting of the Society for Economic Botany, Imperial College, London, United Kingdom. Fulling Award winner for best presentation.
- McClatchey, W. & Alexandra Paul. An Evaluation of Educational Trends in Economic Botany. Contributed
 Paper at the annual meeting of the Society for Economic Botany, Imperial College, London, United
 Kingdom.

1995

- McClatchey, W. *Useful Palms of Fiji*. Contributed Paper at the annual meeting of the Society for Economic Botany, Cornell University, Ithaca, New York.
- Paul, Alexandra & W. McClatchey. Opportunities for Graduate Study in Ethnobotany. Discussion
 presentation at the annual meeting of the Society for Economic Botany, Cornell University, Ithaca, New
 York.

1994

• McClatchey, W. Western Polynesian House Construction Terminology and the Development of a Cultural Cladogram. Contributed Paper at the annual meeting of the Society for Economic Botany, Mexico City, Mexico. (also presented at the University of Florida Graduate Student forum, May 1995.)

1992

• McClatchey, W. *The Ethnopharmacopoeia of Rotuma*. Contributed Paper at the annual meeting of the Society for Economic Botany, Honolulu, Hawaii.

1991

• McClatchey, W. & Paul Cox. *The Use of the Sago Palm in the Island of Rotuma*. Contributed Paper at the annual meeting of the Society for Economic Botany, Rancho Santa Ana Botanical Gardens, California.

POST-DOCTORAL RESEARCHERS SUPERVISED

2010

- Nat Bletter. Modeling of Emergent Diseases and Plant Remedies in SE Asian Cultural Contexts.
- Valentina Savo. Climate Change in European Orchard Systems.

2008-9

- Nat Bletter. Modeling of Emergent Diseases and Plant Remedies in SE Asian Cultural Contexts.
- Han Yeong Lau. Biodiversity Analysis and Conservation using Applied Landscape Ecology and Spatial Modeling in Lao PDR.

2007-8

• Han Yeong Lau. Biodiversity Analysis and Conservation using Applied Landscape Ecology and Spatial Modeling in Lao PDR.

2005-6

 Michael Thomas. Re-Design of Introductory Ethnobotany (BOT 105) offered at the O'ahu and Maui Campuses of the University of Hawai'i. Computer database and on-line course delivery system development.

2004-5

- Lisa Gollin. *Cross Cultural Toxidromes and Identification of Potential Biological Activity in Plants*. Ethnobotanical theoretical and field studies in Polynesia and Indonesia.
- Peter Miller. *Psychoactive Biotechnologies: A Scientific Investigation of Local Innovations with Psychoactive Plants*. Ethnobotanical field studies throughout the Hawaiian Islands on distributions of psychoactive plants, knowledge of psychoactive plants, and means for plant introductions.
- Michael Thomas. Compactorization, Reorganization, and Electronic Cataloging of the University of Hawai'i
 Herbarium Collections. Inventory, computer database development and reorganization within the
 Angiosperm Phylogeny Working Group II system. Production of herbarium website.

CHAIRMAN OF STUDENT RESEARCH COMMITTEES (total = 27)

2017+ (Expected Graduation)

- David Reedy, Ph.D. Botany, *Building Predictive Models of Human Adaptation to Climate Change through Tree Crop Selection*. [Currently researcher, Botanical Research Institute of Texas]
- Esther Chitsende, M.S., Environmental Science, Texas Christian University. *Application for Native Texas Plants in a Sustainable Housing Development*.

2014

- Jared Williams, M.S., Environmental Science, Texas Christian University. *Mitigating Nutrient and Pathogen Storm Water Pollution via Bioretention Techniques: A Comparative Analysis of Three Filter Designs' Pollutant Removal Efficiencies and Filtrate Volumes Released for Irrigative Re-Use at Oscar Dean Wyatt H.S. Fort Worth, TX.*
- Sarah Ziomek, M.S., Environmental Studies, Texas Christian University. *Plant Species Richness of Lyndon B. Johnson National Grassland Ponds*. [Currently, USEPA biologist]

2013

- Jeff Boutain, Ph.D., Botany, Taxonomy, Biogeography, and Ethnobotany of Humulus. [Currently, industry consultant on hops and cannabis genetics]
- Kawika Winter, Ph.D., Botany, Quantification of Ethnobotanical Evolution with the Specific Example of
 `awa (Piper methysticum) in Hawaiian Culture. [Currently, Director, Limahuli Botanical Garden, Kaua`i]

2011

• Lori Tongco, Ph.D., Botany, Conservation Practices of the Kanawan Aytas in Morong, Bataan, Philippines. [Currently assistant professor of biology, University of the Philippines, Diliman]

• Adam Brown, M.S., Botany, *Traditional Botanical Knowledge of the Plain Mennonites: Time, change, and knowledge transitions*. [Completed Ph.D. in Chemistry at University of North Carolina; Currently assistant professor of chemistry, Frostburg State University]

2009

- Anthony Amend, Ph.D., Botany/EECB, *Population Biology of Tricholoma matsutake in Northwestern Yunnan Provence, China*. Earned certificate in Ecology, Evolution, and Conservation Biology. [Currently assistant professor of botany, University of Hawaii]
- Bruce Hoffman, Ph.D., Botany/EECB, Comparisons of Ethnoecological Patterns of Behavior in Two Amazonian Communities. [Currently lead research scientist, Amazon Conservation Team, Suriname]
- David Reedy, M.S., Botany, *Studies of Human Interactions with Cider Apples*. [Currently researcher Botanical Research Institute of Texas]
- Neeva Shrestha, M.S., Botany, Analysis of Nepali Immigrant Ethnobotanical Knowledge in Hawaii. [deceased 2009]
- Jodi Stevens, Ph.D., Botany, Comparative Ethnopharmacology of three Pacific Island communities.

2007

• Uala Lenta, M.S., Botany, *Ethnopharmacology of Hawaiian remedies for cancer*. [Currently, natural products business owner.]

2006

- Orlo Steele, Ph.D., Botany, *The Natural and Anthropogenic Biogeography of Mangroves in the Southwest Pacific*. Earned certificate in Ecology, Evolution, and Conservation Biology. [Currently, professor of forestry, University of Hawaii, Hilo.]
- Tamara Wong, M.S., Botany/EECB, Morinda citrifolia L. (Rubiaceae) growth and light environment in the understory of differing tree canopy species of an agroforestry system. Earned certificate in Ecology, Evolution, and Conservation Biology. [Completed Ph.D. in Ecology; Currently Post-doc for the U.S. Forest Service.]

2005

- Liloa Dunn, M.S., Botany, *Traditional medicinal plants of the Marquesas*. [Currently, Ethnobotany collection manager, Lyon Arboretum, University of Hawaii, Manoa.]
- Carrie Harrington, M.S., Botany, Analysis of competitive inhibition of MAP kinase phosphorylation by polymethoxylated flavanoids from Vitex rotundifolia L.f. [Currently, instructor of biology, University of Hawaii, Leeward.]
- Han Lau, Ph.D., Botany, Development of theoretical models of human interactions with plants based upon observations among the Paiwan and Amis of Taiwan. [Currently, farm manager/owner, Hilo, Hawai`i.]
- Ruth Le'au, B.S., Biology Honors thesis, *Genetic and Folk diversity in Piper methysticum*. [Currently, Forensic Lab Manager, Honolulu Police Department]
- My Lien Nguyen, Ph.D., Botany, Vietnamese foods and changes in traditions in populations moving into new environments. [Currently, Pharmacist, Rochester, New York]

2004

- Donald Bunnell, M.S., Pacific Studies, *Broussonetia papyrifera in ancient and modern Hawai'i*. [Currently, Marine Engineering Researcher, Sealife Park, Hawaii.]
- Kaleleonalani Napoleon, M.S., Botany, *Ethnopharmacology of Hawaiian Limu*. [Completed M.A. in Social Work; Currently, Queens Hospital, Community Outreach, Hawaii.]
- Kawika Winter, M.S., Botany, *Hawaiian 'awa: A gift of the ancestors*. [Completed Ph.D. in Botany; Currently, Director, Limahuli Botanical Garden, Kaua`i.]

2003

• Kamaui Aiona, M.S., Botany, *Ethnobotany and Folk Taxonomy of Hawaiian Limu*. [Currently, Director, Hana Botanical Garden, Hana, Maui.]

- Heather Harlow, M.S., Botany/EECB, Tibetan Traditional Medicine in Exile. Earned certificate in Ecology, Evolution, and Conservation Biology. [Currently, Director and CEO, Red Door Films (Documentaries), Portland, Oregon.]
- Mark Nickum, M.S., Botany, Kalia Mileniume: Ethnobotany of a Tongan Voyaging Canoe. [Completed Ph.D. at University of Florida in Horticulture. Currently, assistant professor of fruit crops, University of Hawaii, Hilo.]
- Michael Wysong, M.S., Botany/EECB, Quantitative Ethnobotanical Studies of Samoan Coastal Plants.
 Earned certificate in Ecology, Evolution, and Conservation Biology. [Completed Ph.D. in Conservation Biology at the Charles Darwin University, Australia; Currently, post-doctoral researcher in Australia.]

1999

Courtney Horwath, B.A., Liberal Studies Honors thesis, Healthcare 2000: Integrative Healing.

COMMITTEE MEMBER OF STUDENT RESEARCH COMMITTEES

2019+ (Expected Graduation)

• Jared Williams, Ph.D., American Lawn Addictions: Effects of environemtnal education on student preferences for zeriscaping as an alternative in North Central Texas, USA. Environmental Science Education, University of North Texas, Denton. Chair: Ruthanne Thompson.

2015

• Patricia Fifita, Ph.D., Anthropology, *Indigenous Articulations of Health and Disease at the Interface of Modernity: An examination of healing practices in Tonga*. Chair: Ty Tegan.

2014

• Vandana Krishnamurthy, Ph.D., Botany, Ethnobotany, trade and population dynamics of Cycas circinalis L., and Cycas swamyi Singh & Radha in the Western Ghats of southern India. Chair: Tamara Ticktin.

2013

- Alea Ausmer, M.S., Forensic Genetics, University of North Texas Health Center. *A Comparative Study of Three Methods to Enhance the Collection of DNA from Plant Material*. Chair: Joseph Warren.
- Steve Carlson, M.A., Anthropology, University of North Texas, Denton. *Climate Change on Southern Appalachian Orchards: Perceptions, practices, and apple diversity*. Chair: James Veteto.
- Tim Gallaher, Ph.D., Botany, Systematics and biogeography of the Pandanaceae with a population genetics approach to the "Pandanus tectorius problem." Chair: Sterling Keeley.
- Lance Mahi La Pierre, M.S. Geography, *Preserving Hawaii's Biodiversity: A Tree, Place, and Culture*. Chair: Stacy Jørgensen.

2012

- Peiluen Lu, Ph.D., Botany, Systematic, evolutions, and biogeography of the plant genera Dracaena Vand. Ex L., Sansevieria Thunb., and Pleomele Salsb. (Aspagaceae). Chair: Cliff Morden.
- Tamara Wong, Ph.D., Botany, *Ecology and Restoration Biology of Alyxia stellta on Kaua`i*. Chair: Tamara Ticktin.
- Jonathan Martinez, Ph.D., Botany, Invasive algae in coral reef habitats of Hawaii. Chair: Celia Smith.

2009

Rebekah Fuller, Ph.D., Botany, Fungi and Polynesia: New Zealand and Cook Island Maori ethnomycology.
 Chair: George Wong.

2008

- J.D. Baker, Ph.D., Anthropology, Medical anthropology of Piper methysticum in Hawai'i. Chair: Nina Etkin
- Leyla Cabugos, M.S., Botany, An evaluation of native species suitability and environmental performance of green roofs in Hawaii. Chair: Tamara Ticktin.

- Catherine Davenport, M.S., Botany, Comparison of properties for the plant fibers of Hau, Olona and Niu in their use as cordage for traditional seafaring and fishing practices. Chair: Isabella Abbott.
- Candice Felling, Ph.D., Botany, Phytogeography and phylogenies of Acacia koa. Chair: Cliff Morden.
- Lara Franco, M.S., Zoology, *Agent-based modeling as an analytical tool for a complex, open system: Coral reefs.* Chair: Chuck Birkeland.

- Nathaniel Bletter, Ph.D., Biology, Lehman College, Bronx, New York, *Comparative study of plants used to treat diabetes, schistosomiasis, and skin infections in two Peruvian cultures*.
- Arika Virapongse, M.S., Pharmaceutical Botany (Khon Kaen University), Ethnomedicine and Materia Medica used by Kui Healers in Northeast Thailand. Chair: Chayan Pichaensoonthon.

2005

- Klaus Dragull, Ph.D., Agriculture, *Isolation and characterization of novel compounds from Piper methysticum*. Chair: C.S. Tang.
- Horangi Sears, M.S., Pacific Studies, Conservation of traditional plant knowledge in Cambodia. Chair: Lyndon Wester.

2004

- Jon Abbott, M.S., Thesis, Anthropology, *Hawaiian perspectives of weeds and weed science. Conflict management and cultural conservation issues.* Chair: Nina Etkin.
- Thomas Galioto, M.S., Geography, *Production of Hawaiian theme gardens for conservation in communities*. Chair: Lyndon Wester.
- Ari Levine, M.S., Anthropology, Piper methysticum usage in modern Hawai'i. Chair: Nina Etkin.
- Clarke Monson, Ph.D., Geography, Flying Foxes and the Chamorro. Chair: Lyndon Wester.

2002

- Sandy Buczinski, Ph.D., Science Ed., *Traditional Environmental Knowledge in the Classroom*. Chair: Pauline China
- Benjamin Feinstein, Ph.D., Science Ed., *Teaching a College Course on Traditional Ecological Knowledge*. Chair: Pauline Chinn.

2001

• Lisa Gollin, Ph.D., Anthropology, *Taban Kenyah (Kenyah Medicine): Linking the Cultural and Biological Significance of Indigenous Medicines in East Kalimantan, Indonesia*. Chair: Nina Etki.n

2000

- Russell Ili, M.S., Botany, From Past to Present, Kahuna Laau Lapaau: Hawaiian Herbal Healers. Chair: Isabella Abbott.
- Michelle Stevens, M.S., Botany, *The Comparative Ecophysiology of Mountain and Coastal Populations of Sida fallax Walp. (Malvaceae) in Hawaii*. Chair: Guillermo Goldstein.

EXTERNAL EXAMINER & STUDENT THESIS REVIEWER

International Foundation for Science, Stockholm, SWEDEN Khon Kaen University, Khon Kaen, THAILAND Leyman College, New York, U.S.A. Lucknow University, INDIA University of Florida, Gainesville, U.S.A. University of Kent at Canterbury, ENGLAND University of the South Pacific, Laucala Campus, FIJI

Frostburg State University, Frostburg, Maryland. External five-year program reviewer for the Ethnobotany BS degree program. (2011)

FIELD SCHOOL PROGRAMS (leader, instructor, organizer)

- 2017 Blue Creek, Belize. Field Botany at Archaeological Sites. June 7-14.
- 2016 Blue Creek, Belize. Field Botany at Archaeological Sites. July 16-23.
- 2015 Yaxunah, Yucatan, Mexico. Conservation Botany and Ethnography. July 18-August 20.
- 2015 Blue Creek, Belize. Field Botany at Archaeological Sites. July 5-9.
- 2014 Yaxunah, Yucatan, Mexico. Conservation Biology. May 5-9.
- 2013 Fort Worth & Corpus Christi, Texas. Urban Youth Conservation Research. January 19-March 16.
- 2012 Kaua`i, Hawai`i. Conservation / Ethnobiology. February 10-March 6.
- 2010 Kaua`i, Hawai`i. Conservation / Ethnobiology. January 3-February 12.
- 2009 Kahana, O`ahu, Hawai`i. Hawaiian Ethnobotany. January 3-May 5.
- 2008 Hawai'i Island. Field Research Methods. March 20-30.
- 2007 Hawai'i Island. Field Research Methods. November 15-23.
- 2006 NE Thailand. Field Research Methods. January 30-February 22.
- 2005 Hawai`i Island. Field Research Methods. March 21-April 1.
- 2004 Hawai'i Island. Field Research Methods. March 20-30.
- 2004 Mo`orea, Tahiti. Field Research Methods. October 30-November 15.
- 2003 Madagascar. Ethnobotany and Conservation Field Methods. June 3-25.
- 2002 Marshall Islands. Ethnobotany and Conservation Field Methods. July 6-August 1.
- 2001 O`ahu, Hawai`i. Ethnobotany Research Methods. June 1-22.
- 1999 Solomon Islands. Field Research Methods in Ethnobotany. June 15-July 30.

SHORT OR SEMESTER COURSES PREPARED TO TEACH

- General Biology
- General Botany
- Evolution
- Botanical and Ethnobotanical Field Methods for Social Scientists (early graduates)
- Introductory Ethnobiology (lower undergraduates)
- Scientific Leadership and Professional Presentations (undergraduates, graduates)
- Polynesian Ethnobiology (upper undergraduates, early graduates)
- Natural Products and History of Medicine (upper undergraduates, early graduates)
- Conservation Biology/Ecology Field Methods (upper undergraduates, early graduates)
- Cognitive Ethnobiology (upper undergraduates, early graduates)
- Grant Writing, Submission, and Assessment (professionals, graduate students or mature undergraduates)

COURSES TAUGHT AT UNIVERSITY OF HAWAII

Semester and year taught

Biology

BIOL 101 Biology & Society Sp99, Fa99, Fa01, Fa02, Fa03

Botany

- BOT 399 Undergraduate Research Fa98, Sp99, Fa00, Sp00, Sp01, Sp02, Fa02, Fa03, Sp04, Fa04, Sp05, Su06, Fa06, Fa08, Sp09, Sp10
- BOT 453 Plant Ecology/Environmental Measurement Sp09, Sp10
- BOT 606 Botanical/Ecological Research Methods Fa01, Fa02, Fa03, Fa04
- BOT 610 Botany Seminar Sp98, Fa03
- BOT 612 Botanical Problems Su99, Sp00, Fa00, Sp01, Su01, Fa01, Sp02, Su02, Fa02, Sp03, Su03, Sp04, Su04, Fa04, Sp05, Su06, Fa09
- BOT 699 Graduate Research Fa98, Sp99, Fa99, Sp00, Su00, Sp01, Su01, Fa01, Sp02, Su02, Fa02, Sp03, Su03, Fa03, Sp04, Su04, Fa04, Sp05, Fa05, Sp06, Su06, Fa06, Sp07, Fa07, Sp08, Fa08, Sp09, Su09, Fa09, Sp10, Su10

Ethnobotany

- BOT 105 Introductory Ethnobotany Fa97, Fa98, Fa99, Fa00, Fa01, Fa02, Fa03, Fa05, Fa06, Fa07, Fa08, Fa09
- BOT 440 Advanced Ethnobotany Fa99, Su01, Fa03, F06, Fa07, Fa08, Sp09
- BOT 442 Medical Ethnobotany Sp99, Su01, Fa02, Fa04, Fa09
- BOT 446 Hawaiian Ethnobotany Fa98, Fa00, Fa01, Sp05, Sp08
- BOT 448 Cognitive Ethnobotany Sp05
- BOT 449 Mekong Ethnobotany Sp09
- BOT 640 Quantitative Ethnobotany Sp00, Su01, Sp04, Fa06

New curriculum/programs

- Developed BS Degree in Ethnobotany, approved by Board of Regents in October 2002.
 - O Degree subsequently adopted by: Frostburg State University; University of Alaska, Fairbanks; modified by University of Arizona.
- Developed competitive plan for a new program of undergraduate training supporting scientists working with Hawaiian Natural Resources called "Hui Konohiki." This was supported by a budget and five new tenure track positions through the Botany Department. Collaboratively developed with K.W. Bridges & L. Kame`eleihiwa

COURSE TAUGHT AT KHON KAEN UNIVERSITY

Semester and year taught

Ethnobotany

• Ethnobotany & Medical Anthropology Wi06

COURSE TAUGHT AT TEXAS CHRISTIAN UNIVERSITY

Semester and year taught

Environmental Science

• Environmental Stewardship Sp13

COURSES TAUGHT AT UNIVERSITY OF FLORIDA

Semester and year taught

Ethnobotany

- Ethnoecology Fa96
- Ethnobotany Sp97

Biology

• General Biology Lab (TA) Sp95

COURSES TAUGHT AT BRIGHAM YOUNG UNIVERSITY

Semester and year taught

Ethnobotany

Ethnobotany Sp94

Biology

General Biology(TA) Fa92

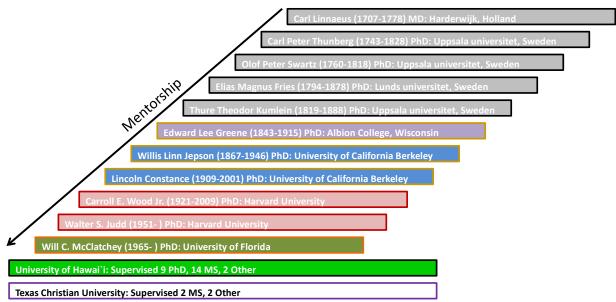
GRANTS AND AWARDS

(Excludes outside contracts/grants with NDA, and grants awarded to mentored graduate students or for their research projects) (Botanical Research Institute of Texas is primarily supported by private individuals and foundations whose donations may be found in the BRIT annual report. www.brit.org)

- Creating Opportunities for Urban Youth to Understand Biodiversity and the Ecology of Life. Rainwater Charitable Foundation. \$243,000. 11/15/12-11/14/13. Co-PI.
- Open Science: An education network in Ethnobiology to coordinate the development of a new culture in the undergraduate science classroom. National Science Foundation, RCN-UBE. \$368,173. 04/01/09-04/31/2014. Co-PI.
- Longevity Foods, SIRT Activation and Diabetic Dyslipidemia. National Institute of Health, NCCAM, R21. \$250,000. 06/01/07-05/30/09. Co-PI.
- *Mechanisms of Phytochemical Aggression in Invasive Species in Hawai`i*. AccelaPure Corporation. \$428,000. 07/06-06/09. Pl.
- Ethnobotany Segues to Science. National Science Foundation, CCLI. \$299,008. 01/07-12/31/09. PI.
- Re-Design of Introductory Ethnobotany (BOT 105) offered at the O'ahu and Maui Campuses of the University of Hawai'i. National Center for Academic Transformation. \$71,586. 04/05-03/07. Pl.
- Compactorization, Reorganization, and Electronic Cataloging of the University of Hawai`i Herbarium Collections. National Science Foundation, Biological Collections. \$84,000. 02/05-02/07. Pl.
- Psychoactive Biotechnologies: A Scientific Investigation of Local Innovations with Psychoactive Plants. University Connections, Technology, Innovation and Society Research. \$35,000. 05/04-01/05. Pl.
- *Identification of Natural Products active in treatment of Anthrax and Botulism*. Home Lands Security Administration with Hawaii Biotech, Inc., \$790,500, 10/03-05/04. Co-PI.
- Identification of Natural Products from Rongelap Atoll active in metaloprotease bioassays. Hawaii ARC collaboration with Hawaii Biotech, Inc. \$10,000. 02/03-08/03. Co-PI.
- Ethnobiology and Genetics in Polynesian Environments. Environmental Protection Agency, \$35,500. 08/03-06/05. Pl.
- Analysis of Terrestrial and Marine Plants from Rongelap and Ailinginae Atolls for Novel Anti-cancer Agents. \$33,000. National Cancer Institutes P-15 Program Grant. 05/02-11/03. Pl.
- Cancer Ethnopharmacology in Traditional Austronesian Medicine. \$45,000. National Cancer Institutes P-15 Program Grant. 01/02-01/03. Pl.
- Building Bridges with Traditional Knowledge Summit meeting support. Society for Economic Botany and International Society for Ethnopharmacology Annual Meetings held in conjunction with the Building Bridges with Traditional Knowledge Summit meetings, Honolulu, Hawai'i. (May 28-June 1) PI on each.
 - o \$30,000. Packard Foundation (Hawai'i Community Foundation). 3/01-6/01.
 - \$10,000. Kamehameha Schools. 5/01-6/01.
 - \$4,000. Hawai'i State, Coastal Zone Management Unit. 5/01-6/01.
 - \$5,000. Hawai'i State, Department of Business, Economic Development, and Tourism. 12/00-6/01.
 - o \$5,000. Alexander and Baldwin Foundation. 1/01-6/01.
 - \$3,000. Papa Ola Lokahi. 4/01-6/01.
 - \$1,000. Hawaiian Wireless Communications. 5/01-6/01.
 - \$500. Jones & Stokes, Inc. 5/01-6/01.
- Ethnobotanical Identification and Collection of Medicinal Plants used by the Babatana and Ririo Tribes of Lauru Island in the Western Solomon Islands. \$24,000. University of Hawaii Seed Capital Program, 5/1/99-12/1/99. Pl.

- Collection and Extraction of Marine Algae for Discovery of New Bio-active Chemical Compounds. \$29,900. 3/2000 6/2001, Hawaii Office of Technology Transfer and Economic Development. Pl.
- Collection and Extraction of Higher Plants for Discovery of New Bio-active Chemical Compounds. \$9,956. 8/5/98 4/1/99. Hawaii Office of Technology Transfer and Economic Development. Pl.
- Development of Ethnobotanical Research and Training Opportunities at the University of Hawai'i. \$10,000, 05/1998-04/2000. Seminole Tribe of Florida. Pl.
- Ethnobotanical Field Study of Medicinal Plants used by Tribes in the Central Mountains of the Island of Choiseul in the Western Solomon Islands. \$15,000, 3/1998-03/1998, American Cancer Society. Pl.

ACADEMIC LINEAGE



Last name: Gustafson **First Name:** Natalie

Date: 5/21/19 Email: natalie@lcrx.com Work Phone: 503-281-4161

List the board, committee or commission to which you are appointed:

Oregon Board of Naturopathic Medicine Formulary Council

Please provide a brief summary of your activities from the last year within your appointment. Be sure to include your term and meeting frequency.

I have been on the OBNM Formulary Council since August 2011, with my current term ending June 2019. We meet every six months, typically in March and September or early October. I would like to express my interest at remaining on this Council for another term and provide a summary of my activity on the council over the last year.

In this last year, we finished clarifying the suggested changes to the formulary rule 850-60-223 to ensure the best wording and inclusion or exclusion of all prescribed medications intended, including a review of abortifacients. We also continued our discussion on ketamine prescribing and safety.

As far as my role on the council, I think the most critical piece is my knowledge and involvement with compounding. There are many changes happening in compounding this year. At the last meeting, I provided a review of the changes at a federal and state level and how these changes may impact naturopathic physicians and patients. We discussed the status of office-use compounding (compounded products that are ordered by a physician to administer at their office without a prescription for one specific patient) and how the upcoming USP chapter regulation changes regarding sterile compounding would also impact naturopathic physicians preparing IVs and other injectables in their offices. In addition, many substances that naturopathic physicians prescribe (including natural substances approved as supplements but requiring a prescription to compound) are currently under review federally and may be restricted from use by compounding pharmacies in the future and we discussed that as well.

I believe it is important especially this year and next to have a pharmacist familiar with compounding on the Formulary Council due to these significant issues. A couple weeks ago I participated in the Drug Compounding Rules Advisory Committee for the Oregon Board of Pharmacy as they are in the process of writing a major revision of Division 45 compounding rules in Oregon. These changes will almost certainly be finalized by the end of the year, in time for the changes to USP Chapter <795>, <797> and <800> regarding nonsterile and sterile compounding practice requirements that go into effect December 1, 2019. I have attended regulatory conferences to stay apprised of the current legal landscape federally as well so am well versed in those areas as well.

Thank you for your consideration.

Sincerely,

Natalie Gustafson

Natalie Gustafson, PharmD

2606 NE Broadway St Suite B Portland, OR 97232 (P): 503-281-4161 (F) 503-281-1990 Natalie@LCRX.com

Education

PharmD Doctor of Pharmacy (Summa Cum Laude) Northeastern University, Boston, MA

Current Positions

Director of Pharmacy, Lloyd Central Compounding Pharmacy, Portland, OR Jan 2012 – Present

Director of Pharmacy, Pacific Compounds Pharmacy, Hillsboro, OR July 2009 – September 2017

Recent CE Courses and Presentations Given The Impact of Delivery Methods in HRT 2019 Invited Speaker for IWHIM Women's Health Symposium Portland, OR 2019 Introduction to Compounding Invited Speaker for NUNM Residents Portland, OR 2018 **Topical Pain Medications** Invited Speaker for NUNM Pain Conference Portland, OR 2018 The Impact of Delivery Methods in HRT Invited Speaker for IWHIM Women's Health Symposium Portland, OR 2018 Low Dose Naltrexone & Autoimmune Conditions Invited Speaker for NUNM Autoimmune Conference Portland, OR 2018 Specialty Compounded Medications in Pediatrics Invited Speaker for IWHIM Pediatric/Adolescent Medicine Portland, OR 2017 Non-Opiate Medication Options: Compounding, Topicals, and More Invited Speaker for COHC Chronic Non-Cancer Pain 101: Provider Workshop Bend, OR Low Dose Naltrexone 2017 Invited Speaker for IWHIM Primary Care for Women Portland, OR 2017 Use of Low Dose Naltrexone and Erythromycin in SIBO Invited Speaker for NUNM SIBO Conference Portland, OR

2017	Introduction to Compounding Invited Speaker for NUNM Residents Portland, OR
2017	The Impact of Delivery Methods in HRT Invited Speaker for IWHIM Women's Health Symposium Portland, OR
2016	Low Dose Naltrexone for Pain Management Invited Speaker for NUNM Pain Management Conference Portland, OR
2016	Topical Pain Management Invited Speaker for OANP's Pain Management Course Portland, OR
2016	The Impact of Delivery Methods in HRT Invited Speaker for IWHIM Women's Health Symposium Portland, OR
2016	The Missing Link Between Cholesterol and Glucose Low Dose Naltrexone: Endorphins Impact on the Gut Invited Speaker for Hawaii Doc Talks, Hawaii
2015	Compounded alternatives in Wound Healing and Scar Prevention Invited Speaker for Columbia Wound Care Consortium, Portland, OR
2014	Managing Treatment of Hypogonadism Invited Speaker for OANP 19 th Annual Pharmacy and Ethics Conference
2014	Use and Considerations of Low Dose Naltrexone & Topical Pain Medications Speaker for several naturopathic physicians, Portland, OR
2014	Use and Considerations of Low Dose Naltrexone Invited Speaker for British Columbia Naturopathic Association, Vancouver, BC
2014	Pharmacodynamics of Hormone Replacement Therapy Invited Speaker for WIBI Women's Health Symposium, Portland, OR
2014	The Impact of Delivery Methods in HRT Invited Speaker for IWHIM Conference, Portland, OR
2013	Holistic Management of Depression and Anxiety Invited Speaker for NWNPC 57 th Annual Convention, Portland, OR
2012	Low Dose Naltrexone and the Importance of Endorphin Regulation Invited Speaker for OANP 17 th Annual Pharmacy and Ethics Conference
2012	Topical Pain Medications Speaker for CE course. Location: Portland and Beaverton

2012	Management of Asthma & COPD Speaker for CE course. Location: Beaverton
2012	CE Course: Pharmacotherapy of Diabetes Mellitus, Hyperlipidemia and Hypertension agents. Speaker for CE course. Location: Portland
2012	Dermatology Treatment Alternatives Speaker for CE course. Location: Portland and Beaverton
2012	Topical Pain Medications Invited Speaker for Pain Society of Oregon
2012	Polypharmacy in the Aging Woman Invited Speaker at Institute of Women's Health and Integrative Medicine Conference
2011	Management of Asthma & COPD Invited Speaker for OANP 16 th Annual Pharmacy and Ethics Conference Location: Portland
2011	Dermatology Treatment Alternatives Speaker for CE course. Location: Portland
2011	Depression, Anxiety & GI Medications Speaker for CE course. Location: Portland
2011	Pain Management- Traditional and Compounded Options Speaker for CE course. Location: Portland
2011	CE Course: Pharmacotherapy of Diabetes Mellitus, Hyperlipidemia and Hypertension agents. Speaker for CE course. Location: Portland
2011	CE Course: Low Dose Naltrexone (LDN): Regulating Immune Function Using Endorphins Speaker for CE Course. Location: Beaverton (spring) & Portland (fall)
2010	CE Course: Managing Drugs, Disease & Herbal Interactions in Diabetes Therapy Invited Speaker for OANP 15 th Annual Pharmacy and Ethics Conference Location: Portland
<u>Trainir</u>	
2019	IACP 25 th Annual Compounders on Capitol Hill
2018	OANP 23 rd Annual Pharmacy and Ethics Conference
2017	OANP 22 nd Annual Pharmacy and Ethics Conference
2017	WIBI's 5 th Annual Women in Balance Symposium

2016	OANP 21 st Annual Pharmacy and Ethics Conference
2016	ACHC USP <800> Workshop
2015	OANP 20 th Annual Pharmacy and Ethics Conference
2015	Sex Hormones and the Brain
2015	Introduction to Transgender Health Care and HRT
2015	Three Treatment Algorithms
2014	OANP 19th Annual Pharmacy and Ethics Conference
2014	Overcoming USP 797 Common Non-compliance issues for sterile compounding
2014	Regulatory Guidelines and standards of practice for pharmacy compounding
2014	Endotoxin testing and environmental monitoring for your pharmacy
2014	Making the grade: practical strategies for improving medication adherence
2013	OANP 18th Annual Pharmacy and Ethics Conference
2012	OANP 17 th Annual Pharmacy and Ethics Conference
2011	OANP 16 th Annual Pharmacy and Ethics Conference
2010	OANP 15 th Annual Pharmacy and Ethics Conference
2010	The Spectrum of BHRT and Wellness (ZRT Conference)
2010	Thyroid Testing and Dosing: A Functional Approach to Assessment and Treatment of Hypothyroidism
2009	The Dosing and Testing of Natural Hormones
2008	Primary compounding training at Professional Compounding Centers of America

Professional Memberships
Formulary Council Member, Oregon Board of Naturopathic Medicine (2011-present)
Professional Compounding Centers of America (PCCA) International Academy of Compounding Pharmacists (IACP) National Community Pharmacists Association (NCPA)

Oregon State Pharmacy Association (OSPA)

Oregon Board of Pharmacy - Staff Delegated Authority Revision date: 10/4/18

Staff Delegated Authority

Subject	Description	Approval Date
Intern Extensions	Authorize staff to extend pharmacy intern licenses one year to individuals that need additional time to complete their schooling and rotations.	6/8/2017
Technician extension requests	Authorize Executive and Administrative Directors and Licensing Department Supervisor to approve Pharmacy Technician extension requests as needed with the following parameter: • The licensee must have a clear Law Enforcement Data System (LEDS) background check; • No active disciplinary action; and • The extension is not to exceed one year from the original date of expiration	6/8/2017
Modified, negotiated, or default Orders	Authorize Compliance Director and Executive Director to execute modified and negotiated consent orders as directed by the Board with pre-specified ranges. Authorize Compliance Director and Executive Director to execute default orders approved by the Board. Authorize Compliance Director and Executive Director to execute and accept Stipulated Orders of license surrender.	6/8/2017
Probation Orders: modification of work restrictions	Authorize Compliance Director and Executive Director together to issue letter granting time-sensitive modifications to probation work restrictions after 1 year from execution of Board Order. Will be presented at next Board meeting in Administrative Discussion.	6/8/2017
License for Consulting Pharmacies (Drugless Pharmacy, Remote Processing, Central Fill)	Authorize Compliance staff to review and approve outlet policies and procedures prior to granting a license	6/8/2017
Licensees on Board Screening Probation	Authorize Compliance staff to follow policy guidelines for non-compliance with probation sanctions	6/8/2017
CPT CE Audit: Failed Audit CE not completed or completed outside of required timeframe	Authorize Compliance staff to issue Notice of Disciplinary Action, per Compliance Guidelines Board to Ratify Notice or Order at next available Board Meeting	10/4/2018
RPH CE audit: Take and pass MPJE in required time frame	Authorize Compliance staff to issue Letter of Concern	6/7/2018
Theft II or lower and greater than 5 years	Authorize staff to issue license and Cover Letter Response from Compliance Director	6/8/2017
One DUI/MIP > 5 years	Authorize staff to issue license and Cover Letter Response from Compliance Director	8/10/2017
One DUI/MIP no BAC available > 5 years	Authorize staff to issue license and Cover Letter Response from Compliance Director	8/10/2017
Marijuana possession less than 1 oz prior to 7/1/2013	Authorize staff to issue license and Cover Letter Response from Compliance Director	6/7/2018
Action taken by another state	Authorize compliance staff to screen and evaluate reported primary state disciplinary action. Staff will present, in Case Review, those related to probations, suspensions, revocations, and violations of Oregon law.	6/8/2017

Oregon Board of Pharmacy - Board Policies Revision date: 10/12/2017

Board Policies

Subject	Description	Approval Date
Foreign manufactures	Staff will not license foreign manufacturers but will license first possessor or manufacturer in the US or territory.	6/8/2017
Device wholesalers	Staff may waive surety bond or VAWD certification for device wholesalers with authorized state inspection.	6/8/2017
Release of information - federal subpoenas	Staff may disclose confidential investigative information to federal agencies in response to subpoenas or in a cooperative investigation.	6/8/2017
Release of information - health care boards/public	Staff may disclose confidential information to other relevant healthcare boards and other public entities consistent with ORS 676.177.	6/8/2017
TCVP	First time request: Compliance staff to review P&P and send to Board as mailing for agenda Discussion Item. Board votes to approve/deny. Staff sends letter x 5 yrs. One-year review: PIC/outlet responds to questions. Staff sends to Board as a mailing for agenda Discussion Item. Board votes to accept report. Five-year review: PIC/outlet responds to questions. Staff sends to Board as a mailing for agenda Discussion Item. Board votes to approved renewal x 5 yrs.	6/8/2017
Wholesalers - designated representative	Designated Representative of more than one facility within multiple states. Notification of need for corporation to appoint additional designated representative has been mailed by licensing. No response to Board's request. Staff may send second letter "certified return receipt" if response is not received within 15 days of original letter from licensing. Second letter to refer to failure to cooperate basis for disciplinary action.	
	Designated representative of more than one corporation within the same facility. Applicant must submit detailed description of managerial process and include the hours that he/she will be physically present at facility. Staff will review information on case-by-case basis.	6/8/2017
	Send to Compliance for Board Case Review	
Wholesaler Applications	Staff may review state wholesale inspection forms and include acceptable inspections on the state approved list.	
	Staff may make determination if the license requires a manufacturer or wholesaler license.	
	Staff may grant waivers if they determine that the license meets the state's small business requirements.	6/8/2017
	Staff may issue a license if the applicant has demonstrated registration with VAWD and submits confirmation of approval to the Board office when VAWD certified.	
	Send to Compliance for Board Case Review	
DUI/MIP in the last 5 years with BAC > 0.15 DUI/MIP in the last 5 years with BAC refused or no BAC available 2 or more DUI/MIP	Staff to request a current drug and alcohol evaluation if one has not been performed with in the last 12 months	8/10/2017

Oregon Board of Pharmacy - Compliance Guidelines for Presentation Revision date: 10/4/18

Guidelines for Presentation

Subject	Description	Recommended Notice of Proposed Disciplinary Action	Recommended Consent Order	Board Presentation	Approval Date			
CS annual inventory missing or not completed (or change in PIC) on time	Issue Non-Compliance Notification	\$1,000 civil penalty per violation	\$1,000 Civil Penalty stay \$700 no further violations of PIC requirements for 3 years	Written Review	6/8/201			
Medication errors	Pharmacists, Interns and Tec	<u>l</u> hnicians	<u> </u>	Case Review	6/8/201			
Non-sufficient funds	Misrepresentation of proper payment of fees via non-sufficient funds	Revoke and \$1,000 civil penalty	Reprimand and stay \$0 - \$1,000	Written Review	6/8/2017			
PIC gap: resident pharmacy	Gap for 1-5 days	Issue Letter of Concern	<u> </u>	Consent Agenda				
	Gap starting with day 6	\$1,000 civil penalty per violation	\$1,000 civil penalty per week	Written Review	6/8/201			
	Gap for 2 months or more; repeat incidents			Case Review				
PIC gap: non-resident pharmacy	No PIC after 90 days			Case Review	6/8/2017			
PIC report missing or not completed on time	Issue Non-Compliance Notification	\$1,000 civil penalty per violation	\$1,000 stay \$700 no further violations of PIC requirements for 3 years	Written Review	6/8/201			
Preceptor	Registration not current: Issue	e Letter of Concern		Consent Agenda	6/8/201			
RPH renewals: CE Audits	CE not completed or completed outside of required timeframe							
	Non-responder	Revoke and \$1,000 civil penalty per violation	Revoke	Case Review				
	Discipline	\$1,000 civil penalty per violation	\$1,000 stay \$0 - \$1,000 and provide documentation of CE licensee was short	Case Review				
	Completed after renewal but before license expired	Issue Letter of Concern		Consent Agenda	6/7/2018			
	OR							
	In Lieu of Discipline Take and pass MPJE and complete and submit documentation of CE licensee was short within 120 days	Refer to Staff Delegated Authorit	у	Consent Agenda				
Technician renewals: CE Audits	CE not completed or complete	ed outside of required timeframe		1				
	Non-responder	Revoke and \$1,000 civil penalty	Revoke	Case Review	10/4/201			
	Discipline	\$1,000 civil penalty per violation	\$1,000 stay \$0 - \$1,000 and provide documentation of CE licensee was short	Written review				

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	Unregistered wholesalers, manufacturers and out-of- state pharmacies	\$10,000 civil penalty per violation	\$10,000 civil penalty stay \$0 - \$10,000	Written Review	6/8/2017
designated reps	If corrective action is not received from designated rep within 30 days	1	\$10,000 civil penalty stay \$0 - \$10,000	Written Review	6/8/2017

Applications and	FELONY (THEFT, DRUGS (I	MARIJUANA), FRAUD, ACTIVE	PROBATION)							
renewals	Convictions	Deny/Revoke	Deny/Revoke	Case Review						
	Arrest or citation with no conviction (diversion; dismissed, case has not gone to trial yet)		Case Review	6/8/2017						
	SEX OFFENDERS									
	Convicted Sex Offenders			Case Review	6/8/2017					
	THEFT									
	Theft II or lower - greater than 5 years	Refer to Staff Delegated Authorit	ty		0/0/47					
	Aggravated, Theft I			Case Review	6/8/17					
	CONTROLLED SUBSTANCE VIOLATIONS									
		Deny/Revoke	Deny/Revoke	Case Review	6/8/17					
	ALCOHOL/MARIJUANA (DUII/POSSESSION)									
	One DUI/MIP > 5 years	Refer to Staff Delegated Authorit	ty							
	One DUI/MIP less than 5 years with BAC greater than 0.15 (request drug and alcohol evaluation per policy) One DUI/MIP less than 5 years and BAC refused or no BAC (request drug and alcohol evaluation) Two or more DUI/MIP (request drug an alcohol evaluation per policy)			Case Review	8/10/2017					
	Marijuana possession less than 1 oz (between 7/01/2013-7/01/2015)	Deny	Grant license with no further violations for 3 years, 3 hours of CE (law or patient safety)	Written Review						
	Illegal marijuana possession (after 7/01/2015) or habitual/excessive use	Deny/Revoke	Deny/Revoke	Case Review	6/8/2017					
	UNSWORN FALSIFICATION	•	, DRUGS, AND ALCOHOL CHARG	ES)						
	Felony conviction	Deny/Revoke and \$1,000 civil penalty per violation	Deny/ Revoke	Case Review	6/8/2017					
	Single LEDS incident	Deny/Revoke and \$1,000 civil penalty per violation	\$1,000 civil penalty stay \$850 no further violations for 3 years, 3 hours of CE	Written Review	6/8/2017					
	Multiple LEDS incidents	Deny/Revoke and \$1,000 civil penalty per violation	Deny	Written Review	6/8/2017					

Administrative Discussion (AD): Case Presented by Compliance Director, independent vote

Case Review (CR): Case Presented by Investigator with Written Report, independent vote

Written Review (WR): Case Presented in like category with Written Report, independent vote

Consent Agenda (CA): Case Presented in single group (No Disciplinary Action) with Written Report, single vote

BOARD OF PHARMACY AY19 CASH FLOW

Actuals through February 2019

OF Appn 30235

O. 7.P	011 30235								
Budget Objects	REVENUE & EXPENDITURES	LAB ORBITS BUDGET	Rstars Financial Plan	EBoard or Adj Budget or Salary Pot	Adjusted Financial Plan	ACTUALS To Date	Unobligated Balance	% Expended	
REVEN	UE								
0205	Other Business Licenses	4,431,667	4,431,667		4,431,667	3,804,639	627,029	86%	
0203	Other NonBusiness Licenses and Fe		505,552		505,552	186,690	318,862	37%	
0505	Fines and Forfeits	420,000	420,000		420,000	292,517	127,483	70%	
0605	Interest and Investments	48,000	48,000		48,000	146,297	(98,297)	305%	
0975	Other Revenue	39,700	39,700		39,700	83,042	(43,342)	209%	
	SubTotal Revenue	5,444,919	5,444,919	0	5,444,919	4,513,185	931,734	83%	
TRANS	FERS								
2443	Transfer out to OHAWorkforce/PD SubTotal Transfers	(409,357) (409,357)	(409,357) (409,357)	0	(409,357) (409,357)	32,961 32,961	(442,318) (442,318)	-8% -8%	
TOTAL	REVENUE & TRANSFERS	5,035,562	5,035,562	0	5,035,562	4,480,224	1,374,052	89%	
		.,,.			.,,		, , , , , ,		
PERSOI	NAL SERVICES								
3110	Regular Employees	3,191,268	3,191,268	104,724	3,295,992	2,644,413	651,579.01	80%	
	Board Member Stipends		-		0				
3160	Temporary Appointments	25,222	25,222		25,222	-	25,222	0%	
3170	Overtime Payments		-		0	505	(505)	0%	
3190	All Other Differential O/Class Lead V	183,457	183,457		183,457	155,626	27,831	85%	
3210	Employment Relations Board Assess	1,083	1,083		1,083	849	234	78%	
3220	Public Employees Retirement Contri		504,012	3,269	507,281	381,269	126,012	75%	
3221	Pension Bond Contribution	195,224	195,224	(3,502)	191,722	164,265	27,457	86%	
				(3,502)					
3230	Social Security Taxes	256,020	256,020	1	256,020	201,493	54,527	79%	
3240	Unemployment Assessment		-		0	1,869	(1,869)	0%	
3250	Workers' Compensation Assessmen	1,380	1,380		1,380	806	574	58%	
3260	Mass Transit Tax	20,334	20,334		20,334	16,693	3,641	82%	
	Flexible Benefits	666,720	666,720	24,720	691,440	522,146	169,294	76%	
		(169,448)		24,720		322,140		0%	
3455	Vacancy Savings-ORBITS only		(169,448)	-	(169,448)	-	(169,448)		
3465	Reconciliation Adjustment-ORBITS of				0	-	-	0%	
3470	Undistributed Personal Services-ORI	BITS			0	-	-	0%	
3991	PERS Policy Adjustment-ORBITS				0			0%	
	SubTotal Personal Services	4,875,272	4,875,272	129,211	5,004,483	4,089,933	914,550	82%	\$ 914,5
SERVIC	ES AND SUPPLIES	,	Proj all	,					
	InState Travel	102,270	102.270		102.270	73.005	29,265	71%	
4125	Out of State Travel	15,724	15,724		15,724	6,325	9,399	40%	
4150	Employee Training	52,335	52,335		52,335	17,391	34,944	33%	
4175	Office Expenses	123,883	123,883		123,883	72,617	51,266	59%	
4200	Telecommunications	43,879	43,879		43,879	46,803	(2,924)	107%	
4225	State Govt. Service Chgs.	119,969	119,969		119,969	131,340	(11,371)	109%	
4250	Data Processing	73,694	73,694		73,694	55,644	18,050	76%	
4275	Publicity & Publications	37,712	37,712		37,712	7,871	29,841	21%	
4300	Professional Services	402,408	402,408		402,408	224,369	178,039	56%	
4315	IT Professional Services	353,340	353,340		353,340	32,550	320,790	9%	
4325	Attorney General	326,595	326,595	86,083	412,678	362,181	50,497	88%	
4375	Employee Recruitment & Develop	207	207	,	207		207	0%	
4400		4,583	4,583		4,583	4 522	51	99%	
	Dues & Subscriptions					4,532			
4425	Facilities Rent & Taxes	219,519	219,519		219,519	150,395	69,124	69%	
4475	Facilities Maintenance	51	51		51	714	(663)	1401%	
4525	Medical Supplies and Services	1,110	1,110		1,110	4,178	(3,068)	376%	
4575	Agency Program Related S&S	229,434	229,434		229,434	161,712	67,722	70%	
								89%	
4650	Other Services & Supplies	278,652	278,652		278,652	248,270	30,382		
4700	Expendable Property	10,499	10,499		10,499	689	9,810	7%	
4715	IT Expendable Property	43,976	43,976		43,976	4,553	39,423	10%	
5550	Data Processing Software				0	-	-	0%	
5600	Data Processing Hardware	8,296	8,296		8,296	-	8,296	0%	
	SubTotal Services and Supplies	2,448,136	2,448,136	86,083	2,534,219	1,605,140	929,079	63%	\$ 929,0
SPECIA	L PAYMENTS	2, , . 30	_,,.00	22,200	-,,,	.,,	,5//	2270	
		11 001	11 001		11 001		11 001	0%	
	Other Special Payments	11,991	11,991		11,991	-	11,991		
	Special Payments to OHA-HPSP	11,991	11,991	0	11,991	- 0	11,991	0% 0%	\$ 11,9
6443	SubTotal Transfore		11,771	U	11,271	0	11,771	0.76	₩ 11/3
6443	SubTotal Transfers								
6443	SubTotal Transfers xpenditures Budget	7,335,399	7,335,399	215,294	7,550,693	5,695,074	1,855,620	75%	\$ 1,855,62
6443	xpenditures Budget	7,335,399	7,335,399	215,294	7,057,070	5,695,074			\$ 1,855,62
6443			7,335,399	215,294		5,695,074	1,855,620 Target	75%	\$ 1,855,6
6443	xpenditures Budget	7,335,399	7,335,399	215,294	7,057,070	5,695,074			\$ 1,855,6

AY17 Ending Cash Balance
Revenue less Expenditures
Total Revenue & Transfers
10tal Revenue & Transfers
10tal Revenue & Transfers
10tal Expenditures
10tal Expenditures not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mac
10tal Expenditures not yet spent
10tal Expenditures not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mac
10tal Expenditures not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mac
10tal Expenditures not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mac
10tal Expenditures not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mac

Revenue received is more than budgeted so zero is not yet received

BOARD OF PHARMACY AY19 CASH FLOW

Actuals through March 2019

OF Appn 30235

Budget		LAB ORBITS	Rstars Financial	EBoard or Adj Budget or	Adjusted Financial	ACTUALS	Unobligated	%	
REVEN	REVENUE & EXPENDITURES	BUDGET	Plan	Salary Pot	Plan	To Date	Balance	Expended	
		4 404 (/ 7	4 404 447		4 404 (/ 7	0.000.444	508.004	89%	
	Other Business Licenses	4,431,667	4,431,667		4,431,667	3,923,664			
0210	Other NonBusiness Licenses and Fe		505,552		505,552	194,827	310,725	39%	
0505	Fines and Forfeits	420,000	420,000		420,000	315,917	104,083	75%	
0605	Interest and Investments	48,000	48,000		48,000	154,706	(106,706)	322%	
0975	Other Revenue	39,700	39,700		39,700	85,954	(46,254)	217%	
	SubTotal Revenue	5,444,919	5,444,919	0	5,444,919	4,675,068	769,851	86%	
TRANS		(400.057)	(400.057)		(400.057)	20.044	(440.040)	004	
2443	Transfer out to OHAWorkforce/PD SubTotal Transfers	(409,357) (409,357)	(409,357) (409,357)	0	(409,357) (409,357)	32,961 32,961	(442,318) (442,318)	-8% -8%	
TOTAL	REVENUE & TRANSFERS	5,035,562	5,035,562	0	5,035,562	4,642,107	1,212,169	92%	
	NAL SERVICES								
3110	Regular Employees	3,191,268	3,191,268	104,724	3,295,992	2,788,695	507,297.02	85%	
	Board Member Stipends		-		0	-			
3160	Temporary Appointments	25,222	25,222		25,222	-	25,222	0%	
3170	Overtime Payments		-		0	505	(505)	0%	
3190	All Other Differential O/Class Lead V		183,457		183,457	166,926	16,531	91%	
3210	Employment Relations Board Assess	1,083	1,083		1,083	892	191	82%	
3220	Public Employees Retirement Contri	504,012	504,012	3,269	507,281	398,983	108,298	79%	
3221	Pension Bond Contribution	195,224	195,224	(3,502)	191,722	172,793	18,929	90%	
3230	Social Security Taxes	256,020	256,020		256,020	212,767	43,253	83%	
3240	Unemployment Assessment				0	1,869	(1,869)	0%	
3250	Workers' Compensation Assessmen	1,380	1,380		1,380	841	539	61%	
3260	Mass Transit Tax	20,334	20,334		20,334	17,565	2,770	86%	
3270	Flexible Benefits	666,720	666,720	24,720	691,440	549,908	141,532	80%	
3455	Vacancy Savings-ORBITS only	(169,448)		24,720		347,700	(169,448)	0%	
			(169,448)	-	(169,448)	-	(109,448)		
3465	Reconciliation Adjustment-ORBITS of				0	-	-	0%	
3470	Undistributed Personal Services-ORE	BIIS			0	-	-	0%	
3991	PERS Policy Adjustment-ORBITS				0	-		0%	
	SubTotal Personal Services	4,875,272	4,875,272	129,211	5,004,483	4,311,744	692,739	86%	\$ 692,73
	CES AND SUPPLIES		Proj all						
4100	InState Travel	102,270	102,270		102,270	76,300	25,970	75%	
4125	Out of State Travel	15,724	15,724		15,724	6,325	9,399	40%	
4150	Employee Training	52,335	52,335		52,335	18,759	33,576	36%	
4175	Office Expenses	123,883	123,883		123,883	70,428	53,455	57%	
4200	Telecommunications	43,879	43,879		43,879	51,947	(8,068)	118%	
4225	State Govt. Service Chgs.	119,969	119,969		119,969	115,797	4,172	97%	
4250	Data Processing	73,694	73,694		73,694	57,226	16,468	78%	
4275	Publicity & Publications	37,712	37,712		37,712	8,026	29,686	21%	
4300	Professional Services	402,408	402,408		402,408	233,897	168,511	58%	
4315	IT Professional Services	353,340	353,340		353,340	32,550	320,790	9%	
4315		326,595	326,595	86,083	412,678	413,550	(871)	100%	
	Attorney General			80,083					
4375	Employee Recruitment & Develop	207	207		207	519	(312)	251%	
4400	Dues & Subscriptions	4,583	4,583		4,583	5,052	(469)	110%	
4425	Facilities Rent & Taxes	219,519	219,519		219,519	158,311	61,208	72%	
4475	Facilities Maintenance	51	51		51	714	(663)	1401%	
4525	Medical Supplies and Services	1,110	1,110		1,110	4,349	(3,239)	392%	
4575	Agency Program Related S&S	229,434	229,434		229,434	167,502	61,932	73%	
4650	Other Services & Supplies	278,652	278,652		278,652	266,706	11,946	96%	
4700	Expendable Property	10,499	10,499		10,499	1,838	8,661	18%	
4715	IT Expendable Property	43,976	43,976		43,976	4,622	39,354	11%	
5550	Data Processing Software	45,776	.5,776		43,770	.,522	57,554	0%	
5600	Data Processing Software Data Processing Hardware	8,296	8,296		8,296		8,296	0%	
			-		0				
SPECIA	SubTotal Services and Supplies AL PAYMENTS	2,448,136	2,448,136	86,083	2,534,219	1,694,416	839,803	67%	\$ 839,80
6085	Other Special Payments	11,991	11,991		11,991		11,991	0%	
		11,991	11,991		11,991	-	11,991	0%	
6443	Special Payments to OHA-HPSP SubTotal Transfers	11,991	11,991	0	11,991	- 0	11,991	0%	\$ 11,99
Total E	xpenditures Budget	7,335,399	7,335,399	215,294	7,550,693	6,006,160	1,544,533	80%	\$ 1,544,53
	LAB OV DO	,			7,057,070		T	4050.	
	LAB % PS	66%			66%		Target	100%	
	LAB % S&S	33%			34%				
	LAB % SP	0%			0%				

AY17 Ending Cash Balance

Revenue less Expenditures

Total Revenue & Transfers

Total Expenditures

Total Expenditures

(6,006,160)

Total Expenditures

(6,006,160)

Total Expenditures

(1,364,054)

AY19 Cash Balance after the Fiscal Month Closed

Budgeted Revenues not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mar

Budgeted Expenditures not yet spent

AY19 Estimated Cash Balance

Cash

4,794,930

(1,364,054)

(1,364,054)

3,430,876

Budgeted Expenditures not yet spent

AY19 Estimated Cash Balance

Cash

Actuals

(1,364,054)

(1,364,054)

(1,364,054)

(1,544,533)

(1,544,533)

Cash Balance Contingency (Months)

Revenue received is more than budgeted so zero is not yet received

BOARD OF PHARMACY AY19 CASH FLOW

Actuals through April 2019

OF Appn 30235

Budge Object	s REVENUE & EXPENDITURES	LAB ORBITS BUDGET	Rstars Financial Plan	EBoard or Adj Budget or Salary Pot	Adjusted Financial Plan	ACTUALS To Date	Unobligated Balance	% Expended	
REVEN	UE								
0205	Other Business Licenses	4,431,667	4,431,667		4,431,667	4,326,304	105,364	98%	
0210	Other NonBusiness Licenses and Fe	505,552	505,552		505,552	213,197	292,355	42%	
0505	Fines and Forfeits	420,000	420,000		420,000	325,612	94,388	78%	
0605	Interest and Investments	48,000	48,000		48,000	162,810	(114,810)	339%	
0975	Other Revenue	39,700	39,700		39,700	88,752	(49,052)	224%	
	SubTotal Revenue	5,444,919	5,444,919	0	5,444,919	5,116,674	328,245	94%	
TRANS	FERS								
2443	Transfer out to OHAWorkforce/PD	(409,357)	(409,357)		(409,357)	32,961	(442,318)	-8%	
	SubTotal Transfers	(409,357)	(409,357)	0	(409,357)	32,961	(442,318)	-8%	
TOTAL	REVENUE & TRANSFERS	5,035,562	5,035,562	0	5,035,562	5,083,713	770,563	101%	
DEDEO	NAL SERVICES								
	Regular Employees Board Member Stipends	3,191,268	3,191,268	104,724	3,295,992	2,920,569	375,422.56	89%	
3160	Temporary Appointments	25,222	25,222		25,222		25.222	0%	
3170	Overtime Payments	,	,		0	881	(881)	0%	
3190	All Other Differential O/Class Lead V	183.457	183,457		183,457	178.025	5.432	97%	
3210	Employment Relations Board Assess		1,083		1,083	933	150	86%	
3220	Public Employees Retirement Contri		504,012	3,269	507,281	415,362	91,919	82%	
3221	Pension Bond Contribution	195,224	195,224	(3,502)	191,722	180,807	10,915	94%	
3230	Social Security Taxes	256,020	256,020	(0,002)	256,020	223,452	32,568	87%	
3240	Unemployment Assessment	200,020	200,020		230,020	1.869	(1,869)	0%	
3250	Workers' Compensation Assessmen	1,380	1,380		1,380	878	502	64%	
3250	Mass Transit Tax	20,334	20,334		20,334	18,417	1,917	91%	
3270	Flexible Benefits	666,720	666,720	24,720	691,440	576,304	115,136	83%	
3455	Vacancy Savings-ORBITS only	(169,448)	(169,448)	24,720	(169,448)	370,304	(169,448)	0%	
3465	Reconciliation Adjustment-ORBITS of		(107,440)	-	(107,448)	-	(107,440)	0%	
3400	Undistributed Personal Services-ORI				0	-	-	0%	
3991		1113				-	-		
3991	PERS Policy Adjustment-ORBITS SubTotal Personal Services	4,875,272	4,875,272	129,211	5,004,483	4,517,499	486,984	0% 90%	\$ 486,984
CEDVI	CES AND SUPPLIES	4,875,272	Proj all	129,211	5,004,483	4,517,499	480,984	90%	\$ 480,984
4100	InState Travel	102,270	102,270		102.270	82.423	19.847	81%	
4125	Out of State Travel	15,724	15,724		15,724	6,325	9,399	40%	
4125		52,335	52,335		52,335	19,873	32,462	38%	
4175	Employee Training Office Expenses	123,883	123,883		123,883	72,480	51,403	59%	
4200			43,879					123%	
	Telecommunications	43,879 119,969	119,969		43,879 119,969	53,820 117,946	(9,941) 2,023	98%	
4225 4250	State Govt. Service Chgs. Data Processing	73,694	73,694		73,694	61.882	11,812	84%	
								23%	
4275	Publicity & Publications	37,712	37,712		37,712	8,691	29,021		
4300	Professional Services	402,408	402,408		402,408	243,606	158,802	61%	
4315	IT Professional Services	353,340	353,340	07.000	353,340	32,550	320,790	9%	
4325	Attorney General	326,595	326,595	86,083	412,678	413,807	(1,129)	100%	
4375	Employee Recruitment & Develop	207	207		207	519	(312)	251%	
4400	Dues & Subscriptions	4,583	4,583		4,583	5,453	(870)	119%	
4425	Facilities Rent & Taxes	219,519	219,519		219,519	166,227	53,292	76%	
4475	Facilities Maintenance	51	51		51	938	(887)	1839%	
4525	Medical Supplies and Services	1,110	1,110		1,110	4,428	(3,318)	399%	
4575	Agency Program Related S&S	229,434	229,434		229,434	168,211	61,223	73%	
4650	Other Services & Supplies	278,652	278,652		278,652	269,848	8,804	97%	
4700	Expendable Property	10,499	10,499		10,499	6,961	3,538	66%	
4715	IT Expendable Property	43,976	43,976		43,976	7,733	36,243	18%	
5550	Data Processing Software		-		0	-	-	0%	
5600	Data Processing Hardware	8,296	8,296		8,296 0	-	8,296	0%	
	SubTotal Services and Supplies	2,448,136	2,448,136	86,083	2,534,219	1,743,720	790,499	69%	\$ 790,499
	AL PAYMENTS								
6085	Other Special Payments	11,991	11,991		11,991	-	11,991	0%	
6443	Special Payments to OHA-HPSP		-		-	-	-	0%	
	SubTotal Transfers	11,991	11,991	0	11,991	0	11,991	0%	\$ 11,991
Total E	xpenditures Budget	7,335,399	7,335,399	215,294	7,550,693	6,261,219	1,289,475	83%	\$1,289,475
					7,057,070				
	LAB % PS	66%			66%		Target	100%	
	LAB % S&S	33%			34%				
	LAB % SP	0%			0%				

AY17 Ending Cash Balance

Revenue less Expenditures

Total Revenue & Transfers

Total Expenditures

Total Expenditures

Total Expenditures

(6, 261,219)

Total Expenditures

(6, 261,219)

Total Expenditures

(1,177,506)

3,617,424

Budgeted Revenues not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mar

Budgeted Expenditures not yet spent

AY19 Cash Balance

Expenditures not yet spent

AY19 Estimated Cash Balance

Cash

Actuals

(6, 261,219)

(1,177,506)

3,617,424

Budgeted Revenues not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mar

(1,289,475)

AY19 Estimated Cash Balance

Cash

Actuals

(1,177,506)

(1,177,506)

(1,177,506)

(1,177,506)

(1,177,506)

3,617,424

Revenue received is more than budgeted so zero is not yet received