Oregon Board of Pharmacy
BOARD MEETING AGENDA
Meeting Location:
Portland State Office Building
800 NE Oregon Street, Portland, OR 97232
August 7-9, 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, August 7, 2019 @ 8:30AM – Conference Room 1A
Thursday, August 8, 2019 @ 8:30AM – Conference Room 1A
Friday, August 9, 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

WEDNESDAY, AUGUST 7, 2019

I. 8:30AM OPEN SESSION, Cyndi Vipperman, CPhT, Presiding

A. Roll Call
B. Board Photos
C. Installation of new Board Member Michelle Murray
D. Agenda Review and Approval *Action Necessary*
E. DOJ Intro for New Member - *Cowan*

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 3:30-4:30PM.

Adjourn

THURSDAY, AUGUST 8, 2019

8:30AM

V. OPEN SESSION, Cyndi Vipperman CPhT, Presiding

A. Roll Call
B. Introduction of new Board Member Michelle Murray
C. Motions for Contested Cases & Disciplinary Action – *Efremoff* *Action Necessary*

VI. GENERAL ADMINISTRATION

A. PDMP Follow-up – *Schnabel/Efremoff/Karbowicz* (approx. 45 min.) **#A**

B. Public Health and Pharmacy Formulary Advisory Committee - Staff
1. Committee Meeting (7/12/19) and Recommendation update **#B**
2. Consider rules & send to Rulemaking Hearing **#B1**
- Div 019 and 020 – Formulary *Actions Necessary*

C. Legislative Update – *Schnabel/Karbowicz*
- SB 9 - Insulin
- SB 689 - Labeling
- HB 2011 – Cultural Competency
- SB 71 – Animal Euthanasia **#B2**
- HB 2935 – Prescription Reader
- HB 2257 - PDMP
- HB 3273 – Drug Take Back*
- SB 910 – Naloxone Signage
- SB 854 – Taxpayer ID in lieu of SSN
- HB 3030 – Armed Services Member - Spouse Licensure
- SB 688 – Armed Services Member – Spouse Licensure - report
- SB 855 – Immigrants/Refuges – annual report and study
- SB 5529 – OBOP Budget

*Note: bill not yet signed by the Governor. Check for passage after 8/9/19.

Lunch – estimated time depending on the length of discussions

D. Discussion Items:
1. Policy Discussion for Board Review - none
2. TCVP: none
3. Strategic Planning Update – *Schnabel/MacLean* (approx. 2-3 hours)
a. Mission, Vision, Values – *Schnabel* **#C** *Action Necessary*
b. Annual Performance Progress overview – *MacLean*
c. Board Best Practices Performance Measure review **#C1** – *MacLean*
d. Other

VII. 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 should not be used 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

FRIDAY, AUGUST 9. 2019
8:30AM

VIII. OPEN SESSION, Cyndi Vipperman CPhT, Presiding

A. Roll Call

IX. General Administration - Discussion Items continued

A. APhA Contraceptive Training Request & Background **#D** CONFIDENTIAL – *Karbowicz Action Necessary*

B. DCCT – Charitable Pharmacy request – **#E** *Karbowicz/Efremoff – Action Necessary*

C. Rural Health Community Council appointment - **#F** *MacLean Action Necessary*

D. Rules

1. Review Rulemaking Hearing Report & Comments - none
2. Consider Adoption of Rules – none
3. Consider Adoption of Temporary Rules – none
4. Rules Update - none
5. Consider rules and send to Rulemaking Hearing *Action Necessary*
    - Div 045 & 006 – Drug Compounding & Definitions **#G**

X. ISSUES/ACTIVITIES

A. Board Meeting Dates

- 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. OSPA Annual Convention 10/5-6/2019 – Portland *Action Necessary*
2. NABP Executive Officers Forum 10/1-2/2019 – Chicago - *Schnabel*
3. NABP District VI-VIII Mtg. Boise, ID, 10/6-9/2019 *Action Necessary*
4. OSPA Fall Seminar 11/16/19 – Portland (booth)
5. NABP Compliance Officer/Legal Counsel Forum -12/4-5/2019
6. OSPA Lane Co. Mid-Winter CE Seminar – 2/15-16/2020 - Eugene

D. Board Member/Staff Presentations – *Vipperman*

- Pharmacy Coalition – 6/18/19
- Professional Practice Roundtable – 6/12/19

E. Financial/Budget Report – **#H** *MacLean*

F. Reports:

1. Board President/Members
2. Executive Director
3. Board Counsel
4. Compliance Director
5. Pharmacist Consultant
6. Administrative Director
7. Licensing Program Manager
8. Operations Policy Analyst

XI. 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 – Jan 1, 2019 – April 30, 2019 - **#Consent 1**
2. MPJE Scores – Jan 1, 2019 – April 30, 2019 **#Consent 2**
3. License/Registration Ratification – May 22, 2019 – July 25, 2019 **# CONSENT – 4**
4. Pharmacy Technician Extensions **– # CONSENT – 3**
5. Board Minutes – June 5-6, 2019 **# CONSENT – #5**

XII. 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 should not be used 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

Pharmacy Data Quality in the Oregon Prescription Drug Monitoring Program.

Findings from an examination of dispensing histories of 25 pharmacies from April 1, 2018 to April 1, 2019.

Oregon Prescription Drug Monitoring Program

Injury and Violence Prevention Section

Oregon Public Health Division

Overview of the Oregon Prescription Drug Monitoring Program (PDMP)

In September 2011, Oregon's PDMP began collecting all Schedule II-IV Controlled Substances dispensed by retail and mail order pharmacies serving Oregon.

The PDMP annually receives approximately 7 million prescriptions from nearly 900 residential and out-of-state pharmacies.

Oregon pharmacies submit data utilizing the 2016 American Society for Automation in Pharmacies (ASAP) Version 4.2A standard. The information submitted to the PDMP is a part of the overall pharmacy record that is also used for patient records and billing insurance claims.

Who uses PDMP Data

Prescribing healthcare professionals
Delegate staff of prescribers
Patients
Licensing Boards
Law Enforcement Agencies
Academic Researchers
Oregon Public Health
Oregon Health Authority

The PDMP is used by:

- Prescribers and pharmacists to aid in managing their patient's treatment and prescriptions.
- Prescribers to review their prescribing history and patterns of prescribing.
- Patients interested to see their own prescription history.
- Licensing Boards and Law Enforcement in the course of investigations.
- Oregon Public Health to create useful tools like the Oregon Drug Overdose and PDMP Dashboard
- Pharmacy Directors to review pharmacy dispensing history for patterns of errors or missing dates of data.
- Medical Directors to review their prescribers prescription histories.

Information is submitted to the PDMP by pharmacies within 72 hours of dispensing of a Scheduled II-IV prescription.

Information provided by pharmacy in a PDMP report

Patient information:
Name
Address
Date of birth
Sex
Species (human or veterinary)

Prescriber information:
Name
Address
DEA number

Pharmacy information:
DEA
Name
Address

Drug information:
Name
Quantity
Days supply
Date written
Date Filled

Data Entry Accuracy and Completeness Matters in the PDMP

The software behind the PDMP works to match all records of a specific patient or a specific prescriber to one report. To do this matching as effectively as possible accuracy and completeness of the data entered by the pharmacist and pharmacy staff is important.

Misspellings, Mistakes, Shorthand or codes, and pharmacy staff haste can impact the quality of the data found within a PDMP report as these entries may not match to the patient or prescriber being queried.

Missing data may impact a prescribers decision to prescribe, could impact the outcome of an Board or Law Enforcement investigation, and could violate State and Federal regulations regarding the reporting of controlled substances.

Example PDMP Prescriber History Report

Prescriber Activity Report

Investigation Type:
Case Number:
Primary Drug Category:
Drug Product Name:
Case Notes:

REPORT MAY BE DOWNLOADED FOR LATER REVIEW IN A PDF OR CSV (EXCEL SPREADSHEET) FORMAT

Download PDF Download CSV

Report Prepared: 05/16/2019
Date Range: 03/16/2018 – 05/16/2019 PRESCRIBER HISTORY IS AVAILABLE FOR A 3 YEAR PERIOD FROM DATE OF SEARCH. REPORT DEFAULT IS 1 YEAR

Prescriber Name

Street Address	Street Address 2	City	State	Zip
800 NE Oregon St.	Ste 705	Portland	OR	97232

Report Criteria

DEA Number	Prescriber First Name	Prescriber Last Name
MD1234567	John	Doe

PRESCRIBER MAY LIST ONE OR MORE ACTIVE DEA NUMBERS REGISTERED IN THEIR NAME

Summary

Prescriptions	11	TOTAL NUMBER OF PRESCRIPTIONS FOR REPORT DATE RANGE
Patients	5	TOTAL NUMBER OF PATIENTS PRESCRIBED TO IN REPORT DATE RANGE
Pharmacies	1	TOTAL NUMBER OF PHARMACIES PATIENT PRESCRIPTIONS FILLED IN

Prescriber Activity

Last	First	DOB	Fill Date	Written Date	Drug Name	Qty	Supply	Store ID	Rx #
Smith	Michael	01/01/2001	04/05/2018	04/05/2018	SUBOXONE 8 MG-2 MG SL FILM	2.0	1	BestPharm	123458
Deer	Jane	02/02/1992	04/05/2018	04/05/2018	SUBOXONE 2 MG-0.5 MG SL FILM	7.0	2	BestPharm	654321
Jones	Davy	03/03/1983	04/05/2018	04/05/2018	SUBOXONE 8 MG-2 MG SL FILM	2.0	1	BestPharm	97016

Dispensers

Store ID	Name	Address	City	State	Zip
BestPharm	Best Pharmacy Services Oregon, INC	1234 Test Avenue	Portland	OR	97016

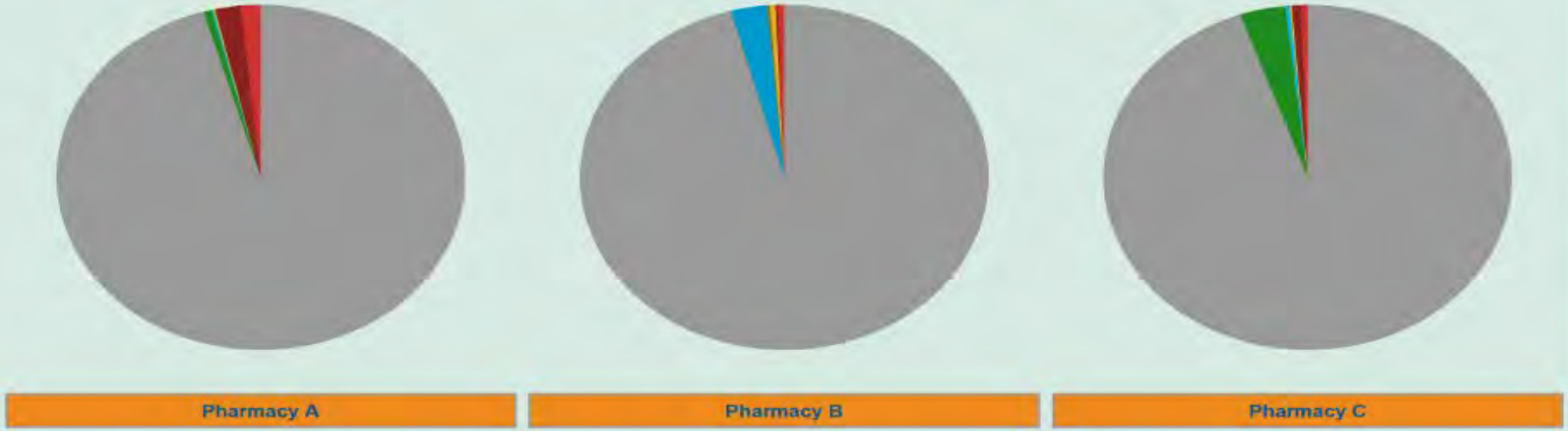
An examination of 25 Oregon pharmacies dispensing histories in the PDMP found entry errors fell into 10 primary categories.

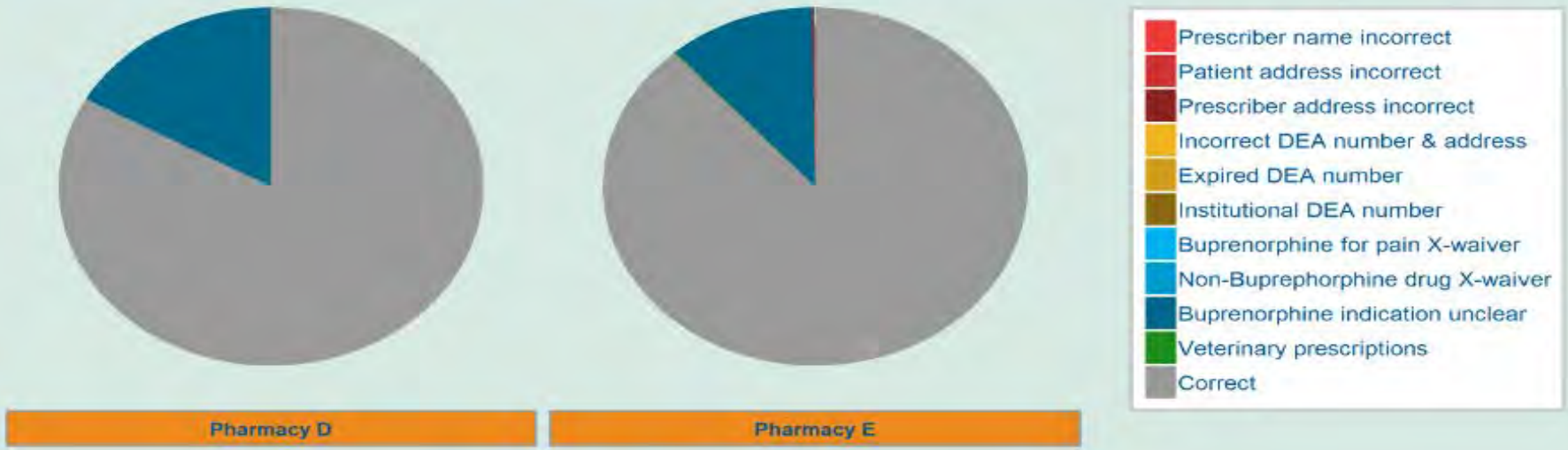
Author 2015 (presented Fall 2015 mtg)

1. Prescriber DEA entered does not exist
2. Prescriber DEA entered expired
3. Institutional DEA suffixes missing
4. Patient address is omitted in part or full
5. Provider DEA indicates X-DEA waiver certification that provider does NOT have.
6 X-DEA number is used for a non-buprenorphine prescription.
7. Buprenorphine prescriptions for medication assisted treatment (MAT) not consistently entered under prescribers X-DEA.
8. Prescriber name entered incorrectly or incompletely
9. Prescriber address omitted in part or full
10. Veterinary prescription does not include “non-human” species code.

Pharmacy Data Errors by Type

AUGUST 2019 / A (presented at 6/2019 mtg)





Prescriber DEA Entry Errors

Data entry errors within the system create problems:

- Records that a prescriber cannot see in their PDMP prescription history
- Records that are rejected and not reported to the PDMP at all.

The PDMP system ties all prescriptions to their providers by their DEA number (ASAP field PRE02).

These errors include dummy DEA's such as: "MD1111119" or with alpha characters not used by healthcare workers such as "ZZ1234567" or "NZ1234567".

During the review period PDMP staff found:

174 prescriptions for 39 prescribers attributed to dummy DEA numbers.
178 prescriptions for 48 prescribers attributed to mis-entered DEA numbers.

Expired DEA Numbers

Expired DEA numbers when used are often accepted within a pharmacy system as they meet the necessary checks within software but once submitted to the PDMP cannot be found by a prescriber or Medical Director when running prescription history reports or by PDMP staff in running reports for Licensing Boards or Law Enforcement.

A review of prescriptions filled, across all pharmacies, during the review year found 3,143 prescriptions written by 191 prescribers were filled under DEA's that had expired as many as 17 years earlier.

Many of those prescribers also had prescriptions in the same, and other pharmacies, under their current DEA. Indicative of out dated information not effectively being purged, or deactivated, in a timely matter.

Prescribers are unable to see these prescriptions in their prescriber history report.

Missing DEA Suffixes on Institutional DEA Prescription Fills:

The 3-5 alpha numeric character following a DEA “MD1234567-AB123” is specific to an individual. This suffix is important and must be included to provide a complete and accurate record.

Medical students and prescribing clinicians working in large facilities (OHSU, Samaritan Health, Providence) with institutional DEA’s have found they cannot find their prescriptions within their prescriber history if a pharmacy has not included their DEA suffix (ASAP field PRE03).

2439 prescriptions were missing DEA suffixes among the reviewed pharmacies. Meaning PDMP system users cannot attribute these prescriptions in to a single prescriber potentially creating a barrier to continuity of care and impacting reviews by Medical Directors, licensing boards, and law enforcement.

Prescribing for Medication-Assisted Treatment

AUGUST 2019 / A (presented at 6/2019 mtg)

Efforts to address the national opioid crisis have prompted a rapid increase in the number of providers in Oregon trained and certified to provide Medication-Assisted Treatment (MAT) to patients diagnosed with opioid use disorder. MAT services involve the prescription of buprenorphine and/or buprenorphine containing drugs such as Suboxone.

Currently Oregon has over 1,200 doctors and nurse practitioners certified to provide MAT services to as many as 275 patients each.

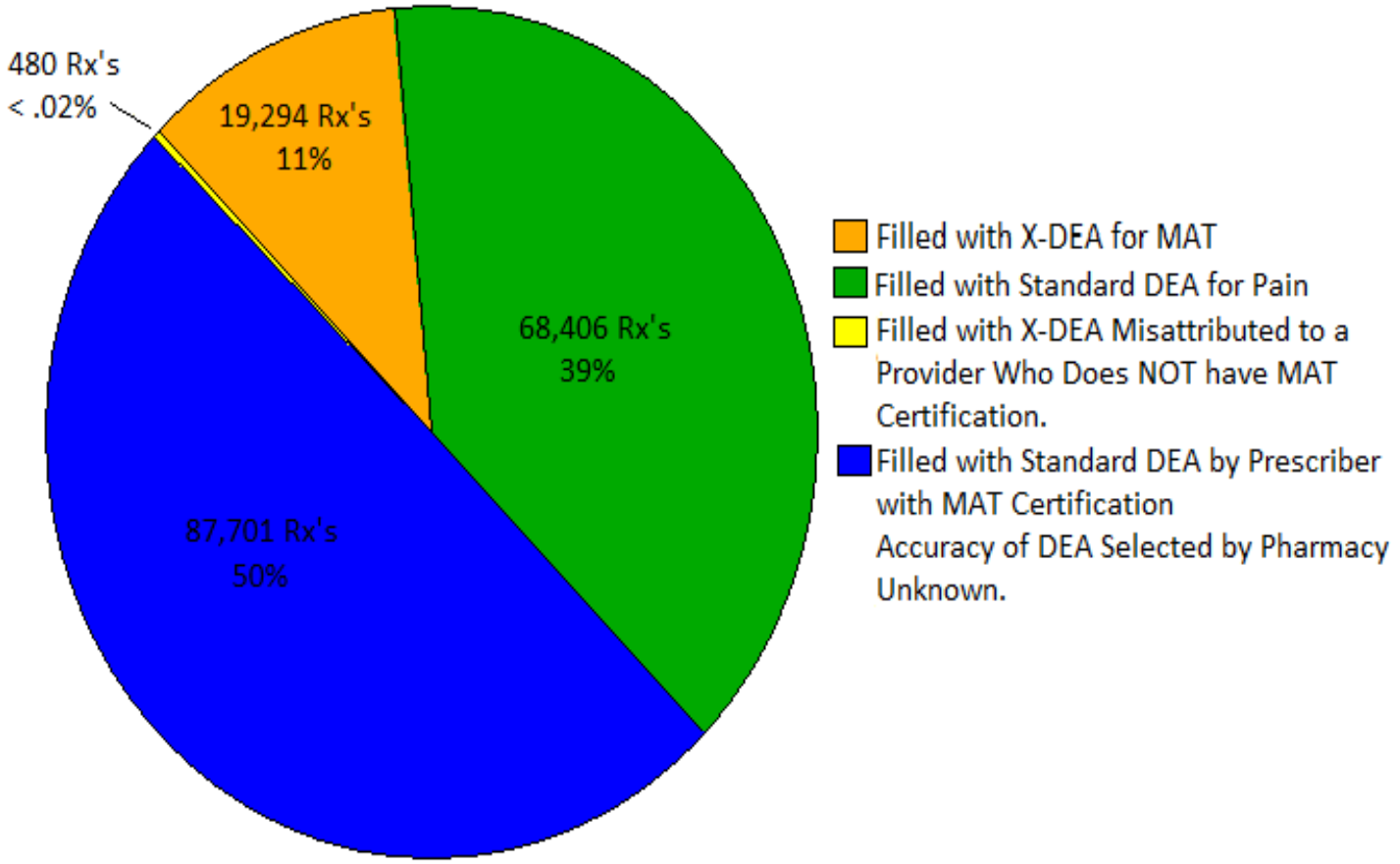
On becoming certified to provide MAT services providers are required to have their standard and "X" DEA registration numbers printed or written on their prescription pad for each prescription of buprenorphine and/or buprenorphine/naloxone*. These providers also agree to periodic DEA audit and inspection of their prescription records and fill history, which can include the DEA requesting PDMP records through an administrative subpoena.

Prescriptions for medications used in MAT are required to be filled under the prescribers X-DEA number (e.g. XD1234567).

Accurate and consistent use of X-DEA numbers of buprenorphine for MAT prescriptions is important.

Use of X-DEA's for Buprenorphine & Buprenorphine/Naloxone

175,401 prescriptions for buprenorphine containing drugs were filled by Oregon pharmacies during the review period.



Pharmacies Not Dispensing With X-DEA's

3 of the pharmacies reviewed were found not using X-DEA numbers on any prescriptions for any of their total 3,112 prescriptions written by confirmed MAT providers.

Pharmacists from these stores when asked why they were not using X-DEA numbers for the prescriptions of buprenorphine containing drugs by known MAT providers responded:

"I'm not sure."

"Well, we were getting error reports on those a couple years ago and stopped using them."

"Isn't the standard DEA good enough?"

Pharmacies found dispensing buprenorphine prescriptions written by MAT providers without using X-DEA's are being asked to review hundreds of prescriptions that may require submitting corrected data.

Not all Buprenorphine Prescriptions are for MAT

Buprenorphine is regularly prescribed for non-MAT purposes under standard DEA's.

PDMP records indicated pharmacies erroneously gave 50 prescribers X-DEA's for 480 prescriptions, to providers not certified for MAT services.

The providers with misattributed X-DEA's cannot see these 480 records when attempting to conduct prescription history reviews. This also impacts the PDMP's ability to produce complete and accurate records when requested by the licensing Boards or Law Enforcement.

X-DEA's Are Not For All Prescriptions

Half of the pharmacies reviewed were found to have numerous instances of prescriptions for medications not containing buprenorphine (opioids, benzodiazepines, pseudoephedrine drugs) being filled under X-DEA numbers.

Pharmacists at the reviewed pharmacies have attributed this error to the hasty selection of the wrong profile for a prescriber within their pharmacy system.

They were advised on the need to submit corrected records for each prescription to be in compliance with the State and Federal requirements.

Data Entry of Prescribers Name

The name entered in the pharmacy system in ASAP fields PRE05 and PRE06 are important in creating accurate data within the PDMP. It is important that only a providers first and last names are entered in these fields.

Instances of errors were found across nearly every pharmacy reviewed with examples often looking like this:

ASAP PRE05	ASAP PRE06
John	M.S.N. F.N.P.-B.C. Jones, John
Jane	APRN FNP-BC Doe
Ann(NP), Smith. W.	W.
Doe, JR., John M (MD)	(MD)

It was found across every pharmacy that many prescribers have multiple profiles within a pharmacy system created at different times with subtle differences that impact the PDMP's ability to match provider profiles.

ASAP PRE05	ASAP PRE06
John	Doe de Deer, MD
John	Doe DeDeer, MD
John	Doe M. DeDeer
John	Doe deDeer, MD
John	Doe deDeer

Prescriber Address Missing or Incomplete

The address of a prescriber is important and is a field entered by a pharmacy to match the practice location used by the prescriber. Within the PDMP this is important in matching prescribers with their prescription history and to our Public Health efforts. Complete and accurate records of prescriber activity are important in the course of Board and Law Enforcement investigations.

Many instances were found where no, or incomplete, information was entered into a prescribers profile by pharmacy staff.

ASAP PRE02	PRE05	PRE06	Entered by Pharmacy			
DEA 1	John	Doe de Deer, MD		PORTLAND	OR	97225
DEA 1	John	Doe de Deer, MD				

Prescriber's Multiple Pharmacy Profiles

Every pharmacy reviewed was found to have multiple profiles for single prescribers with subtle differences that increased the likelihood of pharmacy errors when profiles contained outdated or mis-entered information.

One example from a pharmacy had as many as 5 profiles for one prescriber.

ASAP PRE02	PRE05	PRE06	Entered by Pharmacy			
DEA 1	John	Doe de Deer, MD	11111 SW Street Rd, Ste 300	PORTLAND	OR	97225
DEA 1	John	Doe DeDeer, MD	1111 SW Street Rd, Ste 300	PORTLAND	OR	972255911
DEA 1	John	Doe M. DeDeer	11111 SW Street Rd, Ste 3	PORTLAND	OR	97225
DEA 1	John	Doe deDeer, MD	11111 SW Street Rd, Ste 300	PORTLAND	OR	97225
DEA 2 (expired)	John	Doe deDeer	11111 SW Street Rd, Suite 300	PORTLAND	OR	97225

In discussions with pharmacists it was stated that "many of these [profiles] should have been deactivated". Several pharmacists said they did not have staff regularly scheduled to review prescriber profiles for removal of erroneous or out-dated information.

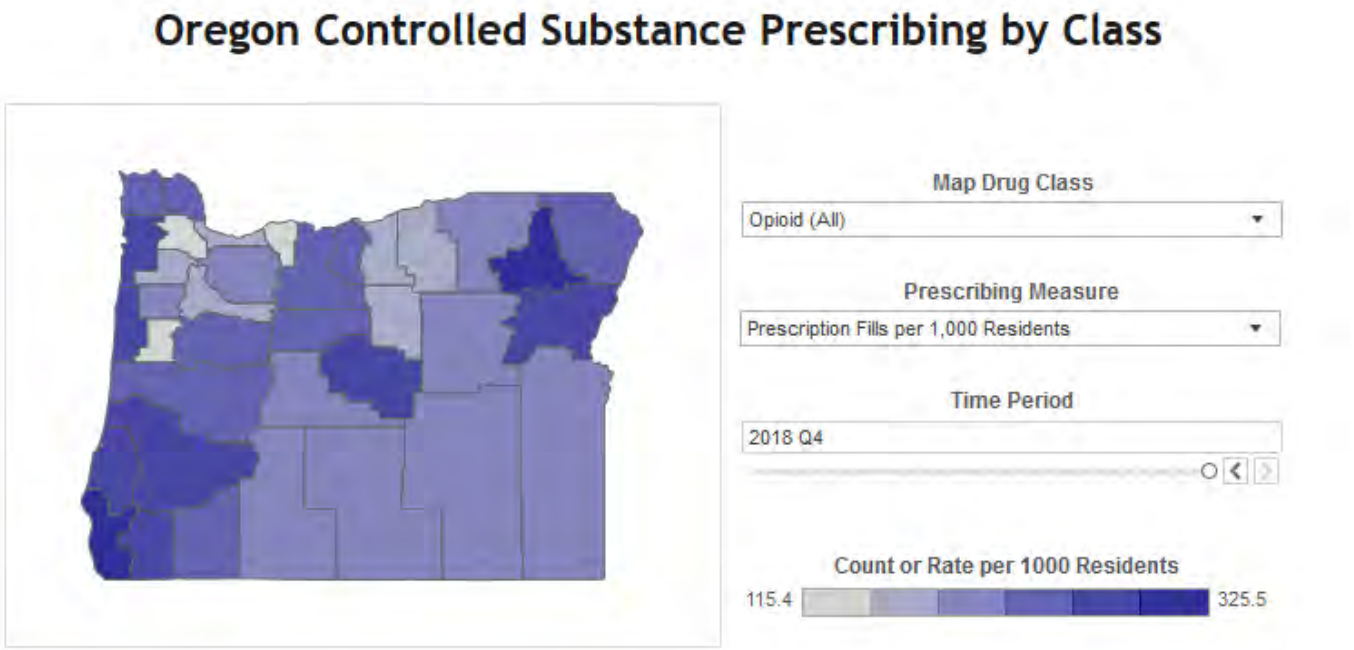
Veterinary Data In The PDMP

By statute the Oregon PDMP only collects data on prescription drugs dispensed for human patients. Species code (ASAP PAT20) matters in our Public Health work.

Each instance of a veterinary prescription not coded as "non-human" it has to be identified, if possible, and then removed from the PDMP data file. Our researchers do this each time they produce data for our Opioid Data Dashboard, Quarterly Reports, and Annual Advisory Commission Report.

During the reviewed year this accounted for more than 40,000 prescriptions written for non-human patients.

Accurately indicating species code with each veterinary prescription improves the quality of data released by the PDMP.



https://www.oregon.gov/oha/ph/preventionwellness/substanceuse/opioids/pages/data.aspx

What Can Be Done To Improve Data Quality in the OR PDMP?

The PDMP in coordination with the Oregon Board of Pharmacy would like to produce educational materials and feedback to pharmacists and pharmacy staff on the regulatory and practical importance of consistently accurate data entry by all including:

- Proper use of X-DEA numbers
- Regular deactivation, or removal, of old and erroneous prescriber profiles
- Regular review of patient and prescriber profiles to ensure all required ASAP fields are complete and current
- Regular spot checking of PDMP dispensing history by Pharmacy Directors and data submitters to ensure accurate and complete data entry by their pharmacy.

The PDMP also hopes to coordinate efforts with the Oregon Board of Medicine and Oregon Medical Association to educate prescribers on better documentation during prescribing by:

- Clear indication if prescription is for MAT or for pain.
- Using plain English in prescribing rather than Latin shorthand for days supply.
- Use of legible printed script on written prescriptions.
- Increasing use and review of the Prescriber History Report for missing or inaccurate data

Contact Information and Resources

Stephanie Vesik, PhD
Stephanie.g.vesik@state.or.us

Data Dashboard: http://public.health.oregon.gov/PreventionWellness/SubstanceUse/Opioids/Pages/data.aspx
Josh Van Otterloo, contact email: **Joshua.VanOtterloo@dhsoha.state.or.us**

Oregon Prescription Drug Monitoring Program:
https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SAFELIVING/PDMP/Pages/index.aspx

Sources: American Society of Addiction Medicine: https://www.asam.org/resources/practice-resources

Drug Enforcement Administration: Title 21, part 1306; section 05 – Prescriptions
https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_05.htm

COUGH AND COLD SYMPTOM MANAGEMENT – BENZONATATE

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe benzonatate to treat cough symptoms.

PRESCRIBING PARAMETERS:

- Maximum: Not to exceed a 7 day supply

CONDOMS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe male and female condoms.

CONTINUATION OF THERAPY

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe any non-controlled medication to extend a patient's prescription therapy to avoid interruption of treatment.

PRESCRIBING PARAMETERS:

- Quantity sufficient for the circumstances
- Maximum quantity: May not exceed a 60 day supply
- Maximum frequency: No more than two extensions in a 12 month period per medication

EMERGENCY CONTRACEPTION

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe prescription and OTC emergency contraception, not including abortifacients.

COUGH AND COLD SYMPTOM MANAGEMENT – INTRANASAL CORTICOSTEROIDS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe prescription and OTC intranasal corticosteroids to treat cough and cold symptoms.

COUGH AND COLD SYMPTOM MANAGEMENT - PSEUDOEPHEDRINE

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe pseudoephedrine to treat cough and cold symptoms.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- INCLUSION CRITERIA: Age 18 and older, verified by positive ID
- EXCLUSION/REFERRAL CRITERIA:
  - Age < 18

PRESCRIBING PARAMETERS:

- Pharmacist must review PDMP prior to issuing prescription, and retain documentation of review
- Maximum quantity: 3.6g or a 60 count quantity per prescription, whichever is less
- Maximum frequency: 3 prescriptions in a 12 month period

COUGH AND COLD SYMPTOM MANAGEMENT – SHORT ACTING B-AGONISTS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe prescription and OTC short acting beta agonists, ***(with or without a spacer)*** to treat cough symptoms.

PRESCRIBING PARAMETERS:

- Maximum: Not to exceed 1 inhaler or 1 box of nebulizer ampules, per year

Revisions to Divisions 020 and 019 are provided.

ORS 689.645 and 689.649 describe intent and legal scope for the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) efforts. Per law, the Committee shall recommend a formulary of drug 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. In Oregon, this includes physicians, nurse practitioners and PAs. The Committee shall periodically review the formulary and recommend revisions to the board and "The formulary may include post-diagnostic drugs and 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."

The law also states that a pharmacist may provide approved patient care services pursuant to a statewide drug therapy management protocol, developed by the PHPFAC; and adopted by rule of the Board. These patient care services include smoking cessation and travel health services. For the purposes of the conversation and past minutes, 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.

Rules have revisions (1) to appropriately reflect statutory authority, including repeal of OAR 855-019-0264; (2) provide clarity for documentation expectations; (3) incorporate recent PHPFAC recommendations; and (4) implement directives of 2019 SB 9.

855-020-0110
Prescribing Practices

(1) A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. A pharmacist shall only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.

(2) A pharmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services via implementation of statewide drug therapy management protocols. The policies and procedures shall describe current and referenced clinical guidelines, and include but not be limited to:

(a) Patient inclusion and exclusion criteria;

(b) Explicit medical referral criteria;

(c) Care plan preparation, implementation, and follow-up;

(d) Prescribing drugs and devices pursuant to the formulary and protocol compendia;

(e) Patient education; and

(f) Provider notification.

~~(2)~~ **(3)** The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond his or her pharmacist expertise by consulting with or referring patients to another health care provider.

~~(3)~~ **(4)** ~~At a minimum,~~ ~~f~~**F**or each drug or device the pharmacist prescribes, the pharmacist must ~~document the following, which constitutes the Visit Summary~~:

~~(a) Create, approve, and maintain a drug therapy management protocol based on current and referenced clinical guidelines that must include:~~

~~(A) Patient inclusion and exclusion criteria; and~~

~~(B) Explicit medical referral criteria; and~~

~~(b)~~ **(a) Assess patient and** ~~C~~**c**ollect subjective and objective information**, including the diagnosis for Formulary Compendia items,** about the patient's health history and clinical status. The **pharmacist's** patient assessment shall be performed in a face-to-face, in-person interaction and not through electronic means; and

~~(6)~~ **(b)** Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the ~~pharmacist's established~~ **statewide** drug therapy management protocol **and policies and procedures**; and

~~(7)~~ **(c)** Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and

~~(8)~~ **(d)** Provide notification, preferably via an interoperable information technology system, to the patient's identified primary care provider or other care providers when applicable, within five business days following the prescribing of a Compendia drug or device.

~~(9)~~ **(5)** The pharmacist shall maintain all records associated with prescribing **and other related activities performed** for a minimum of 10 years, ~~including but not limited to the drug therapy management protocol, the prescription record, consultation, and Visit Summary~~, and a copy must be made available to the patient~~,~~ **and** provider~~, and Board~~ upon request. **Pharmacy records must be retained and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.**

The proposed edits to OAR 855-020-0200 and 855-020-0300 are based on recent Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) discussions and recommendations.

Policy directives if adopted:

- Clarify that all injection supplies are included; original language was not meant to be limiting

- To allow for when a pharmacist issues a prescription for an albuterol inhaler for cough symptoms, to also be able to prescribe and dispense a spacer (non post-diagnostic)

- To add male and female condoms (7/12/2019 PHPFAC recommendation).

855-020-0200
Formulary Compendium

A pharmacist may prescribe, according to regulations outlined in this Division, an FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented ~~on the Visit Summary~~.

(1) Devices and supplies

(a) Diabetic blood sugar testing supplies;

(b) ~~Pen needles~~ **Injection supplies**;

~~(c) Syringes;~~

~~(d)~~**(c)** Nebulizers and associated supplies;

~~(e)~~**(d)** Inhalation spacers;

~~(f)~~**(e)** Peak flow meters;

~~(g)~~**(f)** International Normalized Ratio (INR) testing supplies;

~~(h)~~**(g)** Enteral nutrition supplies; and

~~(i)~~**(h)** Ostomy products and supplies.

~~(2) *Placeholder*~~

855-020-0300
Protocol Compendium

A pharmacist may prescribe, via **statewide** drug therapy management protocol and according to regulations outlined in this Division, an FDA-approved drug and device listed in the following compendium:

(1) Continuation of therapy

(a) A pharmacist may prescribe any non-controlled medication to extend a patient's prescription therapy to avoid interruption of treatment; and

(b) In such cases, a pharmacist shall only prescribe a drug quantity sufficient for the circumstances, not to exceed a 60 day supply, and no more than two extensions in a 12 month period per medication.

(2) Conditions

(a) Cough and cold symptom management

(A) Pseudoephedrine products for patients 18 years of age and older, verified by positive identification, not to exceed 3.6 grams or a 60 count quantity per prescription, whichever is less, or a total of three prescriptions in a 12 month period. Pharmacist must review PDMP prior to issuing prescription and retain documentation of PDMP review;

(B) Benzonatate, for the treatment of cough, not to exceed a 7 day supply;

(C) Short-acting beta agonists, not to exceed 1 inhaler **with or without a spacer,** or 1 box of nebulizer ampules, per year;

(D) Intranasal corticosteroids.

~~(b) Emergency Contraception, not including abortifacients.~~

(3) Preventative care

(a) Emergency Contraception, not including abortifacients.

(b) Male and female condoms.

The proposed minor edits to Division 019 are put forth:

- To repeal outdated language related to protocols

- To describe statutory authority articulated in 2019 SB 9

~~855-019-0264~~
~~State Drug Therapy Management Protocols~~

~~(1) A pharmacist may participate in statewide drug therapy management protocols developed by the Oregon Health Authority to provide approved patient care services including but not limited to:~~

~~(a) Smoking cessation therapy;~~

~~(b) Travel health services; and~~

~~(c) Immunizations.~~

~~(2) The pharmacy must maintain written or electronic policies and procedures for each state drug therapy management protocol in which it participates.~~

~~(3) A pharmacist who participates in a state drug therapy management protocol must:~~

~~(a) Retain the required training documentation set forth by the protocol and make available to the Board upon request; and~~

~~(b) Document the prescription, administration, and patient interaction in the patient's record, and provide notification to the patient's primary care provider when available.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & 2015 OL Ch. 362
History:
BP 8-2015, f. & cert. ef. 12-23-15

855-019-0470

Emergency Insulin. A pharmacist who has completed a Board approved ACPE accredited training program may prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies, not including insulin pump devices, to a person who has evidence of a previous prescription from a licensed health care provider; in such cases, a pharmacist shall prescribe the lesser of a 30-day supply or the smallest available package size, and not more than three emergency refills and supplies in a calendar year.

Revisions to Division 080 – Controlled Substances are provided to address directives of 2019 SB 71, which add sedatives and analgesic medications for use by a humane society or animal control agency personnel to humanely euthanize injured, sick, homeless or unwanted domestic pets and other animals. Registration with the Board as an Animal Euthanasia Drug Outlet will permits the utilization of a limited number of sedative and analgesic drugs for these purposes.

Drug outlet expectations for drugs being administered on-site include: (1) Proper acquisition of drugs, from Oregon registered distributors; (2) Proper and secure drug storage; and (3) Documentation. Recordkeeping requirements related to controlled substances must comply with all related federal and state regulations. Many sedative and analgesic drugs are "highly divertible", therefore an outlet's recordkeeping must be robust.

855-080-0100
Animal Euthanasia

(1) The following requirements shall be met in order for a humane society or animal control agency to be registered or registration renewed to allow the purchase, possession and administration of sodium pentobarbital **and sedative and analgesic medications** for euthanizing injured, sick, homeless or unwanted domestic pets and other animals:

(a) Registration as an animal euthanasia drug outlet is limited to animal control agencies and humane societies for the purpose of purchasing, possessing, or administering sodium pentobarbital and sedative and analgesic medications to euthanize animals. Registration requires submission of an application and a certificate of registration will be issued upon approval. All registrations and renewals shall be accompanied by an annual fee defined in Division 110 of this chapter.

~~(a)~~**(b) Drug** Storage. All supplies of sodium pentobarbital **and sedative and analgesic medications** shall be **acquired from an Oregon registered distributor, and** kept in a locked cabinet. An assigned person designated in writing shall be responsible for the security of the sodium pentobarbital **and sedative and analgesic medications**. Such designated person shall allow withdrawal of the drug only to a person certified by the Oregon State Veterinary Medical Examining Board to administer sodium pentobarbital **and sedative and analgesic medications**;

~~(b)~~**(c)** Records. The following records shall be made at the time of the occurrence and shall be maintained for a minimum of three years, available for inspection by the Board of Pharmacy and its agents:

(A) A record of the withdrawal of sodium pentobarbital **and sedative and analgesic medications**, signed by the person who takes possession of the sodium pentobarbital **and sedative and analgesic medications** for administration;

(B) A record of the weight, species of animal and dosage **of each drug** administered for euthanasia signed by the person who administers the drug and by the designated person responsible for security;

(C) A record of all wastage **of each drug** signed by the person administering ~~the~~ each drug and the designated person responsible for security; and

(D) A weekly record of verification of the stock **of each drug** on hand, minus the amounts withdrawn for administration, signed by the designated person responsible for security;

(E) A record of disposal of any expired or unwanted sodium pentobarbital **and sedative and analgesic medication**s. Disposal shall be in a conformance with **federal regulations** ~~21 CFR 1307.21~~.

(F) Complete and retain the annual Self-Inspection report by February 1 each year.

~~(c)~~**(d)** Audits. The registrant shall submit to random audits of records and analysis of prepared solutions by the **DEA, and** State Board of Pharmacy or its agents.

(2) The humane society or animal control agency shall notify the Board in the event of a significant drug loss or violation related to drug theft within one (1) business day.

(3) At the time a Report of Theft or Loss of Controlled Substances (DEA Form 106) is sent to the Drug Enforcement Administration (DEA), a copy shall be sent to the Board.

~~(2) The fee for registration shall be paid as specified in division 110 of this chapter of rules.~~

~~(3)~~**(4)** The Board will suspend or revoke the registration of an~~y humane society or animal control agency~~ **animal euthanasia drug outlet** which allows a person to administer sodium pentobarbital **or sedative and analgesic medications** who is not certified by the Oregon State Veterinary Medical Examining Board to administer such drug.

Statutory/Other Authority: ORS 475.095, 475.190 & 689.205
Statutes/Other Implemented: ORS 689.151 & 689.155

ORS 475.190 Exception to prescription requirement; rules.

*(**with 2019 SB 71 incorporated**)*

(1) Notwithstanding the provisions of ORS 475.185, upon registration with the State Board of Pharmacy, a humane society or animal control agency may purchase, possess and, subject to subsection (4) of this section, administer sodium pentobarbital **and sedative and analgesic medications** to euthanize injured, sick, homeless or unwanted domestic pets and other animals.

(2) The State Board of Pharmacy, after consultation with the Oregon State Veterinary Medical Examining Board, shall adopt rules according to ORS 183.325 to 183.410 establishing requirements for registration, renewal of registration and revocation or suspension of registration under subsection (1) of this section. Those rules shall include a provision that the State Board of Pharmacy will suspend or revoke the registration of any humane society or animal control agency that allows a person who is not certified under subsection (4) of this section to administer sodium pentobarbital **and sedative and analgesic medications**.

(3) Any person who is registered under ORS 475.005 to 475.285 and 475.752 to 475.980 to deliver or dispense controlled substances may deliver or dispense sodium pentobarbital **and sedative and analgesic medications** to a humane society or animal control agency registered under subsections (1) and (2) of this section.

(4) The Oregon State Veterinary Medical Examining Board, after consultation with the State Board of Pharmacy, shall adopt rules establishing requirements for certification of persons to administer sodium pentobarbital **and sedative and analgesic medications**. Those rules may require that a person complete certain educational or training programs in order to be certified. ~~No person shall~~ **A person may not** administer sodium pentobarbital **and sedative and analgesic medications** unless the person is certified by the Oregon State Veterinary Medical Examining Board. [1983 c.342 §2; 1995 c.440 §28]

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SBAR: Affirming Board Mission, Vision, and Values

S	**Situation:** In preparation for initiating the Strategic Planning Process, the Board will be asked to affirm its Mission, Vision, and Values.
B	**Background:** **Mission** statements describe an organization's primary functions and responsibilities. The Board's Mission statement has been in place for many years and is based on Statute (689.025): *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.* **Vision** statements describe the desired outcomes of carrying out the mission. The Board currently has no vision statement. **Values** are descriptors of an organizations most deeply held values that should guide its activities. Board values, as identified in past strategic planning sessions include: *Accountability; Equity; Integrity; Excellence; Customer Service*.
A	**Assessment:** In preparation for strategic planning, the Board should affirm its Mission, Vision, and Values.
R	**Recommendation:** The Board's Executive Director will facilitate an open discussion by the Board for the purpose of affirming, creating, or revising its Mission, Vision, and Values. These statements will be adopted by vote of the Board and will serve to guide activities of the Board and Board staff in the years to come. **Please come to the August Board meeting with thoughts, ideas, and insights to assist the Board in establishing these guiding principles.** **Attached are some examples and background that may help us get started.**

Date: July 16, 2019

Author: Joe Schnabel

SBAR Attachment: Mission, Vision, Values

Mission Statement: A great mission statement helps your company define its direction and stay on track. A good mission statement helps everyone in the company make the right decisions. Your mission statement provides the guardrails you need to stay on track. When you set goals, you should be able to ask yourself, "Do these goals align with my mission?". If yes, you're probably headed in a good direction.

It is an action-oriented vision statement, declaring the purpose an organization serves to its audience. That often includes a general description of the organization, its function, and its objectives. Ultimately, a mission statement is intended to clarify the "what," the "who," and the "why" of a company. It's the roadmap for the company's vision statement.

Tips for writing a great mission statement (from honeybook.com)

- **Be specific**
  - Avoid general statements that are not unique to your organization.
- **Focus on the future**
  - Think about your mission as the high-level goal for the next several years.
- **Provide direction**
  - Make sure your mission statement is something everyone in your organization can understand and use to help prioritize their work.
- **Make it unique**
  - Describe what makes your organization different and why it matters.
- **Be concise**
  - Get to the heart of your business in a clear manner. The longer, the harder to remember.
- **Base it on your company values**
  - Talk about what values define your organization and how you're improving your customers lives.

Examples:

- 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.
- NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.
- The mission of Southwest Airlines is dedication to the highest quality of Customer Service delivered with a sense of warmth, friendliness, individual pride, and Company Spirit.

Vision Statement: A vision statement describes where the company wants a community, or the world, to be as a result of the company's services or work.

- Innovating and collaborating today for a safer public health tomorrow. – NABP
- A world without Alzheimer's disease. – Alzheimer's Association
- One day, all children in this nation will have the opportunity to attain an excellent education. – Teach for America
- Better health and wellbeing for all Australians, now and for future generations. – Australia Department of Health
- Healthy Californians through quality pharmacists' care. – California Board of Pharmacy

Values: Core values are meaningful statements that define what's important to your organization and govern how you conduct it.

Your point of uniqueness must be something your competitors won't also claim. Every organization wants to shout "But really, we are the best!", and it may well be true, but there's still no marketing juice there. Skip the Defaults and figure out what actually makes your organization unique.

There's always something deeper, something more interesting. That's where the magic is. Push through the obvious answers, and you'll find that little gem inside that will make all the difference for your organization.

Examples:

Accountability; Equity; Integrity; Excellence; Customer Service. – Oregon Board of Pharmacy

Integrity; Transparency; Responsiveness; Compassion. – California Board of Pharmacy

Openness, honesty, integrity, courage, respect, diversity, and balance. – Disney

Most common values words (*on BoP list):

- Integrity*
- Respect
- Innovation
- Teamwork
- Excellence*
- Customer focus
- Trust
- Diversity
- Accountability*
- Openness
- Quality
- Honesty
- Passion
- Safety
- Community
- Service
- Collaboration
- Responsibility
- People
- Commitment

Many more on the following pages (Some possibilities in **bold**):

Above and Beyond
Acceptance
Accessibility
Accomplishment
Accountability*
Accuracy
Accurate
Achievement
Activity
Adaptability
Adventure
Adventurous
Affection
Affective
Aggressive
Agility
Aggressiveness
Alert
Alertness
Altruism
Ambition
Amusement
Anti-Bureaucratic
Anticipate
Anticipation
Anti-Corporate
Appreciation
Approachability
Approachable
Assertive
Assertiveness
Attention to Detail
Attentive
Attentiveness
Availability
Available
Awareness
Balance
Beauty
Being the Best
Belonging
Best
Best People
Bold
Boldness
Bravery
Brilliance
Brilliant
Calm
Calmness
Candor
Capability
Capable
Careful
Carefulness
Caring
Certainty
Challenge
Change
Character
Charity
Cheerful
Citizenship
Clean
Cleanliness
Clear
Clear-Minded
Clever
Clients
Collaboration
Comfort
Commitment
Common Sense
Communication
Community
Compassion
Competence
Competency
Competition
Competitive
Completion
Composure
Comprehensive
Concentration
Concern for Others
Confidence
Confidential
Confidentiality
Conformity
Connection
Consciousness
Consistency
Content
Contentment
Continuity
Continuous Improvement
Contribution
Control
Conviction
Cooperation
Coordination
Cordiality
Correct
Courage
Courtesy
Craftiness
Craftsmanship
Creation
Creative
Creativity
Credibility
Cunning
Curiosity
Customer Focus
Customer Satisfaction
Customer Service*
Customers
Daring
Decency
Decisive
Decisiveness
Dedication
Delight
Democratic
Dependability
Depth
Determination
Determined
Development
Devotion
Devout
Different
Differentiation
Dignity
Diligence
Direct
Directness
Discipline
Discovery
Discretion
Diversity
Dominance
Down-to-Earth
Dreaming
Drive
Duty
Eagerness
Ease of Use
Economy
Education
Effective
Effectiveness
Efficiency
Efficient
Elegance
Empathy
Employees
Empower
Empowering
Encouragement
Endurance
Energy
Engagement
Enjoyment
Entertainment
Enthusiasm
Entrepreneurship
Environment
Equality
Equitable*
Ethical
Exceed
Expectations
Excellence*
Excitement
Exciting
Exhilarating
Exuberance
Experience
Expertise
Exploration
Explore
Expressive
Extrovert
Fairness
Faith
Faithfulness
Family
Family Atmosphere
Famous
Fashion
Fast
Fearless
Ferocious
Fidelity
Fierce
Firm
Fitness
Flair
Flexibility
Flexible
Fluency
Focus
Focus on Future
Foresight
Formal
Fortitude
Freedom
Fresh
Fresh Ideas
Friendly
Friendship
Frugality
Fun
Generosity
Genius
Giving
Global
Goodness
Goodwill
Gratitude
Great
Greatness
Growth
Guidance
Happiness
Hard Work
Harmony
Health
Heart
Helpful
Heroism
History
Holiness
Honesty
Honor
Hope
Hopeful
Hospitality
Humble
Humility
Humor
Hygiene
Imagination
Impact
Impartial
Impious
Improvement
Independence
Individuality
Industry
Informal
Innovation
Innovative
Inquisitive
Insight
Insightful
Inspiration

Integrity*
Intelligence
Intensity
International
Intuition
Intuitive
Invention
Investing
Investment
Inviting
Irreverence
Irreverent
Joy
Justice
Kindness
Knowledge
Leadership
Learning
Legal
Level-Headed
Liberty
Listening
Lively
Local
Logic
Longevity
Love
Loyalty
Mastery
Maturity
Maximizing
Maximum Utilization
Meaning
Meekness
Mellow
Members
Merit
Meritocracy
Meticulous
Mindful
Moderation
Modesty
Motivation
Mystery
Neatness
Nerve
No Bureaucracy
Obedience
Open
Open-Minded
Openness
Optimism
Order
Organization
Original
Originality
Outrageous
Partnership
Passion
Patience
Patient-Centered
Patient-Focused
Patients
Patient-Satisfaction
Patriotism
Peace
People
Perception
Perceptive
Perfection
Performance
Perseverance
Persistence
Personal Development
Personal Growth
Persistent
Persuasive
Philanthropy
Play
Playfulness
Pleasantness
Poise
Polish
Popularity
Positive
Potency
Potential
Power
Powerful
Practical
Pragmatic
Precise
Precision
Prepared
Preservation
Pride
Privacy
Proactive
Proactively
Productivity
Profane
Professionalism
Profitability
Profits
Progress
Prosperity
Prudence
Punctuality
Purity
Pursue
Pursuit
Quality
Quality of Work
Rational
Real
Realistic
Reason
Recognition
Recreation
Refined
Reflection
Relationships
Relaxation
Reliability
Reliable
Resilience
Resolute
Resolution
Resolve
Resourceful
Resourcefulness
Respect
Respect for Others
Respect for the Individual
Responsibility
Responsiveness
Rest
Restraint
Results
Results-Oriented
Reverence
Rigor
Risk
Risk Taking
Rule of Law
Sacrifice
Safety
Sanitary
Satisfaction
Security
Self Awareness
Self-Motivation
Self Responsibility
Self-Control
Self-Directed
Selfless
Self-Reliance
Sense of Humor
Sensitivity
Serenity
Serious
Service
Shared Prosperity
Sharing
Shrewd
Significance
Silence
Silliness
Simplicity
Sincerity
Skill
Skillfulness
Smart
Solitude
Speed
Spirit
Spirituality
Spontaneous
Stability
Standardization
Status
Stealth
Stewardship
Strength
Structure
Succeed
Success
Support
Surprise
Sustainability
Sympathy
Synergy
Systemization
Talent
Teamwork
Temperance
Thankful
Thorough
Thoughtful
Timeliness
Timely
Tolerance
Tough
Toughness
Traditional
Training
Tranquility
Transparency
Trust
Trustworthy
Truth
Understanding
Unflappable
Unique
Uniqueness
Unity
Universal
Useful
Utility
Valor
Value
Value Creation
Variety
Victorious
Victory
Vigor
Virtue
Vision
Vital
Vitality
Warmth
Watchful
Watchfulness
Wealth
Welcoming
Willfulness
Winning
Wisdom
Wonder
Worldwide
Work/Life Balance

SBAR: Refrigeration Waiver Request

S	**Situation:** • Diabetes Community Care Team (CP-0000015) is requesting a waiver of **OAR 855-044-00550(1)(j) Drug Distribution** which states: (1) A charitable pharmacy may not distribute a donated prescription drug that: (j) Requires refrigeration.
B	Pertinent background information related to the situation includes the following responses: **Q1:** Describe in detail the verifiable source of donated insulin, such as physician samples, as mentioned. This includes the name(s) and location(s) of any clinic(s) and their proximity to DCCT. **A1:** DCCT will only accept refrigerated items from within the health care community. (ie physicians' offices, long term care facilities, licensed wholesalers and distributors, drug manufacturers.) These sources will include but not be limited to: a. Dr. Mary Allison-Smith, Endocrinologist, University Health Center. 1590 E 13th Ave, Eugene, OR 97403 – 5 mile distance (15 min travel time) b. Valley West Nursing Home – 2300 Warren St, 0.5mile distance (5min travel time) c. Oregon Medical Group – 600 Country Club Rd, 6 miles distance (20min travel time) d. Other clinics and medical facilities in the Eugene Springfield area within a 20 mile radius and 30 minute travel time **Q2:** Describe in detail how insulin will be transported to maintain cold drug storage chain of custody. **A2:** Transportation between facilities of donated items. If items are being donated by a facility that does not have transportation procedures in place then the transportation of donated items will be done by a DCCT pharmacist. DCCT will arrange pick up services of donated items and ensure that transportation of all items will be done with appropriate storage (medical grade ice chest, and thermometer). Additional records will be added to the donation form to show the transportation time and temperature and will be saved for board review and inspection. Items will be promptly entered into DCCT refrigerator and recorded; Storage of these items will be verified. Pharmacist in charge will ensure that the donating facility is meeting the guidelines of storage for the products that are being donated. Verification of storage will include but not be limited to – review of refrigeration procedures and temperature logs. **Q3:** How will DCCT pharmacists be reasonably assured the insulin has been stored correctly? **A3:** Storage of these items will be verified. Pharmacist in charge will ensure that the donating facility is meeting the guidelines of storage for the products that are being donated. Patients will be informed that their medication has been donated by a medical facility and procedures have been implemented to ensure that the medication has been under appropriate storage conditions at all times.
A	**Assessment:** Agency background – similar policy item details: ✓ Outside/In – approved June 2013: Allowed the transfer of MAP insulin to the CP within Outside-In Pharmacy. The refrigerated medication was the possession of the pharmacy upon receipt from wholesaler or manufacturer. Waiver has expired. ✓ Volunteers In Medicine – approved Dec 2014: VIM permitted to accept and provide insulin and possibly other refrigerated drugs. Drug supplied by drug companies and arrive in cold storage. VIM promptly transfers these drugs to their medication refrigerator. ✓ SIRUM Request (August 2016): Request made for refrigeration waiver. Board requested specific policy for cold chain custody, to include transport and storage. Never received.
R	**Recommendation:** Information requested was received. Recommend Board discussion.

Waiver Request To: Oregon Board of Pharmacy
re: OAR 855-044-0050 (1)(j)
Requested by: Diabetes Community Care Team
July 12, 2019

The Diabetes Community Care Team (DCCT), a recently opened charitable pharmacy specializing in treating individuals with diabetes in Eugene and the surrounding areas, is requesting waiver of the Oregon Administrative Rules regarding the distribution of certain drugs by charitable pharmacies. Specifically, DCCT is requesting waiver of the requirements in OAR 855-044-0050 stating that:

(1)(j) Requires refrigeration.

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)(j)

• *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. 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.

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.

DCCT staff are trained in the laws and regulations regarding charitable pharmacies. DCCT staff will be informed regarding the ruling of the board on this request. Implementation of this request would not cause disruption or problems in the flow of pharmacy services.

- ***Procedures to ensure safety of refrigerated items (insulin):***

The DCCT understands the boards concerns regarding ensuring the quality and stability of refrigerated items being donated to a charitable pharmacy. To meet these concerns the DCCT will implement the following procedures:

1. DCCT will only accept refrigerated items from within the health care community. (ie physicians offices, long term care facilities, licensed wholesalers and distributors, drug manufacturers.) These sources will include but not be limited to:
    a. Dr. Mary Allison-Smith, Endocrinologist, University Health Center. 1590 E 13th Ave, Eugene, OR 97403 – 5 mile distance (15 min travel time)
    b. Valley West Nursing Home – 2300 Warren St, 0.5mile distance (5min travel time)
    c. Oregon Medical Group – 600 Country Club Rd, 6 miles distance (20min travel time)
    d. Other clinics and medical facilities in the Eugene Springfield area within a 20 mile radius and 30 minute travel time
2. Storage of these items will be verified. Pharmacist in charge will ensure that the donating facility is meeting the guidelines of storage for the products that are being donated. Verification of storage will include but not be limited to – review of refrigeration procedures and temperature logs.
3. Transportation between facilities of donated items. If items are being donated by a facility that does not have transportation procedures in place then the transportation of donated items will be done by a DCCT pharmacist. DCCT will arrange pick up services of donated items and ensure that transportation of all items will be done with appropriate storage (medical grade ice chest, and thermometer). Additional records will be added to the donation form to show the transportation time and temperature and will be saved for board review and inspection. Items will be promptly entered into DCCT refrigerator and recorded.
4. Patients will be informed that their medication has been donated by a medical facility and procedures have been implemented to ensure that the medication has been under appropriate storage conditions at all times.

Requester's Contact Info:

Julie Dewsnup, RPh, CDE, AAHIVP
DCCT Executive Director
2101 Bailey Hill Rd., Suite D
Eugene, OR 97405
855-211-3228
Juliedew@dcct.life
Cell: 541-257-8553
Fax: 541-600-8149

From: d-n wiley
To: MACLEAN Karen S * BOP
Subject: Rural Health Coordinating Counsel Letter of Interest
Date: Wednesday, July 10, 2019 7:01:41 PM
Attachments: Nancy Wiley resume.pdf

Dear Ms. Maclean,

I was excited to receive the Board of Pharmacy's request for volunteers for an appointment to the Rural Health Coordinating Counsel. I was born in the small town of Cottage Grove, and am fortunate to practice here as well. I presently live with my family in the unincorporated community of Dorena, where I was raised and my extended family all lives here as well. I feel very fortunate that I am able to serve my community in an area I love, working in the profession I love.

There are several pressing issues I see routinely in my practice setting that the Rural Health Coordinating Counsel could impact. Rural residents have been more affected by opioid abuse/misuse. Practitioner turnover is a huge challenge for rural residents as recruiting and retention of practitioners in rural areas is so difficult. Poor immunization rates in rural areas is another issue that pharmacists in particular can address. I have worked with Dorena School here in my community to do flu vaccine clinics and am working with our middle school to do a TDaP clinic at registration. Immunizations are definitely something I am excited about at my pharmacy, where we routinely exceed 1000 vaccines annually in a community of less than 10,000 people.

The healthcare challenges faced by rural populations are the challenges faced by my patients, friends, and family. Thank you for your consideration of my application for this exciting opportunity.

Sincerely,
Nancy Wiley

NANCY WILEY

75474 Wicks Rd PO Box 186| Dorena, Or 97434 | 541-942-7384|
wiley384@msn.com

PROFESSIONAL SUMMARY

Oregon licensed pharmacist with last 11 years as retail pharmacy manager supervising ten staff. Retail staff pharmacist experience for 5 years. Hospital pharmacist 5 years.

LICENSURES AND TRAINING

Oregon Pharmacist License

Preceptor License

APhA Immunization Certificate

Current American Red Cross BLS Certificate

Comprehensive Contraceptive Education Certificate

EXPERIENCE

Pharmacist in Charge, Walmart **2008 – Present**

Cottage Grove, Or

Pharmacy Manger of the year market 961 (18 stores) for 2019

Implemented a strong immunization program that ultimately has grown to vaccinate over 1000 patients annually (in a city of only 10,000 people)

Immunization champion for our pharmacy market

Consistently exceed performance goals on customer expectations, patient medication adherence, wait times

Only pharmacy manager in my market to receive an “exceeds expectations” on 2018 performance evaluation

All manner of personnel supervisory duties including: hiring, terminating, writing annual performance evaluations, scheduling, coaching, and training

Organizing off-site vaccination clinics

Organizing wellness day events to perform vaccinations and health screenings such as blood pressure, blood sugar, bmi and cholesterol checks

Staff Pharmacist, Walmart **2006 – 2008**

Cottage Grove, Or

Medication dispensing in busy retail setting with emphasis on building customer relationships and providing high quality service

Staff Pharmacist, Mckenzie-Willamette Medical Center 2001-2006

Springfield, Or

Worked with physicians to provide medication dosing services for: vancomycin, aminoglycosides, heparin, warfarin, digoxin, and numerous other drugs

Adjusted medication regimens based on renal function, age, coexisting disease states

Ensured proper antibiotic therapy based on microbiology culture reports

Drug information expert resource for physician and nursing staff

Discharge counseling for patients

Wrote drug work ups for the pharmacy and therapeutics committee

Staff Pharmacist and Intern, Bi-mart 1998-2001

Eugene/Springfield, Or

Medication dispensing in busy retail setting

Meeting the challenge of being highly adaptable and self-sufficient while working as a float pharmacist in multiple locations

Proficiency in operations of both the ScriptPro automated dispensing and PDX systems

EDUCATION

Oregon State University – Corvallis, Or – Bachelor of Science in Pharmacy
Phi Kappa Phi Honor for Junior Year (top 10% of class)

REFERENCES

Joseph Abraham PharmD

Market Manager, Present Supervisor, Walmart

479-295-8242 *joseph.g.abraham@walmart.com*

Monty Howard Rph
Pharmacist, Walmart
541-221-2730 mhboater@hotmail.com

John Loranger
Market Manger, Walmart
541-200-5359 lonerangerff@yahoo.com

Dwight Isborn Rph
Pharmacist, retired
541-521-6711 dbisborn@gmail.com

Updates to Division 045 – Drug Compounding are provided. This is a rules revision; this is not a re-write.

Current regulations (adopted in February 2008) are written in "the spirit" of USP Chapters 795 and 797. They were drafted prior to the publication of USP <800> (February 2016). On 2/26/2018, the Pew Charitable Trusts published their research on State Oversight of Drug Compounding. For safety assurances aligned with national standards, in 2013 the Board stated that the rules needed to be updated to full compliance with USP (Resources available: USP website). Efforts to strengthen compounding rules are needed due to the critical safety implications for patients.

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) Documentation.

Note: There is a distinction between compliance with safety standards and compliance with 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. 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 and documentation.

POLICY DISCUSSIONS:

1. Outline compliance general expectations / timeframe

2. Review Jan 2018 "Compounding Accreditor Examples" list. Determine date that all Oregon pharmacy drug outlets must have initial accreditation

3. Describe "phase-out" for human compounded drug shared services

4. Shared services – definition update

Division 45
~~STERILE AND NON-STERILE~~ **DRUG** COMPOUNDING

855-045-0200
Application

(1) These rules ~~(OAR 855-045-0200 to 855-045-0270)~~ apply to any person, including any business entity, located in **or outside** Oregon that engages in the practice of compounding **a** drugs~~,~~ **for use or distribution in Oregon.** ~~or any person, including any business entity, located in any other state that compounds drugs for the use of patients located in Oregon. Compounding~~

~~of radiopharmaceuticals is specifically exempted from these rules where these rules are in conflict with the rules or guidelines established by the Nuclear Regulatory Commission, the Radiation Protection Services of the Oregon Department of Human Services or any other applicable agency.~~ Any person located outside Oregon that compounds **a** drug~~s~~ for the use ~~of~~ **by a** patient~~s~~ located in Oregon is ~~expected~~ to follow the compounding rules of their home state or these rules, whichever are more stringent.

Or, delete 40-42 all together?

(2) These rules apply to sterile and non-sterile compounding of **a drug** ~~medications that are prepared for a specific patient and that are prescribed or ordered subject to a valid practitioner – patient relationship~~.

(3) **All drug compounding must adhere to standards of the current edition of the United States 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. This includes, but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 825, 1072, 1116, 1160, 1163, 1211 and 1229.5.** ~~Whilst the Board does not insist on rigid application 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 adhere to those guidelines that apply to their practice setting and in all situations to comply with the spirit of USP 795 and USP 797.~~

~~(4) Any compounding activity that is not pursuant to a valid prescription or an order to prepare 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 following exceptions:~~

~~(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 855-006-0005;~~

~~(b) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on a routine, regularly observed pattern;~~

~~(c) Notwithstanding any other provisions of this rule, the preparation of a patient specific product utilizing all non-sterile commercial components, as defined in these rules as Category 1 compounding, is not considered compounding under these rules provided that:~~

~~(A) Preparation of these products is an infrequent occurrence;~~

~~(B) Quantity of product prepared does not exceed the requirements of a single prescription except that small quantities can be prepared upon request for in-office use by licensed practitioners.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-045-0210

~~**Definitions**~~ **Registration**

(1) A pharmacy drug outlet that compounds a drug and dispenses a patient specific drug must register with the Board as a retail drug outlet or an institutional drug outlet or both if dispensing to both an ambulatory and residential patient. This applies to resident and non-resident pharmacies.

(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 accreditation by a Board approved entity, every 3 years at a minimum, in order to distribute or dispense compounded preparations into and within Oregon.

(3) A non-resident drug outlet that distributes a non-patient specific drug into Oregon must be registered with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.

(4) A resident drug outlet that distributes a non-patient specific human drug compound within or outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155

~~As used in this division of administrative rules:~~

~~(1) "Airborne Particulate Cleanliness Classification" means the level of cleanliness defined by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). The levels used in these rules are:~~

~~(a) ISO Class 5 is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air.~~

~~(b) ISO Class 7 is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air.~~

~~(c) ISO Class 8 is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air.~~

~~(2) "Beyond Use Date" (BUD) means the date after which the preparation may not be dispensed or administered to a patient. BUD has the same meaning as "Expiration Date".~~

~~(3) "Biological Safety Cabinet" (BSC) means a ventilated cabinet with an inward airflow for personnel protection, a downward, High Efficiency Particulate Arresting (HEPA) filtered, laminar airflow for product protection, and a HEPA filtered exhaust system for environmental protection.~~

~~(4) Categories of compounding: In these rules, compounding is defined as:~~

~~(a) Category 1: Nonsterile — Simple: Generally, the mixing of two or more commercial products. In these rules, this is not considered to be compounding.~~

~~(b) Category 2: Nonsterile — Complex: Generally, compounding with bulk drug substances or when calculations are required.~~

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

~~(d) Category 4: Sterile — Risk Level II: Medium-Risk, as defined in OAR 855-045-0250.~~

~~(e) Category 5: Sterile — Risk Level III: High-Risk, as defined in OAR 855-045-0250.~~

~~(5) "Compounding Aseptic Isolator" (CAI) means a glove box isolator with a microbially retentive HEPA air filter that maintains an aseptic compounding environment within the isolator throughout the compounding and material transfer process.~~

~~(6) "Compounded Sterile Preparation" (CSP) means:~~

~~(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 contamination, and includes all preparations compounded in IV rooms; or~~

~~(b) A preparation containing nonsterile ingredients, or employing nonsterile components and devices, that must be sterilized before administration; or~~

~~(c) Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the 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 sprays, and ophthalmic and otic preparations.~~

~~(7) "Compounding pharmacy" means any pharmacy where sterile or non-sterile compounding occurs on a regular basis.~~

~~(8) "Parenteral Admixture" means a sterile preparation that is the combination of one or more sterile products with an appropriate admixture vehicle.~~

~~(9) "Laminar Airflow Hood" (LAF) means a workspace where the work surface is subjected to a constant, HEPA filtered airflow that is directed towards the user.~~

~~**Statutory/Other Authority:** ORS 689.205~~
~~**Statutes/Other Implemented:** ORS 689.155~~

855-045-0220
Personnel **and Responsibilities**

All drug compounding must adhere to standards of the current edition of the United States 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. This includes, but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 1072, 1116, 1160, 1163, 1211 and 1229.5.

(1) **All** ~~P~~**p**ersonnel who prepare **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 aseptic manipulations.~~

(2)The ~~pharmacist in charge~~ **Pharmacist-in-Charge** (PIC) **and the drug outlet** shall establish**, maintain and enforce** ~~pharmacy P~~**p**olicies and ~~P~~**p**rocedures ~~that contain protocols~~ in accordance with the ~~guidelines~~ **standards** in USP **Chapters** ~~797,~~ for **all aspects and categories of the compounding operation of non-sterile and sterile preparations that include written procedures for:** ~~the initial training and testing of all personnel and for annual retesting in aseptic manipulative skills for those personnel involved in low and medium risk compounding.~~

(a) Personnel Qualifications, to include training, evaluation and requalification;

(b) Hand hygiene;

(c) Garbing;

(d) Engineering and environmental controls, addressing but not limited to equipment certification and calibration, air and surface sampling, and viable particles;

(e) Cleaning activities, addressing but not limited to sanitizing and disinfecting, to include compounding personnel and other staff responsible for cleaning;

(f) Components, addressing but not limited to selection, handling, and storage;

(g) Creating Master Formulation Records;

(h) Creating Compounding Records;

(i) Establishing BUDs;

(j) Continuous quality assurance program and quality controls, addressing but not limited to release testing, end-product evaluation, quantitative/qualitative testing;

(k) Completed compounded preparations, to include handling, packaging, storage and transport;

(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the Board within 10 working days in the event of a patient-level recall of a compounded drug.

~~(3) Personnel involved in high-risk compounding must be retested in aseptic manipulative skills at least semi-annually.~~

~~(4) The PIC shall ensure that training protocols are followed and records are kept for the training of all new personnel and for all continuing education and periodic testing that is completed.~~

~~(5) The PIC is responsible for the procedures and the overall operation of all activities within the pharmacy and must:~~

~~(a) Ensure all pharmacy personnel involved in preparing compounded products are trained and 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 compounded product. This verification shall be accomplished by a review of each compounded product that includes but is not limited to:~~

~~(A) Ensuring that the drug, dose and dosage form ordered are appropriate for the patient;~~

~~(B) Verifying that the correct drugs and components were selected;~~

~~(C) Confirming that the calculation and quantity of each drug and component is correct;~~

~~(D) Verifying the label is correct and where appropriate contains all the information specified in OAR 855-041-0065 and these rules.~~

~~(c) Document verification by the pharmacist responsible for the review.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~**855-045-0230**~~
~~**General Requirements**~~

~~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 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 of the pharmacist or a similar community.~~

~~(1) A pharmacist engaged in compounding shall:~~

~~(a) Conform to all relevant federal laws and rules;~~

~~(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 prescriber-patient relationship;~~

~~(c) Compound only products that are not commercially available except as allowed in OAR 855-045-0240(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 855-045-0200(4)(c);~~

~~(d) Maintain all records in accordance with OAR 855-045-0270;~~

~~(e) Perform final product verification.~~

~~(2) The pharmacist-in-charge of a compounding pharmacy including a pharmacy that only prepares sterile parenteral products shall ensure that policies and procedures for that pharmacy are reviewed not less than annually, are available for all staff to refer to, and are complied with by all staff. The policies and procedures for a compounding pharmacy shall include but are not limited to, the following:~~

~~(a) An organized index;~~

~~(b) Product formula information;~~

~~(c) Specifications for a compounding log book in compliance with OAR 855-045-0270;~~

~~(d) Conditions and surveillance of the compounding environment;~~

~~(e) Compounding procedures including requirements for use of gowns, shoe covers or dedicated shoes, hair covers, gloves and masks;~~

~~(f) Cleaning and equipment maintenance procedures;~~

~~(g) QA plan and documentation;~~

~~(h) Shipping and delivery procedures;~~

~~(I) Product labeling;~~

~~(j) Procedures for final product verification by the pharmacist;~~

~~(k) Compounded product quality procedures including procedures for establishing BUD;~~

~~(l) Training requirements for all staff;~~

~~(m) Safety procedures and training for personnel handling hazardous materials including:~~

~~(A) Use of personal protective equipment;~~

~~(B) Availability of Manufacturers' Safety Data Sheets;~~

~~(C) Emergency procedures related to spills, fire, or exposure to hazardous materials.~~

~~(n) Requirements for availability of reference materials.~~

~~(3) Pharmacies that compound sterile products including parenteral products shall, when appropriate, also include in their policies and procedures:~~

~~(a) Establishment of BUD;~~

~~(b) End Product Testing;~~

~~(c) Random sampling of both the environment and CSPs.~~

~~(4) The pharmacist-in-charge of a compounding pharmacy shall ensure that a quality assurance plan is written for that pharmacy and that:~~

~~(a) It includes record keeping requirements for cleaning, testing and calibration of all equipment and devices;~~

~~(b) Pharmacies that compound sterile products shall additionally include:~~

~~(A) Schedules and protocols for End Product Testing. Pharmacies mixing High Risk Level CSPs or extending Beyond Use Dating (BUD), must establish an End Product Testing schedule that includes random sampling. End Product Testing of a mixing process must show an acceptable sampling of the total preparations prepared annually;~~

~~(B) Protocols for establishing BUDs. BUDs may not exceed those in USP 797 guidelines unless 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 available for review for three years.~~

~~(5) Bulk chemicals require a certificate of analysis.~~

~~(6) The labeling of bulk chemical containers shall contain:~~

~~(a) The date obtained;~~

~~(b) The BUD, which shall be established as specified in the pharmacy policies and procedures but not more than five years after opening unless additional testing is conducted to extend that BUD by not more than one year.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-045-0240
~~**Sterile Parenteral Products**~~ **Labeling**

(1) In addition to **the labeling requirements specified in Division 041, the label of a compounded drug dispensed or distributed must contain the following, at a minimum:** ~~complying with all the other rules in this chapter of rules that are appropriate to their practice setting, pharmacists compounding sterile parenteral products must comply with the following specific rules.~~

(a) **The generic or official name of each active ingredient;** ~~Establish, maintain and enforce written policies and procedures associated with the pharmacy's preparation and dispensing of parenteral products. Policies and procedures shall be available for inspection at the pharmacy.~~

~~These policies and procedures shall include all requirements of OAR 855-045-0230 as appropriate to the practice setting and:~~

(b) The strength or concentration of each active ingredient, to include primary solution for a sterile parenteral preparation;

(c) The name of the base, diluent, or primary excipient;

(d) The dosage form and route of administration;

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

(f) The total quantity of the drug product;

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

(h) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety; and

(i) A statement that the product is a compounded preparation (An auxiliary label may be used on the container to meet this requirement).

~~(A) Requirements for compounding, labeling and storage of the products;~~

~~(B) Requirements for administration of parenteral therapy;~~

~~(C) Requirements for storage and maintenance of equipment and supplies.~~

~~(b) Labeling: In addition to regular labeling requirements, the label shall include:~~

~~(A) Rate of infusion, as appropriate;~~

~~(B) Beyond Use Date;~~

~~(C) Storage requirements or special conditions, if applicable;~~

~~(D) Name, quantity and concentration of all ingredients contained in the products, including primary solution;~~

(**j)** ~~E~~) ~~Initials~~ **Identity** of the pharmacist who verified the accuracy of the completed product.

~~(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.~~

~~(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:~~

~~(a) Prepare multiple source commercially available premixed parenteral admixtures;~~

~~(b) Prepare single source premix parenteral admixtures if the individual components of the premixed parenteral solution are commercially available;~~

~~(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;~~

~~(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.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~**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 contamination by microbial, chemical or physical agents. Low-Risk and Medium-Risk Level CSPs are determined by the potential for microbial contamination during preparation, and High-Risk Level CSPs by the potential for not being properly sterilized before administration to patients. These risk levels are defined, and products must be prepared and managed as follows:~~

~~(1) Low Risk Conditions:~~

~~(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;~~

~~(b) No more than three commercially manufactured sterile products and entries into one container of sterile product during preparation;~~

~~(c) Manipulations limited to:~~

~~(A) Aseptically opening ampoules;~~

~~(B) Penetrating sterile stoppers on vials with sterile needles and syringes;~~

~~(C) Transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and sterile containers for storage and dispensing.~~

~~(d) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:~~

~~(A) BUD less than or equal to 48 hours at controlled room temperature;~~

~~(B) BUD up to14 days: under refrigeration;~~

~~(C) BUD up to 45 days: in solid frozen state at -20 °C.~~

~~(2) Medium Risk Conditions:~~

~~(a) CSPs compounded aseptically under Low-Risk Conditions but with the addition of one or more of the following conditions:~~

~~(A) Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions;~~

~~(B) The compounding process includes complex aseptic manipulations other than single-volume transfer;~~

~~(C) The compounding process requires unusually long duration, such as that required to complete dissolution or homogenous mixing.~~

~~(b) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:~~

~~(A) BUD less than or equal to 30 hours: at controlled room temperature;~~

~~(B) BUD up to 9 days: under refrigeration;~~

~~(C) BUD up to 45 days: in solid frozen state at -20 °C.~~

~~(3) High Risk Conditions:~~

~~(a) CSPs compounded from non-sterile ingredients, including products manufactured for other routes of administration, or a non-sterile device is employed before terminal sterilization;~~

~~(b) Exposure to an air quality environment that does not meet ISO 5 or better conditions for more than one hour for any of the following:~~

~~(A) Sterile contents of commercially manufactured products;~~

~~(B) CSPs that lack effective antimicrobial preservatives;~~

~~(C) Sterile surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs.~~

~~(c) Prior to terminal sterilization:~~

~~(A) Nonsterile procedures including weighing and mixing occur in an air quality environment that does not meet ISO 7 or better conditions;~~

~~(B) Compounding personnel are improperly gloved or garbed;~~

~~(C) Water-containing preparations are stored for more than 6 hours.~~

~~(d) In the absence of sterility testing:~~

~~(A) A preparation must be properly stored prior to administration as follows:~~

~~(i) For a BUD not to exceed 24 hours, at controlled room temperature;~~

~~(ii) For a BUD up to three days, under refrigeration;~~

~~(iii) For a BUD up to 45 days, in solid frozen state at -20 °C.~~

~~(B) All nonsterile devices must be rinsed thoroughly with sterile, pyrogen-free water then thoroughly drained or dried immediately before use;~~

~~(C) Terminal sterilization is required as follows:~~

~~(i) CSP solutions passed through a filter with a nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter;~~

~~(ii) Sterilization of high-risk level CSPs by filtration must be performed with a sterile 0.22 micron porosity filter entirely within an air quality environment better than or equal to ISO 5.~~

~~(4) Immediate-use:~~

~~(a) A compounded preparation intended for immediate use may be prepared in an air quality environment that does not meet ISO 5 or better conditions and a preparer is not required to wear gloves or gown, provided that it is prepared using aseptic manipulation, only sterile ingredients, products, components and devices are used, and it meets all of the following conditions:~~

~~(A) No more than three sterile ingredients, products, components and devices are used;~~

~~(B) Only simple manipulation techniques employed;~~

~~(C) The preparer completes the preparation without interruption and with no direct contact contamination;~~

~~(D) Administration must begin within one hour of preparation;~~

~~(E) If prepared by someone other than the person who will administer the drug, labeling must include patient name, name and quantity of ingredients, name of person who prepared it, and exact one hour BUD.~~

~~(b) Provided that such preparations do not involve the use of hazardous materials, they are classified as "Low Risk".~~

~~(5) "Same-day-use": In this rule, the term "Same-day-use" means that the administration of the preparation shall commence within 24 hours from the time of preparation. A same-day-use product that is prepared using aseptic manipulation in a controlled environment with ISO 5 or better class air quality conditions, using only sterile, ingredients, products, components and devices, may be classified as Low or Medium risk provided that it meets all the following conditions:~~

~~(A) Only simple manipulation techniques employed;~~

~~(B) The environment meets or exceeds the following conditions:~~

~~(i) The mixing cabinet is located in an area that restricts airflow to prevent drafts and reduce particle counts;~~

~~(ii) There is a partitioned area around the mixing cabinet to create a buffer zone, which must be at least the width of the hood in front of the mixing cabinet;~~

~~(iii) The buffer zone must be clearly identified to prevent cardboard or outer packing material intruding into the buffer zone and to prevent any intrusion during the compounding process;~~

~~(iv) The environment is cleaned daily.~~

~~(C) The preparer completes the preparation without interruption and with no direct contact contamination;~~

~~(D) Batch preparation will not exceed eight CSPs;~~

~~(E) Administration of the preparation must begin within twenty-four hours of preparation;~~

~~(F) The preparer must use gloves, shoe covers or dedicated shoes, hair covers, gown and mask.~~

~~(6) Single-dose vial.~~

~~(a) The BUD shall be no greater than one hour from time of initial entry if accessed in an environment worse than ISO 5;~~

~~(b) The BUD may be up to 24 hours from time of initial entry if appropriately stored and accessed only in an environment better than or equal to ISO 5;~~

~~(c) Medications in a single dose ampoule may not be reused.~~

~~(7) Multi-dose vial. The BUD may be up to one month or the manufacturer's assigned BUD whichever is shorter, from time of initial entry, in accordance with the pharmacy policies and procedures.~~

~~**Statutory/Other Authority:** ORS 689.205~~
~~**Statutes/Other Implemented:** ORS 689.155~~
~~**History:**~~
~~BP 2-2008, f. & cert. ef. 2-20-08~~

~~**855-045-0260**~~
~~**Pharmacies and Equipment**~~

~~Minimum standards for pharmacies and equipment are dependent on the risk level of the products being prepared.~~

~~(1) Pharmacies and equipment for the preparation of immediate-use CSPs shall be in accordance with OAR 855-045-0250(4).~~

~~(2) Effective January 1, 2009, for preparation of low-risk level CSPs, an ISO 5 certified or better Biological Safety Cabinet (BSC), or a Compounding Aseptic Isolator (CAI), or a Laminar Airflow Hood (LAF) shall be used.~~

~~(3) Effective January 1, 2009, for preparation of medium-risk level CSPs, an ISO 5 certified or better BSC, CAI or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or~~

~~better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. These areas must have positive airflow unless used to prepare hazardous 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.~~

~~(4) Effective January 1, 2009, for preparation of high-risk level CSPs, an ISO 5 certified or better BSC, CAI, or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. Unless used to prepare hazardous drugs, the buffer room or zone shall have a 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 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.~~

~~(5) Hazardous drugs must be prepared in compliance with state and federal regulations.~~

~~(6) Radiopharmaceuticals must be prepared in accordance with OAR 855-042-0005 through 0025.~~

~~(7) Pharmacy policies and procedures must include protocols for cleaning and monitoring that include:~~

~~(a) A cleaning policy that requires the cleaning of all work surfaces in ISO 7 and 8 areas to be performed at least daily. Floors in ISO 7 and 8 areas cleaned at least daily. Surfaces that are used to prepare CSPs must be cleaned either with a high-level disinfectant or with a medium-level 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 appropriate disinfectant solution;~~

~~(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 buffer room or anteroom has been altered;~~

~~(c) Maintenance, and documentation of maintenance, of all equipment in accordance with manufacturer's specifications.~~

~~(8) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.~~

~~Statutory/Other Authority:~~ ~~ORS 689.205~~
~~Statutes/Other Implemented:~~ ~~ORS 689.155~~

855-045-0270
Records

(1) ~~Except for products prepared subject to OAR 855-045-0200(4)(c),~~ ~~a~~**A**ll ~~appropriate~~ compounding **records, including training documents, master formulation records, compounded preparation records, individual prescription records, and records of** ~~logs, formula worksheets and documentation of the preparation, verification,~~ dispensing or transfer of all compounded ~~products~~ **preparations** must be **maintained in written or electronic format,** stored in 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 stored in a secure off-site location if retrievable within three business days. Required records include, but are not limited to:**

(a) Standard operating procedures, including documented annual review;

(b) Personnel training, competency assessment, and qualification records, including corrective actions for any failures, including gloved fingertip and thumb sampling test and aseptic manipulation validation. The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations. At a minimum, the record must contain:

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

(B) Documentation of initial and continuing competency evaluation, to include dates and results of required elements outlined in the outlet's policies and procedures; and

(C) Name and signature of the pharmacist who is designated as responsible for validation of the completion of all training.

BACKGROUND:

Item (C) was rewritten to allow for flexibility. Training may be performed by a pharmacy staff member, under the direction of the oversight pharmacist. The PIC is additionally responsible for overall activities.

(c) Engineering and environmental control records, including equipment, calibration, certification, environmental air and surface monitoring procedures and results, as well as documentation of any corrective actions taken;

(d) Cleaning and disinfecting of all compounding areas and equipment;

~~(e) Engineering and environmental control records,~~

(2) **Records for compounding must utilize a master formulation record. All master formulation records must be approved by the pharmacist for compounded preparations, and records for all preparations** ~~The formula worksheets for compounding pharmacies~~, excluding those for patient specific IV admixture products, must **contain, at a minimum** ~~include but are not limited to the following~~:

(a) The name, strength and dosage form of the preparation;

(b) Physical description of the final preparation;

(c) Ingredient identities and amounts;

(d) Complete instructions for preparing the product, including equipment, supplies, and a description of the compounding steps;

(e) Calculations needed to determine and verify quantities of components and doses of ingredients;

(f) Compatibility and stability information, including references;

(g) Beyond-use-date (BUD) assignment and storage requirements, including reference source;

(h) Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration;

(i) Quality control procedures and expected results; and

(j) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.

(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:

(a) Drug name**,** ~~and~~ strength**, and dosage form of the preparation;**

(b) Physical description of the final preparation;

(c) Master formulation record reference for the preparation;

~~(b)~~ **(d)** Quantity prepared;

~~(c)~~ **(e)** Date **and time** prepared;

~~(d)~~ **(f)** Pharmacy unique lot number;

~~(e)~~ **(g) Name, quantity, and** ~~M~~**m**anufacturers' lot number~~s~~ and expiration date~~s of~~ **for** all ingredients used to prepare **and package** compounded product;

POLICY DISCUSSION:

Does the Board want to build awareness around drug packaging, as it relates to compounded drug products?

~~(f)~~ **(h)** Beyond Use Date;

~~(g)~~ **(i)** Identity of verifying pharmacist;

~~(h)~~ **(j)** ~~Names~~ **Identity** of all ~~technicians~~ **personnel** involved in **each step of** the process;

~~(I) Copy of the label used for the compounded product;~~

~~(j) Mixing instructions;~~

~~(k) Physical evidence of the proper weight of each dry chemical or drug used;~~

(j) Documentation of the proper weight and measurement of each ingredient;

~~(l)~~ **(k)** Pharmacist **documented** verification that the correct formula**, calculations,** and the correct **measurements** ~~weights or volumes~~ of ~~chemical or~~ drugs were used;

~~(m) Certification of completion of any additional testing, including endotoxin, required by the pharmacy's policies and procedures~~

(l) Total quantity compounded;

(m) BUD assignment and storage requirements, including reference source, if differs from master formulation record;

(n) Description of final preparation and Product Identification Label (PIL);

(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 corrective actions for any failure.

~~(n)~~ **(p)** Any other information required by the pharmacy's policies and procedures.

~~(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.~~

POLICY DISCUSSION:

~~(3)~~ **(4) Non-patient specific drug compounding is permitted for:** ~~Record of maintenance and certifications for all equipment must be retained for a minimum of three years and be available for inspection by the Board.~~ **~~Compounding activity that is not pursuant to a valid prescription or an order to prepare for administration and for a specific patient is considered to be manufacturing, and any person engaged in manufacturing must be registered in accordance with Division 060, with the following exceptions:~~**

(a) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on routine, regularly observed patterns is permitted. Pharmacy shall retain documentation; or

Is more clarification needed here?

Pursuit of patient safety – we are seeing more pharmacies centralize compounding processes and "batching"

Not enough 503Bs to meet all need yet, however "1 mile radius" FDA guidance is still in draft

(b) Preparing veterinary non-patient specific drug compounding by a pharmacy located in Oregon for a veterinary practitioner located in Oregon only is permitted. Pharmacy shall retain documentation. ~~compounded products by an Oregon pharmacy for a practitioner located in Oregon, documented by use of Board approved Shared Pharmacy Services agreement.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

Update to Division 006 – Definitions. Edits to clarify the acceptable use of a Shared Services agreement in Oregon.

Note: Other items left over in this definition are no longer performed under a Shared Pharmacy Services agreement. In 2013, the Board adopted rules in Division 041 related to Central Fill and Remote Processing designations which could be added to a pharmacy drug outlet registration (RP or IP) with approved policies and procedures. This replaces the use of Shared Pharmacy Services for dispensing, drug utilization review, claims adjudication, refill authorizations. Today a collaborative drug therapy agreement (CDTA) may be used to facilitate therapeutic interventions.

855-006-0005
Definitions

As used in OAR chapter 855:

(28) "Shared Pharmacy Service" means a written agreement, that has been **processed** ~~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:~~

~~(a) Dispensing;~~

~~(b) Drug utilization review;~~

~~(c) Claims adjudication;~~

~~(d) Refill authorizations;~~

veterinary non-patient specific drug ~~C~~**c**ompounding by a pharmacy located in Oregon for a **veterinary** practitioner ~~or dispenser located in Oregon for Oregon outlets and practitioners~~ located in Oregon only**.**~~; and~~

~~(f) Therapeutic interventions.~~

Idaho State Board of Pharmacy
1199 W Shoreline Lane Ste 303 Boise, Idaho 83702-9103 http://bop.idaho.gov
P.O. Box 83720 Boise, Idaho 83720-0067 208.334.2356 208.334.3536 fax

July 12, 2019

To: Idaho State Board of Pharmacy

From: Nicki Chopski

Re: 2019 NABP District 6/7/8 Meeting

The Idaho Board of Pharmacy will host the 2019 District Meeting in Boise on October 6-8, 2019.

Day	Time	Event
Sunday	3-5pm	Registration
	5-8pm	Dinner and Cultural Event (The Reef –Food and Live Music)
Monday	8-9am	Registration
	9-9:05	Color Guard
	9:05-9:15	Welcoming Remarks: Holly Henggeler, Idaho Board Chair
	9:15-9:30	Welcome from Idaho Governor Brad Little
	9:30-9:45	AACP Report: AACP President
	9:45-10:00	NABP Report: Jay Campbell, NABP President
	10:00-11:00	Opening Keynote: Permissionless Innovation Speaker: Adam Thierer Thierer is the author of Permissionless Innovation. Receive your complimentary copy of his work. He will speak about the book, and the clash of regulatory visions.
	11:00pm-11:30pm	Networking Break: Network with attendees and discuss the opening keynote. During the break, registrants can get their books signed by Thierer, or visit a side room with immunizing technicians, prescribing pharmacists, and research posters.
	11:30-12:30pm	Presentation #2: Achieving a "Full" Pharmacist Scope of Practice Speaker: Ross Tsuyuki Tsuyuki is a lecturer at the Alberta College of Medicine. He has published frequently on pharmacist prescribing, and has recently advanced the concept of a "full" scope of practice as opposed to an "advanced scope of practice."
	12:30-1:30	Lunch
	1:30-2:30	NABP/AACP Initial District Breakouts (Business Meetings) This will allow time to transact required business, and consider resolutions. The breakout will also include the NABP/AACP update.
	2:30-2:45	Networking Break
	2:45-3:30	Presentation #3: Lessons from Nursing: Closing the Gap in Can vs. May Presenter: Alex J. Adams, PharmD, MPH Evaluates nursing scope of practice issues and reviews the seminal study on the gap between *can vs. may* in scope of practice.
	3:30-4:15pm	The Great Debate: Is a "Standard of Care" Model the Right Approach to Achieve "Full" Scope and Close the Gap Between Can and May?

	4:15-5:30pm	Break
	5:30-7:30pm	Dinner and Cultural Event (Albertsons Stadium)
Tuesday	9-10:00am	Keynote: Perspective from Nursing: the Nurse Licensure Concept Jim Puente, Director, Nurse Licensure Compact Puente will present on the NLC, how states retain enforcement ability, and the financial impact on states.
	10:00- 10:30am	Networking Break: We will provide time for attendees to network and discuss the opening keynote. During the break, registrants can visit a side room with immunizing technicians, prescribing pharmacists, and research posters.
	10:30- 11:30am	AACP Session- Pharmacists as Independent Prescribers: Initial Considerations from Idaho State University Speaker: Jennifer Adams, PharmD- Associate Dean
	11:30am- 1:00pm	Lunch
	1:00-2:30pm	NABP/AACP Final District Breakouts Finalize any remaining district business and resolutions
	2:30-2:45	Break
	2:45pm- 4:00pm	Moderated Discussion / Hot Topics Session focuses primarily on the 2 major conference themes: scope and enhancing license mobility and additional topics from attendees.
	4:00-close	Closing session: Each district presents its resolutions for consideration by the other districts; any other NABP/AACP announcements
	5:30-	Dinner and Cultural Event (Basque Block)

***Schedule subject to change if necessary**

BOARD OF PHARMACY Actuals through May 2019
AY19 CASH FLOW
OF Appn 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	
REVENUE									
0205	Other Business Licenses	4,431,667	4,431,667		4,431,667	5,091,689	(660,022)	115%	
0210	Other NonBusiness Licenses and Fe	505,552	505,552		505,552	240,179	265,373	48%	
0505	Fines and Forfeits	420,000	420,000		420,000	326,932	93,068	78%	
0605	Interest and Investments	48,000	48,000		48,000	171,938	(123,938)	358%	
0975	Other Revenue	39,700	39,700		39,700	92,168	(52,468)	232%	
	SubTotal Revenue	5,444,919	5,444,919	0	5,444,919	5,922,905	(477,986)	109%	
TRANSFERS									
2443	Transfer out to OHA--Workforce/PD	(409,357)	(409,357)		(409,357)	56,241	(465,598)	-14%	
	SubTotal Transfers	(409,357)	**(409,357)**	**0**	**(409,357)**	**56,241**	**(465,598)**	-14%	
TOTAL REVENUE & TRANSFERS		**5,035,562**	**5,035,562**	**0**	**5,035,562**	**5,866,664**	**(12,388)**	**117%**	
PERSONAL SERVICES									
3110	Regular Employees	3,191,268	3,191,268	104,724	3,295,992	3,050,701	245,290.52	93%	
	Board Member Stipends		-		0	-			
3160	Temporary Appointments	25,222	25,222		25,222	689	24,533	3%	
3170	Overtime Payments		-		0	1,730	(1,730)	0%	
3190	All Other Differential O/Class Lead V	183,457	183,457		183,457	187,812	(4,355)	102%	
3210	Employment Relations Board Assess	1,083	1,083		1,083	974	109	90%	
3220	Public Employees Retirement Contri	504,012	504,012	3,269	507,281	431,651	75,630	85%	
3221	Pension Bond Contribution	195,224	195,224	(3,502)	191,722	188,747	2,975	98%	
3230	Social Security Taxes	256,020	256,020		256,020	234,034	21,986	91%	
3240	Unemployment Assessment		-		0	1,869	(1,869)	0%	
3250	Workers' Compensation Assessmen	1,380	1,380		1,380	916	464	66%	
3260	Mass Transit Tax	20,334	20,334		20,334	19,264	1,070	95%	
3270	Flexible Benefits	666,720	666,720	24,720	691,440	603,281	88,159	87%	
3455	Vacancy Savings-ORBITS only	(169,448)	(169,448)	-	(169,448)	-	(169,448)	0%	
3465	Reconciliation Adjustment-ORBITS only				0	-	-	0%	
3470	Undistributed Personal Services-ORBITS				0	-	-	0%	
3991	PERS Policy Adjustment-ORBITS				0	-	-	0%	
	SubTotal Personal Services	**4,875,272**	4,875,272	129,211	5,004,483	4,721,668	282,815	94%	$ 282,815
SERVICES AND SUPPLIES			Proj all						
4100	InState Travel	**102,270**	102,270		102,270	89,848	12,422	88%	
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	20,382	31,953	39%	
4175	Office Expenses	**123,883**	123,883		123,883	83,708	40,175	68%	
4200	Telecommunications	**43,879**	43,879		43,879	56,900	(13,021)	130%	
4225	State Govt. Service Chgs.	**119,969**	119,969		119,969	120,024	(55)	100%	
4250	Data Processing	**73,694**	73,694		73,694	63,500	10,194	86%	
4275	Publicity & Publications	**37,712**	37,712		37,712	8,957	28,755	24%	
4300	Professional Services	**402,408**	402,408		402,408	251,549	150,860	63%	
4315	IT Professional Services	**353,340**	353,340		353,340	33,914	319,426	10%	
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	6,598	(2,015)	144%	
4425	Facilities Rent & Taxes	**219,519**	219,519		219,519	182,058	37,461	83%	
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	182,915	46,519	80%	
4650	Other Services & Supplies	**278,652**	278,652		278,652	277,912	740	100%	
4700	Expendable Property	**10,499**	10,499		10,499	6,370	4,129	61%	
4715	IT Expendable Property	**43,976**	43,976		43,976	14,524	29,452	33%	
5550	Data Processing Software		-		0	-	-	0%	
5600	Data Processing Hardware	**8,296**	8,296		8,296	-	8,296	0%	
			-		0	-			
	SubTotal Services and Supplies	**2,448,136**	2,448,136	86,083	2,534,219	1,825,175	709,044	72%	$ 709,044
SPECIAL 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 Expenditures Budget		**7,335,399**	**7,335,399**	**215,294**	**7,550,693**	**6,546,843**	**1,003,850**	**87%**	**$ 1,003,850**
					7,057,070				
	LAB % PS	66%			66%		Target	100%	
	LAB % S&S	33%			34%				
	LAB % SP	0%			0%				

			Cash
AY17 Ending Cash Balance			4,794,930
Revenue less Expenditures		Actuals	
Total Revenue & Transfers		5,866,664	
Total Expenditures		(6,546,843)	
Total Revenues & Transfers less Expenditures		**(680,179)**	(680,179)
AY19 Cash Balance after the Fiscal Month Closed			**4,114,750**
Budgeted Revenues not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mad			0
Budgeted Expenditures not yet spent			(1,003,850)
AY19 Estimated Cash Balance			**3,110,901**
Cash Balance Contingency (Months)			9.89 months

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