The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

Wednesday, February 5, 2020

I. OPEN SESSION, Cyndi Vipperman, CPhT, Presiding
   a. Roll Call
   b. Agenda Review and Approval  

II. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.165, 676.175, ORS 192.660 (1) (2) (f) (L).
   a. Deliberation on Disciplinary Cases and Investigations
   b. Legal Advice pursuant to ORS 192.660(2)(f)

III. Contested Case Deliberation pursuant to ORS 192.690(1) – Not open to the public

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 4:00PM.
   a. Executive Director Position Description discussion - Vipperman

Adjourn

Thursday, February 6, 2020

V. OPEN SESSION, Cyndi Vipperman, CPhT, Presiding
   a. Roll Call
   b. Motions related to Disciplinary Actions – Efremoff  
   c. Recognition of outgoing Board Member Dianne Armstrong – Vipperman

NOTE: The Board may rearrange its agenda to accommodate the Board or Members of the public.
VI. GENERAL ADMINISTRATION
   a. Rules
      i. Review Rulemaking Hearing Report & Comments - none
      ii. Consider Adoption of Rules – none
      iii. 2019 Report to the Legislature #A - Melvin
      iv. Consider Adoption of Temporary Rules – none
      v. Consider sending rules to Rulemaking Hearing – none
   vi. Policy Discussions - Karbowicz
      1. Div 019, 021 and 025 – Continuing Education
      2. Div 020 – Statewide Drug Therapy Protocols (3) #A2 – A2a
      3. Div 041 – Prescription Reader Accessibility #A3
      4. Div 041 – Prescription Labeling
      5. Div 080 – Schedule I additions #A4

   b. Public Health and Pharmacy Formulary Advisory Committee - Karbowicz
      i. Committee Meeting and Recommendations update – none

   c. Discussion Items:
      i. Waivers and Requests:
         1. Chattem Inc. request #B1 - Hennigan
      ii. Other
         1. OVMEB appearance approx. 1:00PM #B4 - Lori Makinen, Executive Director
         2. Strategic Planning
            a. 2020-2024 Plan Review & Tactics – Schnabel Action Necessary
         3. FDA 50 state update – Efremoff/Fox

VII. ISSUES AND ACTIVITIES* (Items in this section may occur anytime during the meeting as time allows)
   i. Reports:
      1. Board President/Members
      2. Executive Director
      3. Board Counsel
      4. Compliance Director
      5. Pharmacist Consultant
      6. Administrative Director
      7. Licensing Manager

   ii. Financial/Budget Report - #C MacLean

   iii. Legislative Update – Schnabel

   iv. Board Meeting Dates
      • 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)
v. 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.)

- May 27, 2020
- November 24, 2020
- May 26, 2021
- November 23, 2021

vi. Conferences/Meetings - Schnabel

PAST MEETINGS
1. NABP Board Member Forum – Jan 28-29, 2020

FUTURE MEETINGS
1. OSPA Lane Co. Mid-Winter CE Seminar – 2/15-16/2020 – Eugene
2. Tri-County Pharmacy Education Event – 3/18/2020 - Tigard
4. NABP Annual Meeting – 5/14-16/2020, Baltimore, MD

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

a. NAPLEX Scores – none
b. MPJE Scores – none
c. License/Registration Ratification December 5, 2019 – January 22, 2020 - #CONSENT-1
d. Pharmacy Technician Extensions – none
e. Board Minutes – November 6-7, 2019 and December 11-12, 2019 - #CONSENT-2 and -3

IX. OPEN FORUM - At the completion of regular Board business, the Board provides an opportunity to make comments or present issues of general interest. The Board will not deliberate any issues or requests during Open Forum. Therefore, Open Forum 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
January 28, 2020

Oregon Legislative Assembly
VIA E-MAIL

Re: ORS 183.403 Report from the Oregon Board of Pharmacy

Dear Legislators:

The Oregon Board of Pharmacy is pleased to submit this executive summary and report as required pursuant to Chapter ORS 183. In calendar year 2019, the Oregon Board of Pharmacy adopted, amended, and repealed rules as described below.

The Oregon Board of Pharmacy has taken the following rulemaking actions:

Rules Adopted, Amended, or Repealed (ORS 183.335(2) and (3))
- Adopted 2
- Amended 18
- Repealed 8

Temporary Rules Adopted, Amended, or Suspended (ORS 183.335(5))
- Adopted 1
- Amended 0
- Suspended 0

BP 8-2019 Filed: 12/17/2019 2:23 PM
855-041-1131 Adopt

Statement of Need:
2019 HB 2935 directed the Board to adopt rules related to accessibility services for visually impaired patients.

Justification:
2019 HB 2935 became operative on January 1, 2020. Adopting this rule informs pharmacies of new requirements.

Sincerely,

Rachel Melvin
Rules Coordinator
Oregon Board of Pharmacy

The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.
Revisions to ORS 689.645 and 689.649 state 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. A statewide protocol consists of a standardized patient assessment process and treatment care plan under which a pharmacist may assess and identify a patient’s medical need, then prescribe and dispense a drug or device to the patient.

Oregon Administrative Rule 855-020-0300 Protocol Compendium is revised to incorporate recent PHPFAC recommendations. Policy directives if adopted:
- To add Tobacco Cessation protocol (10/25/2019 PHPFAC recommendation)
- To add Travel Medications protocol (10/25/2019 PHPFAC recommendation)
- To add Post-Exposure Prophylaxis (PEP) protocol (10/25/2019 PHPFAC recommendation)

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.
(3) Preventative care

(a) Emergency Contraception, not including abortifacients.

(b) Male and female condoms.

(c) Tobacco Cessation, NRT and Non-NRT Protocol (v. June 2020). A pharmacist may provide patient care services pursuant to this protocol upon documented completion of a minimum of 2 hours of tobacco cessation continuing education.

(d) Travel Medications Protocol (v. June 2020). A pharmacist may provide patient care services pursuant to this protocol upon documented completion of: APhA Immunization Training Program certificate (or equivalent), minimum of 4 hour certificate related to pharmacy-based travel medicine services intended for the pharmacist, and minimum of 1 hour of travel medication continuing education every 2 years.

(e) Post-exposure prophylaxis (PEP) Protocol (v. June 2020). A pharmacist may provide patient care services pursuant to this protocol upon documented completion of a training program related to the prescribing and dispensing of HIV prevention medications, to include trauma-informed care.

[Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645 & ORS 689.649
MEMO

January 6, 2020

To: Oregon Board of Pharmacy

From: Public Health Division, Health Promotion & Chronic Disease Prevention

We are pleased to provide the Oregon Board of Pharmacy this set of resources to support pharmacists and pharmacies around the State to aid cessation efforts for both youth and adults in our Oregon communities. We know that cessation attempts increase at the beginning of the new year and would like to support the Oregon Board of Pharmacy to disseminate information and resources to pharmacists and pharmacies now.

In addition to a list of resources by Oregon county, Health Promotion & Chronic Disease Prevention has created toolkits for different groups to support cessation efforts. There is a toolkit specific to pharmacies on the OHA website along with many other cessation resources – scroll down to Digital media toolkit; click on Toolkit for Pharmacies. In this toolkit you can find: guidance for pharmacists supporting individuals wanting to stop smoking as well as print materials that could be displayed in pharmacies.

In addition, we would like to highlight a few specific actions pharmacies and pharmacists can take to help anyone who needs support with quitting e-cigarettes or tobacco - More help helps!

- ADVISE on options for FDA-approved nicotine replacement therapy (such as gum and patches). Nicotine Replacement Therapy could be available at no cost, depending on the insurance plan.

- REFER to Oregon Tobacco Quit Line or the new Native Quit line:
  - English: 1-800-QUIT-NOW (1-800-784-8669) or quitnow.net/oregon
  - Spanish: 1-855-DÉJELO-YA (1-855-335-35692) or quitnow.net/oregonsp
  - Native Quit Line for Alaska Indians and Native Americans: 1-800-QUIT-NOW (1-800-784-8669), then press “7”
  - TTY: 1-877-777-6534

**The Quit Line staff are ready and able to support those that need to quit tobacco and e-cigarettes and can provide telephonic counseling and nicotine replacement therapy to support quitting.

- REFER youth and young adults to the Oregon Tobacco Quit Line or a text-based e-cigarette quit program from the Truth Initiative –
  - Text “DITCHJUUL” to 88709

Health Promotion and Chronic Disease Prevention is available to provide an overview of these resources to the Oregon Board of Pharmacy and explore how best to disseminate to and support pharmacies and pharmacists in Oregon.

Thank you for your collaboration!
For more information contact: Hilde Hinkel janet.h.hinkel@dhssoha.state.or.us
On December 12, 2019, the Board adopted temporary rule OAR 855-041-1131 to address directives of 2019 HB 2935 which require accessibility services for visually impaired patients. These rules are intended for all prescription drugs dispensed directly to Oregon patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies. Operative date per statute was January 1, 2020.

Impacts: In Oregon, it is estimated that 104,500 patients are visually impaired

Documents relied upon include: Title VI of the Civil Rights Act of 1964 (42 USC 2000d)

OAR 855-041-1131 Prescription Reader Accessibility

A pharmacy shall notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request; a prescription reader is a device designed to audibly convey labeling information. A pharmacy that provides a prescription reader shall make it available to the person for at least the duration of the prescription, shall confirm it is appropriate to address the person’s visual impairment, and shall ensure that prescription labels are compatible with the prescription reader. This requirement does not apply to an institutional drug outlet, dispensing a drug intended for administration by a healthcare provider.

Statutes Implemented: 2019 OR Ch 438
(U) Clonazolam Identified in Overdose Incidents in Oregon and Idaho

(U) Recent reports of non-fatal overdose incidents have been reported in the Portland area. Clonazolam, a chemical sold as a designer drug online and part of the benzodiazepine drug class, was identified in these cases in Oregon and Idaho. In Portland, OR the drug was in liquid form and referred to as "liquid benzos" found in small vials similar to those in photo 1. In Idaho, law enforcement agencies have reported seizures of counterfeit "Xanax" bars, in which the clonazolam was in pressed into crude counterfeit Xanax pills, similar to those seen in photo 2.

INDICATORS
(U) Clonazolam is a psychoactive research chemical that acts as a sedative and muscle relaxant. It is a derivative of clonazepam and alprazolam, which are used to often treat anxiety and insomnia, among other medical uses. According to open sources, clonazolam has been reported to be fast-acting and its effects can be felt within 20-60 minutes. Due to its high potency it can produce heavy sedation and effects even when ingested in low doses such as 0.5mg.1 Because of its high potency, it may be more dangerous than other benzodiazepines available on the market, especially when taken in higher doses.2

(U) Currently there is limited regulation on clonazolam and it is uncontrolled in most of the United States. Virginia and Louisiana are the only states that currently have clonazolam listed as a schedule I substance under their state’s controlled substance laws. This lack of regulation allows for the product to be openly sold on the internet and easy to obtain in its various forms to include liquid (photo 3), pellets/pills, blotters and powder.

CONCERNS
(U) Overdoses related to clonazolam are being reported as presenting with symptoms similar to an opiate related overdose. The symptoms often include slurred speech, lack of coordination, drowsiness and profoundly altered mental status. A high level of toxicity can cause a patient to become comatose and need immediate airway management. Fatal overdoses are rare but can occur with high level doses or if mixing benzodiazepines with other depressants such as alcohol, barbiturates or opioid painkillers.4 Although the symptoms are similar to an opioid overdose, the use of naloxone is not effective in reversing benzodiazepine overdoses.5

REQUEST FOR INFORMATION
(U) The Oregon-Idaho HIDTA Investigative Support Center is interested in reports involving clonazolam or other designer benzodiazepines to assess the emerging trend and public safety impact for our communities. Information can be sent to OrIdHIDTA@doj.state.or.us.

1  https://testcountry.com/pages/all-you-need-to-know-about-clonazolam
2  https://www.serenityatsummit.com/research-chemicals/clonazolam/
3  https://www.reddit.com/r/benzodiazepines/comments/a5msln/clonazolam_solution_just_came_in_today/
4  https://drugabuse.com/benzodiazepines/overdose/
5  https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone

Potential wording for designer diazepines from OSP

Schedule I also includes any compounds in the following structural classes (a – b), and their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Benzodiazepine class: A fused diazepine and benzene ring structure with a phenyl connected to the diazepine ring, with any substitution(s) or replacement(s) on the diazepine or benzene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Clonazolam, Flualprazolam

(b) Thienodiazepine class: A fused diazepine and thiophene ring structure with a phenyl connected to the diazepine ring, with any substitution(s) or replacement(s) on the diazepine or thiophene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Etizolam
Revisions to Division 080 – Controlled Substances are provided to address an immediate public safety concern related to benzodiazepine overdoses reported in Portland, Oregon and Idaho. (see lines 119-122)

Chapter 855
Division 80
SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0015
Definitions

As used in these rules:
(1) "Act" means the Uniform Controlled Substances Act, ORS Chapter 475, and rules thereunder;
(2) "CFR" means Code of Federal Regulations;
(3) The term "registration" or variants thereof means the annual registration required of manufacturers, distributors and dispensers of controlled substances under ORS 475.125, and the term "registrants" or variants thereof refers to persons so registered; provided that where references of this nature are used in CFR sections referred to in these rules, the reference is to the registration requirements and registrants under the Federal Controlled Substances Act, and Title 21, CFR.
(4) "USC" means United States Code;
(5) Terms not defined in this rule have the definitions set forth in ORS 475.005.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035 & 475.940

855-080-0020
Schedules

Pursuant to ORS 475.005(6) those drugs and their immediate precursors classified in Schedules I through V under the Federal Controlled Substances Act, 21 U.S.C. Sections 811 to 812 and as amended by the Board pursuant to ORS 475.035 are the controlled substances for purposes of regulation and control under the Act. Those schedules are set out in OAR 855-080-0021 through 855-080-0026.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035
Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21CFR part 1308.11, and unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) 1,4-butanediol;
(b) Gamma-butyrolactone
(c) Methamphetamine, except as listed in OAR 855-080-0022;
(d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)
(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.

(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,

(A) Methylmethcathinone (Mephedrone);
(B) Methyleneedioxyppyrovalerone (MDPV);
(C) Methyleneedioxyethylcathinone (Methylone);
(D) 2-Methylamino-3',4'-methyleneedioxy-butyrophonone (Butylone);
(E) Fluoromethcathinone (Flephedrone);
(F) 4-Methoxymethcathinone (Methedrone).

(2) Schedule I also includes any compounds in the following structural classes (2a–2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of
this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH-201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;

(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);

(e) Naphthylmethylinfides: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(g) Naphthylmethylindenones: Any compound containing a 1-(1-naphthylmethyl) indene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class include but are not limited to: UR-144, XLR-11 and A-796,260;

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;

(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring
to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and

(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-
carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further
substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring
to any extent. Examples of this structural class include but are not limited to: AKB48.

(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs
855-080-0022 through 0026 (Schedules II through V) or is not an FDA approved drug.

(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs
855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are
derived from fentanyl by any substitution on or replacement of the phenethyl group, any
substitution on the piperidine ring, any substitution on or replacement of the propanamide group,
any substitution on the phenyl group, or any combination of the above.

(5) Schedule I also includes any compounds in the following structural classes (a – b), and
their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V)
or FDA approved drugs, unless specifically excepted or when in the possession of an FDA
registered manufacturer or a registered research facility, or a person for the purpose of
sale to an FDA registered manufacturer or a registered research facility:

(a) Benzodiazepine class: A fused 1,4-diazepine and benzene ring structure with a phenyl
connected to the diazepine ring, with any substitution(s) or replacement(s) on the 1,4-
diazepine or benzene ring, any substitution(s) on the phenyl ring, or any combination
thereof. Examples of this structural class include but are not limited to: Clonazolam,
Flualprazolam

(b) Thienodiazepine class: A fused 1,4-diazepine and thiophene ring structure with a
phenyl connected to the 1,4-diazepine ring, with any substitution(s) or replacement(s) on
the 1,4-diazepine or thiophene ring, any substitution(s) on the phenyl ring, or any
combination thereof. Examples of this structural class include but are not limited to:
Etizolam

(5) (6) Exceptions. The following are exceptions to subsection (1) of this rule:

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose
of its sale to a legitimate manufacturer of industrial products and the person is in compliance
with the Drug Enforcement Administration requirements for List I Chemicals;

(b) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose
of the legitimate manufacture of industrial products;

(c) Marijuana and delta-9-tetrahydrocannabinol (THC).
Schedule II consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.12 and any quantity of methamphetamine, its salts, isomers and salts of its isomers as an active ingredient for the purposes of currently accepted medical use.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035, 475.059, 475.065 & 2017 OL Ch. 021

Schedule III consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.13; and

(1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.

(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.

(3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active ingredient.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

Schedule IV consists of:

(1) The drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.14, unless specifically excepted or listed in another schedule: and

(2) Products containing carisoprodol or the salts of carisoprodol as an active ingredient.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035
Schedule V

Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.15.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

Excluded Substances

The following drugs and their generic equivalents are excepted from the schedules in OAR 855-080-0021 through 855-080-0026:

1. Benzedrex inhaler (Propylhexedrine).
2. Vicks — Vapor inhaler (Levmetamfetamine).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
(1) Definition

(a) ‘Administer’ means the direct application of a drug or device whether by injection, inhalation, ingestion or any other means, to the body of an animal patient by:

(A) A veterinarian, Certified veterinary Technician or employee under the veterinarian’s supervision; or
(B) A client or their authorized agent at the direction of the veterinarian.

(b) ‘Dispense’ or ‘Dispensing’ means, under a lawful prescription of a veterinarian, the preparation and delivery of a prescription drug, in a suitable container appropriately labeled for subsequent veterinary patient administration, to a client or other individual entitled to receive the prescription drug. Controlled substances and legend drugs shall be dispensed, ordered or prescribed based on a VCPR.

(2) Policies and Procedures. The veterinary facility must:

(a) Maintain written policies and procedures for drug procurement and management, including storage, security, integrity, access, dispensing, disposal, record-keeping and accountability; and

(b) Maintain all drug records required by federal and state law.

(3) Drug Security: All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficient to deny access to unauthorized persons. Controlled drugs must be kept in a locked cabinet with access limited to persons authorized by the Managing Veterinarian.

(4) Storage of Drugs: All drugs, including drug samples, must be stored according to manufacturer’s published guidelines and in appropriate conditions of temperature, light, humidity, sanitation, ventilation and space.

(5) Prescription Labeling: A prescription must be labeled with the following information:

(a) Name of patient;
(b) Name or initials of prescriber;
(c) Name, address, and phone number of the facility;
(d) Date of dispensing;
(e) Name and strength of the drug;
(f) Quantity dispensed;
(g) Directions for use;
(h) Manufacturer’s expiration date, or an earlier date if preferable, after which the drug should not be administered to the patient.

(6) Dispensing and Drug Delivery

(a) The veterinarian or their representative must orally counsel the client concerning all new drugs prescribed, unless circumstances would render oral counseling ineffective.
(b) If requested, a prescription shall be provided to a client for drugs and medications prescribed by the veterinarian under a valid VCPR.

(c) Rabies vaccine shall be administered only by an Oregon-licensed veterinarian, a Certified Veterinary Technician under direct supervision of an Oregon-licensed veterinarian, or a person authorized by the Oregon Public Health Veterinarian pursuant to OAR 333-019-0017.

(7) Disposal of Drugs: Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to the supplier. At the discretion of the veterinarian, outdated drugs may be dispensed as long as the client is informed and there is no fee charged for the drugs.

(8) Record Keeping

(a) For all controlled drugs, a dispensing record must be maintained separately from the patient chart and retained for a minimum of three years. The record must show, at a minimum, the following:

(A) Name of patient
(B) Dose, dosage form, quantity dispensed;
(C) Directions for use;
(D) Date of dispensing; and
(E) Initials of person dispensing the prescription.

(b) All records of receipt and disposal of drugs must be retained for a minimum of three years.

(c) All records required by these rules or by other state or federal law must be readily retrievable and available for inspection by the Board’s inspector or inspectors from other agencies having jurisdiction.

(9) Drug Acquisition: The veterinary facility must verify that all controlled drugs are acquired from a source registered with the Board of Pharmacy.

(10) Inspection: Veterinary facilities shall be periodically inspected to ensure compliance with these rules. Veterinary facilities shall be expected to annually complete and maintain the self-inspection form prior to inspection, and shall make all drug record and storage available for inspection. The self-inspection form will be available from the Board on its website or upon request.
**SBAR:** Previous Request - Sanofi Corporation, 1025 Sandhill Rd., Reno NV. Requesting to add registration #W1-0004046-CS to the previously approved Board request (October 2018) for a Designated Representative for more than one registration.

### Situation:
Sanofi Corporation has three subsidiary companies (Wholesale Outlets) located in the same physical location, 1025 Sandhill Rd., Reno NV. Each company holds an individual registration number (W1-0001795, W1-0002444, W1-0002455). They wish to add a 4th registration, Chattem, Inc., W1-0004046-CS to the approval.

Each company is requesting a specific authorization per OAR 855-065-0009(1) which states that a designated representative (DR) may not be listed for more than one registrant without the approval of the Board. If granted, this will allow a single DR to oversee the day to day operations of all registrants in the same physical location.

### B
- Due to our registration requirements, each company must be registered.
- By granting this authorization, OBOP would allow a single DR at the facility providing consistent oversight and awareness of the daily operations of the wholesale distributors.

### Related OAR(s):
**855-065-0005** - Definitions
(7) "Designated Representative" means an individual designated by each wholesale distributor registered by the Board who will serve as the primary contact person for the wholesale distributor with the Board and who is responsible for managing the company's operations at that registered location.

**855-065-0009** - Personnel
As a part of the registration or re-registration application, an applicant for registration as a Class I Wholesaler must name a Designated Representative (DR) for each wholesale distributor registered under these rules. The DR must:

1. **Be employed in a full-time managerial position by the wholesale distributor and may not be listed as the DR for more than one registrant without the specific written authority of the Board.**
2. Have at least two years verifiable full-time managerial or supervisory experience in a pharmacy or with a wholesale distributor registered under these rules or with another state.
3. Have verifiable experience in record keeping and storage of prescription drugs.
4. Be actively involved in and aware of the daily operations of the wholesale distributor.
5. Be knowledgeable about all policies and procedures of the wholesale distributor.
6. **Be physically present at the wholesale distributor during normal business hours, which must be posted to be visible to the public, except when absent due to emergency, authorized absence or legitimate business reason (as used in this rule, “normal business hours" means at least six hours between 6.00 am and 7.00 pm on at least five days between Monday and Saturday every week, excluding national and local holidays). Class I wholesalers located within Oregon must designate a replacement DR and notify the Board accordingly, when any absence of the DR exceeds 15 days.**
7. The DR must conduct a self-inspection of the facility by September 1 each year, and document the results of this self-inspection on Oregon Wholesaler Self-Inspection Form provided by the Board. The DR must certify in writing, under penalties of perjury, that the information recorded on the Oregon Wholesaler Self-Inspection Form is correct. This form must be retained for three years and must be made available to the Board within two days upon request.
The DR must ensure that the wholesale drug outlet has policies and procedures in effect and implemented to ensure that the outlet employs adequate personnel with the education and experience necessary to engage in the wholesale distribution of drugs safely and lawfully.

### Assessment:
- If approved, Mr. DeLong would serve as the DR for the facility.
- Each of the following are examples of consistent oversight and awareness of the daily operations of the wholesale distributors:
  - Single management team on site
  - Product storage under same roof
  - Single inventory system is utilized for all products located in discrete locations
  - Standard Operating Procedures are shared by all 4 registrants
  - A single security system is used to monitor physical storage
  - A single personnel training program is used

### Recommendation:
- The staff recommends approving the authorization to allow a Mr. Steve DeLong to act as a single Designated Representative for registration numbers W1-0001795, W1-0002444, W1-0002455 & W1-0004046-CS
  - All registrants are in the same physical location which will allow consistent oversight and awareness and physical presence during normal business hours by the appointed DR.

Inquiry Date: 7/25/19
Board review: February 2020 meeting
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INTRODUCTION

On behalf of the Board members and staff of the Oregon State Board of Pharmacy, I am pleased to present the Board’s Strategic Plan for 2020-2024. The purpose of this plan is to outline the direction and priorities for change which have been established by the Board and which we believe will ensure that pharmacy practice is regulated in the interest of public health and safety, result in exceptional service to our licensees, and advance the health of Oregonians.

In the past two years, four new Board Members have been appointed, and one Inspector and one Licensing Representative have been added to the Board staff. In addition, seven members were appointed to the newly established Public Health and Formulary Advisory Committee. This group of new Board/Committee members and staff represent a diverse mix of highly qualified individuals that will result in effective deployment of our mission on behalf of the citizens of Oregon. We are committed to continuing to improve our affirmative action, diversity, equity and inclusion efforts in recruitment and retention of Board and Committee members and staff.

We would like to acknowledge the input of stakeholders who share their views on priorities for pharmacy regulation in order to allow pharmacists, pharmacy technicians and drug outlets to provide the best possible care to all Oregonians. The practice of pharmacy and pharmaceutical supply chain have continued to undergo profound change due to technological advances, changes in healthcare delivery, increasing complexity in the supply chain, fragmentation of care, “remote” practice, social and political shifts, drug shortages, health disparities, access issues, opioid abuse, compounding and medication safety, internet access to medications, natural disasters, and a variety of political and economic forces.

The five strategic goal areas outlined in this Strategic Plan will guide the work of the Board and staff to create the regulatory structure necessary to incorporate and encourage the best pharmacy practices to ensure public health and safety. This plan will be reviewed and updated annually to make sure that desired outcomes are being met and to encourage safe and contemporary pharmacy practice. The five strategic goal areas include:

- Technicians
- Technology
- Licensing
- Regulation
- Communication

As we begin to implement these initiatives, we encourage continued active engagement with the Board and participation in Board Meetings, Committee Meetings, Rules Hearings, and other Board activities.

Joe Schnabel, Pharm.D., R.Ph.
Executive Director
OUR PURPOSE

Mission
The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

Vision
Partners for a Healthy Oregon

Values
These values reflect both how our Board and staff strive to conduct ourselves, and the behaviors we seek to instill across the practice of pharmacy in Oregon.

**Integrity**
*We meet commitments to public health & safety and are accountable for our words and actions*
Includes …
- Honesty
- Ethics
- Respect

**Quality**
*We strive to deliver a consistent standard of excellence*
Includes …
- Excellence
- Value
- Worth

**Safety**
*We are committed to protecting the health, safety and welfare of the public*
Includes …
- Protection
- Security
- Care

**Accountability**
*We accept responsibility for our actions, products, decisions and policies*
Includes …
- Trust
- Responsibility
- Transparency

**Professionalism**
*We are committed to promoting excellence in pharmacy practice*
Includes …
- Expertise
- Commitment
- Competence
A variety of trends in the practice of pharmacy are impacting the Board’s regulatory activities, daily work and strategic priorities. Many of these changes offer potential benefits to the public, the pharmacy profession and health care—while others pose clear risks. All, however, require careful monitoring and response from the Board to ensure public safety is maintained and that licensing, regulation, enforcement and outreach efforts keep pace with the evolving landscape.

Some of the issues facing the Board of Pharmacy include:

**Access and distribution:** New options to obtain prescription and over-the-counter medicines are being proposed and/or implemented. These must be examined to ensure that public safety is not jeopardized in the name of convenience.

**Changing business models:** Consolidation in the retail pharmacy business and hospital/health care networks mean large organizations have increasing influence on the practice of pharmacy, including policies and procedures, staffing levels, and economics.

**Regulation trends:** As in many regulated industries, there are often external pressures to relax regulation to mitigate economic realities. The Oregon Board of Pharmacy strives to maintain a regulatory environment focused solely on public health and safety, while enabling practices that improve efficiency and access. The Board supports rule changes only when the outcomes are assured to maintain protection of the public.

**Pharmacy and Clinical Collaboration:** Increasingly, other healthcare providers are engaging with pharmacists as partners in developing more effective care plans—particularly for patients with chronic conditions and in providing preventative care services to improve public health.

The Board encounters the effects of these and other issues and trends on a daily basis. In this strategic plan, goals have been outlined to address them directly and/or to position the Board to adapt and more effectively fulfill its public safety-focused mission.
At its annual Strategic Planning meeting in November 2019, the Board, Executive Director and the staff leadership team identified and evaluated a wide range of trends and challenges facing the practice of pharmacy and our agency. This process and deliberation led to agreement on five critical Strategic Areas and goals on which attention and resources will be focused.

**TECHNICIANS**

**Goal:** Articulate the regulatory structure where the accountabilities of pharmacists and the role of pharmacy technicians are aligned to enhance safety, access, service and efficiency

**TECHNOLOGY**

**Goal:** Articulate the regulatory structure where the accountabilities of pharmacists and the use of technology are aligned to enhance safety, access, service and efficiency

**LICENSING**

**Goal:** Clarify drug outlet licensing and standards to promote appropriate licensure

**REGULATION**

**Goal:** Systematically refresh rules and standardize the rule development approach to improve clarity and compliance

**COMMUNICATION**

**Goal:** Improve and maintain stakeholder and public engagement through proactive communication strategies

The Board gave clear direction to the Executive Director and staff that meaningful progress should be made toward accomplishing these goals over the next two to four years—while recognizing that these will remain important issues over an even longer time span. We will regularly assess progress and refine our goals and resource commitments as we work to achieve these key objectives.

Background on each goal, key actions and outcome measures are provided.
TECHNICIANS

Goal: *Articulate the regulatory structure where the accountabilities of pharmacists and the role of pharmacy technicians are aligned to enhance safety, access, service and efficiency*

The Board seeks to develop clear rules to ensure that pharmacists understand their legal scope of practice and their accountability to provide patient care services and safe pharmacy practices. Permitting pharmacists to more fully and effectively utilize technician support must be structured to improve safety, access and patient care services.

The Board seeks rule alignment to clearly describe the role of pharmacy technicians and how they assist the pharmacist in the practice of pharmacy. Regulatory structures developed for technician roles should delineate requirements for training, quality assurance, and pharmacist supervision.

**Key Actions:**
1. Review and evaluate applicable statutes for development of rules that clearly articulate the role of a pharmacist and functions that only a pharmacist may perform. (June, 2020)
2. Review and evaluate applicable statutes for development of rules for requirements for training and guidelines for adequate supervision of technicians who assist the pharmacist in the practice of pharmacy. (August, 2020)
3. Review and evaluate applicable statutes and rules for technician licensure to determine if changes in rules are necessary to facilitate roles. (December, 2020)

**Outcome Measures:**
- Draft rules for Board consideration that clearly delineate the role of the pharmacist and practices of pharmacy that must only be performed by a pharmacist.
- Draft rules for Board consideration that clearly delineate requirements for training and supervision of technicians.
- Draft rule update for licensure of Pharmacy Technicians and Certified Oregon Pharmacy Technicians.
- Increase in pharmacist provision of patient care services while maintaining safety in dispensing services.
TECHNOLOGY

Goal: *Articulate the regulatory structure where the accountabilities of pharmacists and the use of technology are aligned to enhance safety, access, service and efficiency*

The Board seeks to develop clear rules to ensure that pharmacists understand their scope of practice and their accountability to provide patient care services and safe pharmacy practices while permitting the use of technologies that improve safety, access, service and efficiency. Regulatory structures developed for use of technology should be function-based and delineate individual pharmacist accountabilities for each critical stage of automated processes.

**Key Actions:**

1. Review and evaluate industry trends and applicable statutes and rules for use of technology to develop clear, function-based rules and pharmacist accountabilities. (October, 2020)
2. Clearly outline requirements for quality assurance and accountability for each critical stage of automated processes. (December, 2020)

**Outcome Measures:**

- Draft rules for Board consideration that clearly delineate the use of technology and pharmacist accountabilities in the practice of pharmacy.
- Defined accountabilities for each critical step in automated processes.
- Increase in pharmacist provision of patient care services while maintaining safety in dispensing services.
- Effective quality assurance plan applied to all automated pharmacy processes.
LICENSING

Goal: Clarify drug outlet licensing and standards to promote appropriate licensure

The Board promotes patient safety through appropriate licensing and regulation of all drug outlets engaged in the manufacture, dispensing, delivery or distribution of drugs and medical devices. License categories should clearly guide applicants to the appropriate license type.

Key Actions:

1. Create and implement a consistent, ongoing process to review and evaluate applicable statutes for each drug outlet licensing authority, leading to development of rules that clarify the appropriate license category. (August, 2020)

2. Review and evaluate legislative and budgetary considerations that may be required to implement changes to drug outlet categories. (October, 2020)

Outcome Measures:

- Draft rules for Board consideration that clarify the appropriate license category for each outlet category.
- Decrease in questions from applicants regarding appropriate license type for which to apply.
Goal: *Systematically refresh rules and standardize rule development to improve clarity and durability*

The Board proactively reviews and updates rules to provide clear expectations to licensees and registrants to promote compliance and patient safety. Rule updates should emphasize clarity and durability to allow practice variation that improves safety, access, service and efficiency.

**Key Actions:**

1. Create standard procedures and schedule to accomplish five-year rule review that emphasizes clarity and durability. (August, 2020)
2. Conduct routine, scheduled, and systematic review of Board of Pharmacy rules by section and draft revisions for Board consideration. (December, 2020)

**Outcome Measures:**

- Rule review standards and guidelines are implemented and used to prepare all rule updates.
- At least four rule sections are reviewed, updated and presented to Board for consideration annually.
COMMUNICATION

Goal: *Improve and maintain stakeholder and public engagement through proactive communication strategies*

The Board communicates through multiple platforms to collaborate, educate, promote patient safety and enhance consumer protection.

**Key Actions:**

1. Develop and implement a communication plan at all levels of the agency to improve access to relevant information and streamline communications. (June, 2020)
2. Create and maintain a new website as the Board’s primary communication tool. (June, 2020)
3. Develop a consistent process to review and update FAQs related to licensing and compliance. (October, 2020)
4. Develop standardized methods to triage and respond to correspondence to improve timely communications that are maintained in accordance with public records retention requirements. (December, 2020)

**Outcome Measures:**

- Create modern materials for agency communications, including branding and plain language used for presentations and other public documents.
- Webpages updated to provide focused information.
- Updated FAQs published.
- Transition to an enhanced list-serve email service.
### BOARD OF PHARMACY

**AY21 Cash Flow**

**OF Apn 30235**

<table>
<thead>
<tr>
<th>Budget Objects Revenue &amp; Expenditures</th>
<th>LAB</th>
<th>ORBITS Budget</th>
<th>Salary Plan</th>
<th>EBoard or Adjusted Salary Plan</th>
<th>ORB or Salary Plan</th>
<th>LAB %</th>
<th>LAB % SP</th>
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<tbody>
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<td>7,146,250</td>
<td>7,146,250</td>
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<td>5,972,247</td>
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<td><strong>Transfers</strong></td>
<td>(244,146)</td>
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<td>(244,146)</td>
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<td>(244,146)</td>
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<td><strong>SubTotal Transfers</strong></td>
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<td>(244,146)</td>
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<td><strong>Total Revenue &amp; Transfers</strong></td>
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<td>1,820,389</td>
<td>5,977,903</td>
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<td>3350 Workers Compensation Assessment</td>
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<td>1,096,904</td>
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<td><strong>Services and Supplies</strong></td>
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<td>4335 Employee Recruitment &amp; Develop</td>
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<td>653</td>
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<tr>
<td>4400 Dues &amp; Subscriptions</td>
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<td>4425 Facilities Rent &amp; Taxes</td>
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<td>53</td>
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<tr>
<td>4525 Medical Supplies and Services</td>
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<td>4575 Agency Program Related SAS</td>
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</tr>
<tr>
<td>4650 Other Services &amp; Supplies</td>
<td>284,656</td>
<td>284,656</td>
<td>284,656</td>
<td>74,566</td>
<td>210,070</td>
<td>26%</td>
<td></td>
</tr>
<tr>
<td>4700 Expendable Property</td>
<td>13,526</td>
<td>13,526</td>
<td>13,526</td>
<td>-</td>
<td>13,526</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>4715 IT Expendable Property</td>
<td>43,363</td>
<td>43,363</td>
<td>43,363</td>
<td>1,082</td>
<td>42,281</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>5000 Board Processing Hardware</td>
<td>8,611</td>
<td>8,611</td>
<td>8,611</td>
<td>-</td>
<td>8,611</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>5500 Other Current Liabilities</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SubTotal Services and Supplies</strong></td>
<td>2,945,667</td>
<td>2,945,667</td>
<td>2,945,667</td>
<td>770,048</td>
<td>2,175,619</td>
<td>26%</td>
<td></td>
</tr>
<tr>
<td><strong>Special Payments</strong></td>
<td>12,447</td>
<td>12,447</td>
<td>12,447</td>
<td>-</td>
<td>12,447</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td><strong>SubTotal Transfers</strong></td>
<td>12,447</td>
<td>12,447</td>
<td>12,447</td>
<td>0</td>
<td>12,447</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td><strong>Total Expenditures Budget</strong></td>
<td>8,761,878</td>
<td>8,782,531</td>
<td>8,782,531</td>
<td>1,886,952</td>
<td>6,895,579</td>
<td>21%</td>
<td></td>
</tr>
</tbody>
</table>

**2020 February / C**

**AY21 Ending Cash Balance**

**Revenue Less Expenditures**

| Total Revenue & Transfers | 8,782,399 |
| Total Expenditures | (7,755,707) |
| **Total Revenue & Transfers less Expenditures** | (1,026,692) |

**AY21 Cash Balance after the Fiscal Month Closed**

| 4,136,766 |

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

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

Budgeted Expenditures not yet spent

**AY21 Estimated Cash Balance**

| (2,785,813) |

Cash Balance Contingency (Months) | (7.61)