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 8, 2018

I. 8:30AM OPEN SESSION, Rachael DeBarmore, R.Ph, Presiding

   A. Roll Call
   B. Board Member Photos
   C. Installation of new Board Member Wassim Ayoub, RPh - DeBarmore
   D. Agenda Review and Approval  

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

NOTE: Due to a heavy case load this meeting, Executive Session is expected to carry over into Thursday, August 9, 2018 until approximately 11:00AM. The Board may convene Open Session on August 8, 2018 to Adjourn.

Open Session to Adjourn
THURSDAY, AUGUST 9, 2018

8:30AM
IV. OPEN SESSION, Rachael DeBarmore, R.Ph, Presiding

A. Roll Call
B. Resume Executive Session to complete remaining items:

EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (k).

C. Items for Consideration and Discussion:
   1. Deliberation on Disciplinary Cases and Investigations
   2. Personal Appearances
   3. Deficiency Notifications
   4. Case Review

V. OPEN SESSION - PUBLIC MAY ATTEND
Note: we anticipate starting Open Session around 11:00AM Thursday, August 9, 2018.

D. Introduction of new Board Member Wassim Ayoub, RPh - DeBarmore

VI. GENERAL ADMINISTRATION

A. Rules
   *First Look ** Second Look *** Third Look
   1. Review Rulemaking Hearing Report & Comments - none
   2. Consider Adoption of Rules - none
   3. Consider Adoption of Temporary Rules – none
   4. Rules Review:
      • Div 045 – Compounding w/comments for review #A
   5. PIC and Community Pharmacy Personnel and Compliance Rules Advisory Committee – 6/29/18 Meeting Update #A1
   6. Consider rules and send to Rulemaking Hearing
      • Div 041 - Auto Refill correction #A2 Action Necessary
   7. Policy Issues for Discussion:
      • Drug Shortages & BUD Extension request #A3 – Efremoff/Karbowicz
      • Syringes follow up inquiry – Karbowicz #A4
      • Technology Informational – Karbowicz

Noon – Lunch break (Some or all of the items above or below may occur before or after lunch depending on the length of the Board’s discussions.)

B. Public Health and Pharmacy Formulary Advisory Committee – Watt/Karbowicz
   1. Committee meeting update #B
   2. Committee Recommendation update #B1
   3. Consider rules & send to Rulemaking Hearing

NOTE: The Board may rearrange its agenda to accommodate the Board or members of the public.
Div 020 – Prescriptive Authority & Formulary draft rules **B2-B4**

Some of the items scheduled for Friday may occur on Thursday afternoon if there is time.

**FRIDAY, AUGUST 10, 2018**

8:30AM

VII. OPEN SESSION, Rachael DeBarmore, R.Ph, Presiding

A. Roll Call
B. Motions for Contested Cases & Disciplinary Action – Efremoff  
Action Necessary
C. Strategic Planning – DeBarmore/Watt/MacLean
   • 2018 session update

D. General Administration resumed

Discussion Items:
1. Waiver Requests:
   • Planned Parenthood, report and renewal – **E** - Karbowicz  
Action Necessary

2. TCVP:
   • Columbia Memorial Hospital TCVP Request – **F** Karbowicz/Efremoff  
Action Necessary

3. Other:
   • Goal setting – DeBarmore
   • Key Performance Measures - **G-G1** MacLean
   • Board Best Practices Performance review **H** - MacLean  
Action Necessary

**VIII. Approve Consent Agenda**  
Action Necessary

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

1. NAPLEX Scores – none
2. MPJE Scores – none
3. License/Registration Ratification – May 26, 2018 – August 1, 2018
4. Pharmacy Technician Extensions – June 1, 2018 – June 30, 2018
5. Board Minutes – April 4-5, 2018, June 6-7, 2018, July 10, 2018

**IX. ISSUES/ACTIVITIES**

A. Board Meeting Dates
   • October 3-4, 2018  Portland  
   • November 7 (8*), 2018  Portland (Strategic Planning) (*may be 2 days)
   • December 12-13, 2018  Portland
   • February 6-8, 2019*  Portland (*3 day meeting)
   • April 3-4, 2019  Portland
   • June 5-6 (7*), 2019  Portland (*may extend to 3 days)
• August 7-9, 2019* Portland  (*3 day meeting)
• October 2-3, 2019 Portland
• November 6-7, 2019 Portland  (Strategic Planning)
• December 11-12, 2019 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 27, 2018
• November 27, 2018
• May 22, 2019
• November 26, 2019

C. Committees/Meetings
1. OSPA Annual Convention, 10/12-14/2018, Portland – Watt/Efremoff/ ?
2. NABP District VI-VIII, Mtg Kansas City, MO 10/14-17/2018 - Vipperman/Watt
3. OSHP Fall Meeting –11/10/18, Portland - ?
4. OSPA Lane Co. Mid-Winter CE Seminar, Eugene – 2/16-17, 2019 - ?

D. Board Member/Staff Presentations – DeBarmore
• Pharmacy Coalition – none
• Professional Practice Roundtable – none
• APhA Institute on Alcoholism & Drug Dependencies Training, Salt Lake City, UT May 30 - June 4, 2018 - Gin

E. Financial/Budget Report – Watt/MacLean #I - K
• 2019-21 Proposed Licensee Fees #L

F. Legislative update – Watt

G. Reports:
1. Board President/Members
2. Executive Director
3. Board Counsel
4. Compliance Director
5. Pharmacist Consultant
6. Administrative Director
7. Licensing Program Supervisor
8. Project Manager

X. 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
DIVISION 045 RE-WRITE - COMPOUNDING

These rules are intended to describe the Board’s registration and compliance expectations related to drug compounding. The rule (1) identifies purpose (2) outlines registration criteria, (3) describes general compounding requirements, including (i) compounding personnel, (ii) labeling, (iii) quality controls, and (iv) recordkeeping. The rule outlines additional specific requirements for performing sterile compounding, including personnel and recordkeeping.

The Board expects drug compounding to adhere to standards set forth in the United States Pharmacopeia (USP) and the USP-NF. The Board recognizes that USP Chapters 795, 797, and 800 are currently undergoing a re-writing process, with an expected date of enforcement of December 1, 2019. (See USP Updates on Compounding Standards). Additionally, these rules articulate requirements that serve to more clearly define expectations when the USP Chapter standards are ambiguous or insufficient.

Rules 855-045-0200 through 855-045-0630 are proposed to be repealed.

855-045-0500

COMPOUNDING

Purpose

(1) These rules apply to any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for the use by a patient located in Oregon. Any person located outside Oregon must follow the compounding rules of their home state or these rules, whichever are more stringent.

(2) These rules apply to sterile and non-sterile compounding of medications.

(3) All drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP <795>), 797 (USP <797>) and 800 (USP <800>) as well as all applicable 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.

(4) Compounding pharmacies and personnel must comply with federal and state regulations regarding compounding and handling hazardous drug products.

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

(1) “Batch” means any specific quantity greater than one of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation carried out during a single time period.

(2) “Beyond-Use Date” and “BUD” means the date and time after which a compounded product must not be used (or stored or transported). The date is determined from the date and time the preparation is compounded, according to risk level.

(3) “Hazardous Drug” means any drug identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control or any drug that meets at least one of following six criteria.
   (a) Carcinogenicity.
   (b) Teratogenicity or developmental toxicity.
   (c) Reproductive toxicity in humans.
   (d) Organ toxicity at low doses in humans or animals.
   (e) Genotoxicity.
   (f) New drugs that mimic existing hazardous drugs in structure or toxicity.

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

Registration

(1) A pharmacy 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 sterile compounded preparations into and within Oregon.

(3) A non-resident facility distributing non-patient specific drugs into Oregon must be registered with the FDA as a 503B Outsourcing Facility and register as an Oregon Manufacturer.
(4) A resident facility distributing non-patient specific drugs outside of Oregon must register with the FDA as a 503B Outsourcing Facility and register as an Oregon Manufacturer.

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

888-045-0530

General Requirements for Compounding

(1) All active pharmaceutical ingredients must be obtained from an FDA and Board registered manufacturer.

(2) The accuracy of identities, concentrations, amounts, purity, and sterility of ingredients in compounded products must be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.

(a) If the correct identity, concentration, amount, purity and sterility of ingredients and components of compounded products cannot be confirmed, such ingredients and components must be discarded immediately.

(3) The equipment, components, devices, and utensils used for compounding of a drug preparation must be of appropriate design and capacity and must also be designed to protect the compounder from hazardous materials. Minimum standards for pharmacies and equipment are dependent on the risk level of the products being prepared. A pharmacy must comply with all USP standards commensurate with level of compounding being performed.

(a) Equipment must be of suitable composition that a surface which contacts a component is neither reactive nor alters the purity of a compounded preparation.

(b) Equipment must be stored to protect it from contamination and must be located to facilitate its use, maintenance and cleaning.

(c) Automated, mechanical, electronic and other types of equipment must be routinely inspected, cleaned and calibrated per the stricter requirement of USP or the manufacturer’s specification.

(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 Division 060, with the following exceptions:

Commented [KF*B12]: Can there be exceptions for shortages when importing non-US based products?
Staff note: This is managed by FDA processes. Pharmacies may order medications through legal means, authorized by FDA.

Commented [KF*B13]: Many ingredients used in compounded products are not sterile. This proposed rule seems to prohibit the use of any non-sterile ingredient in a compounded product. Suggest adding “where applicable”

Commented [KF*B14]: Comment: How do you define “protect from hazardous material” for equipment or utensil? To our knowledge this is not language from USP. The concern is that by providing these kind of statements out of context from USP chapters that these become challenging to enforce or define. This section also states that the “pharmacy must comply with all applicable USP standards.” If the Board would like for the rules to follow USP chapters, then perhaps it is simpler to just refer to the relevant USP chapter that the Board would like followed. We are not sure the added complexity and ambiguity of (3) is helpful.
(a) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on a history of receiving valid prescription drug orders for the compounded or sterile prepackaged drug product; or

(b) Preparing non-controlled compounded products by an Oregon pharmacy for a practitioner located in Oregon, documented by use of Board approved Shared Pharmacy Services agreement.

(5) A drug product that is commercially available may only be compounded if:

(a) It is medically warranted by the prescribing practitioner to provide an alternate ingredient, dosage form, or strength of significance, for an identified individual patient; or

(b) The commercial product is not reasonably available in the market in time to meet the patient’s needs.

(c) Justification of compounding pursuant to OAR 855-045-0530(5) must be documented and retained by the pharmacy for a minimum of three years and be made available for inspection.

Staff recommends removing (5)

(6) Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties included on the Difficult to Compound List or that has been included in 21 CFR 216.24 in compounding or has been withdrawn or removed from the market for safety or efficacy reasons is prohibited.

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

855-045-0540

Compounding Personnel and Responsibilities

(1) All personnel, who prepare and supervise the preparation of compounded pharmaceuticals must be provided with appropriate training and testing before they begin to prepare or supervise preparation of such compounded products, including theoretical principles and practical skills of manipulations.

(2) All personnel must possess the education, training and competency necessary to properly and safely perform compounding duties undertaken or supervised.
(3) 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.

(4) The pharmacist in charge (PIC) and the drug outlet must establish pharmacy’s standard operating procedures and processes in accordance with the guidelines of current USP Chapters, as applicable, for all compounding related activities of the pharmacy and is responsible for the overall ongoing validation of the compounding competency of pharmacists and technicians.

(5) A pharmacist who engages in compounding must:

(a) Perform and document the review and verification of each step of the compounding process;

Or (a) is responsible for the review and verification of each step of the compounding process

(b) Provide written information about the compounded preparation’s active ingredient(s) to the patient at the time of dispensing. If there is no written information available, the patient must be advised that the drug had been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the medication; and

(c) Compound batch sizes that have been determined are of an appropriate size to maintain product integrity and safety.

(d) Maintain proper BUDs for all compounded preparations, including aliquots.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
OAR 855-045-0550

Labeling

(1) In addition to the labeling requirements as specified in Division 41, the label of a compounded drug or medication order dispensed or distributed must contain the following, at a minimum:

(a) The generic or official name of each active ingredient;

(b) The strength or concentration of each active ingredient;

(c) The name of the base or diluent;

(d) The dosage form or route of administration;

Commented [KF*B24]: Suggestion to remove (a) per “It is common practice for a pharmacy technician to perform steps of a compounding process with pharmacist verification at the end of the process or at key points in the compounding process. It would be extremely burdensome for a pharmacist to perform each step of a compounding process.”

Commented [KF*B25]: Clarification and suggestion to remove: “It is unclear if this rule was meant for institutional pharmacies who compound or just retail pharmacy outlets. It would be extremely burdensome for a pharmacist to notify every patient in the institutional outlet (“inpatient”) or retail outlet (“ambulatory infusion centers”) when their medication was compounded.

Commented [KF*B26]: Will the Board consider allowing common acronyms, as there may be a long list of ingredients?

Commented [KF*B27]: Is this needed? Comment suggested this is tedious Comment proposed changing wording to: “The name of the base, diluent, or primary excipient.”
(e) The total quantity of the drug product;

(f) A beyond-use-date (BUD), compliant with current USP chapters;

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

(h) A statement that the product has been compounded by the pharmacy (An auxiliary label may be used on the container to meet this requirement).

(2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the compounded drug dispensed or distributed must contain the following, at a minimum:

(a) The name, quantity and concentration of the drug added and the primary solution;

(b) The beyond use date, to include date and time;

(c) Recommended frequency/schedule for administration;

(d) The infusion rate, when applicable;

(e) The name or initials of person performing admixture;

(f) The identification of the pharmacy where the admixture was performed; and

(g) The name or initials of the verifying pharmacist.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
855-045-0560
Quality Controls for Compounding

(1) The pharmacist-in-charge and drug outlet must develop and the pharmacy must follow quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation.

(2) The pharmacist-in-charge must adhere to the provisions of all applicable USP chapters for development and ongoing adherence to quality control procedures. Such procedures must be documented and be available for inspection.

(3) The pharmacist-in-charge must establish a written adverse event reporting process and recall procedure. The recall procedure must include notification to the Board in the event of a patient-level recall of a compounded drug product.
Records

(1) All compounding records, including training documents, master formulation records, compounded preparation records, and individual prescription records, must be maintained electronically or manually, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board.

(2) The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations. At a minimum, the record must contain:

(a) Documentation of initial and continuing competency, training, and education for personnel; and

(b) Name and signature of the PIC or other pharmacist employed by the pharmacy who is designated as responsible for validating the completion of all training.

(3) The pharmacy must maintain an organized index of master formulation records for all compounded products.

(4) Records for compounding must utilize a master formulation record. All master formula records must be developed and approved by the pharmacist for compounded preparations, and records for all preparations must contain, at a minimum:

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

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

(c) Description of all ingredients and their quantities;

(d) Compatibility and stability information, including references when available;

(e) Equipment needed to prepare the preparation when appropriate;

(f) Mixing instructions that must include:

(A) Order of mixing;

(B) Mixing temperatures or other environmental controls;

(C) Duration of mixing; and
(D) Other factors pertinent to the replication of the preparation as compounded.

(g) Sample labeling information, to contain, at a minimum:

(A) Generic name and quantity or concentration of each active ingredient;

(B) Assigned BUD;

(C) Storage conditions; and

(D) Prescription or control number, whichever is applicable.

(h) Containers and closures used in dispensing;

(i) Packaging and storage requirements;

(j) Descriptions of final preparation;

(k) Quality control procedures and expected results; and

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

(5) Any compounded product must be documented and the unique compounded preparation record, must include but not be limited to the following:

(a) Name, strength, and dosage of the preparation;

(b) Master Formulation Record reference for the preparation;

(c) Names and quantities of all components;

(d) Sources, lot numbers and expiration dates of components;

(e) Total quantity compounded;

(f) Name of the person who prepared the preparation, name of the person who performed the quality control procedures, and name of the compounder who approved the preparation;

(g) Time and date of preparation;

(h) Assigned control or prescription number;

(i) Assigned BUD;

Commented [KF=B38]: Question: Does technician/pharmacist initials suffice here? Or do we need 3 initials now?
(j) Physical evidence of the proper weight of each ingredient;

(k) Duplicate label as described in the Master Formulation Record;

(l) Description of final preparation;

(m) Results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)

(n) Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

Commented [KF*B39]: MULTIPLE Comments:

"It is not practical for every ingredient to have documentation of proper weight, as often volume is sufficient. Requiring physical evidence would be extremely costly for outlets in Oregon. Additionally, it is not clear if a pharmacist signature would suffice this rule or if actual documentation of the physical weight or volume is necessary (i.e., picture or scale recordings). Again, requiring documentation of a picture or scale recordings would be extremely costly for outlets in Oregon. Our recommendation is for the rule to be changed to "physical evidence of proper weight or volume of each ingredient" and that a pharmacist signature be acceptable.

Question: Is this for sterile and non-sterile or non-sterile only?

What’s an example of what OBOP would like to see for this?

Analytical scales attached to computers have their data recorded electronically when capturing tares and weights—there is no physical evidence.

If kept, consider adding "volumes" (as well as weights)

Re-write "Documentation of the proper weight and amount of each ingredient."

Commented [KF*B40]: Question: Would a barcode that contains this suffice?

Staff response: Per P&P, so long as the barcode connected to the Master Formulation Record of THAT particular preparation.
STERILE COMPOUNDING

855-045-0600

Purpose – Sterile Compounding

The requirements of this chapter apply to any person or facility that compounds sterile drug preparations (CSPs). These rules represent minimum sterile compounding practices for the preparation of drug products to be dispensed or administered. The minimum standards of the current edition of the United States Pharmacopeia Chapter <797> and all other applicable USP Chapters regarding sterile compounded products must be met unless requirements listed are more stringent.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
OAR 855-045-0610

Personnel Compounding Sterile Preparations (CSPs)

(1) These rules apply to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared.

(2) Compounding personnel are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.

(3) Documented related training for each person, including temporary personnel, must be performed and completed by the PIC or other supervising pharmacist prior to sterile compounding or supervising the preparation of sterile preparations, and must include, at a minimum:

(a) Fundamentals of sterile compounding manipulations;

(b) Responsibilities of compounding personnel;

(c) Purpose and utilization of policies and procedures;

(d) Use of all applicable equipment and supplies, to include automated compounding devices;

(e) Facility and personnel environmental sampling metrics, to include but not limited to:

(A) Garbing competency;

(B) Hand hygiene and proper work practices competency, via gloved fingertip sampling;

Commented [KF*B41]: Will the Board want to remove any of these components, if they are ultimately removed from USP?

This section outlines the required P&P and documented training for persons compounding Sterile preparations.

Commented [KF*B42]: (See also line 245) Question/Comment: Can a technician do this? Says must be performed and completed by a pharmacist, but technicians are often a better choice.

Consider incorporating “Assigned duties” to allow for more specificity, so that not ALL persons have to be trained in ALL facets of sterile compounding, but rather only in the assigned duties they are performing.

Commented [KF*B43]: Propose: Documented training and competence for each person, including temporary personnel, must be verified by the PIC or other supervising pharmacist prior to sterile compounding or supervising the preparation of sterile preparations, and must include, at a minimum:
(C) Media-fill testing of aseptic manipulation competency, at least annually for low and medium-risk level compounding and semi-annually for high-risk level compounding; and

(D) Cleaning and disinfecting competency, to include surface sample testing;

(f) Understanding of primary and secondary engineering controls, such as function, use, testing, and certification;

(g) Assignment of BUDs;

(h) Quality assurance, quality releases and final checks of CSPs;

(i) Labeling and packaging controls;

(j) Batch documentation;

(k) Cleaning and disinfecting of controlled environments;

(l) Filtration and sterility processes, moist and dry-heat sterilization, bacterial endotoxin (pyrogen) testing, as applicable to risk level; and

(m) Hazardous drug material handling and disposal.

(4) Personnel who fail any element of subsection (3) must be re-instructed and re-evaluated by trained sterile compounding personnel prior to performing compounding duties. Documentation to be kept on file for 3 years.

(5) The Pharmacist-In-Charge (PIC) must possess the education, training and proficiency necessary to properly and safely perform compounding duties undertaken or supervised.

(6) The PIC and drug outlet must establish and enforce written policies and procedures in compliance with standards set forth in the current Chapters of USP and USP-NF, and are designed to ensure accountability, accuracy, quality, safety and uniformity in the sterile compounding process. They must include but not be limited to:

(a) Education, training, and competency evaluation of all regular and temporary personnel;

(b) Proper hand hygiene and garbing for all CSP compounding;

(c) Proper maintenance and calibration of primary and secondary engineering controls as well as other areas and equipment used in the compounding process;

(d) Compounding procedures including but not limited to the use of automated compounding devices, and other specific procedures for CSPs.
(e) CSP compounding methodology and formula information, to include assignment of appropriate risk levels for all CSPs;
(f) Determination of beyond-use-dates;
(g) For non-sterile-to-sterile batch compounding, written policies and procedures must include:
   (A) Process validation for chosen sterilization methods; and
   (B) End-product evaluation, quantitative, and qualitative testing;
(h) Appropriate sterilization and other preparation checks and release tests of CSPs;
(i) Verification of compounding accuracy and sterility for CSPs;
(j) Labeling, to include all names and amounts/concentrations of active ingredients;
(k) Proper maintenance of environmental quality and control, to include appropriate environmental sampling testing;
   "For discussion: Include a new section for environmental controls?"
(l) Finished preparation release checks and tests;
(m) Cleaning and disinfecting the direct and contiguous compounding areas;
(n) Recall procedures for CSPs;
(o) Drug disposal, including hazardous waste if applicable. Hazardous waste disposal must comply with all federal and state regulations;
(p) Procurement, container selection, shipping, delivery and storage of pharmaceutical materials including compounded drug preparations and components used in the compounding of sterile preparations and drug delivery devices;
(q) Patient care and instructions;
(r) Quality assurance and control, to include adverse event and recall reporting per OAR 855-045-0570.
(7) A pharmacist who compounds or supervises sterile preparations must:
   (a) Possess the education, training and proficiency required to properly and safely perform compounding duties undertaken or supervised;
Commented [K*B46]: As it is currently written, the proposed rules seem to indicate that any non-sterile-to-sterile preparation of more than one vial or container would require sterility and end-product testing. Concerned that this requirement could have a substantial negative impact on patient care and access. For example, preservative-free dosage forms are individually packaged and would seem to require sterility and end-product testing under the proposed rules. The delayed access and increased cost associated with these requirements could prevent patients from receiving their much-needed medications. USP General Chapter <797> currently indicates sterility testing and bacterial endotoxin [pyrogen] testing should be done for high-risk level CSPs prepared in batches of more than 25 identical containers.
Propose: adding “when appropriate” to (B)
Commented [K*B47]: Comments included:
A few of the hot topics that are not outlined well in current 797:
   Ante room pressure requirement. Some people read the chapter and think the buffer room only has to be positive to the general area, but there shall be a differential between each ante room to general of minimum 0.020” water column. The non-hd shall be 0.020” to ante and HD rooms are -0.010” to -0.030” to ante or wherever they are accessed from. Airflow displacement should be discouraged (40 fpm or meat curtains).
   Airflow visualization studies (often called smoke studies). Clearly required at no frequency in 797 and 800 in the hoods. Some people want to make those required every 6 months, I think that is bad and could write a book to you as to why. I suggest airflow visualization be required for hoods AND rooms every 4 years or when changes are made to layout, HVAC or process.
   Turbulent flow ISO 5 areas are not allowed in 797, but people are still using turbulent flow isolators as well as poorly designed integrated iso 5 areas.
   HEPA filter integrity for the clean rooms is suggested in current 797, I am told it will be required in new 797. It would be nice to just be able to do it and stop the back and forth arguing with clinical IQ, who believe it is required now.
   Room temp. Currently 797 says should be below 20 C, 800 says shall, new 797 will likely be shall. Clarifying now might help a lot of poor, sweaty techs (and certifiers).
   Dynamic vs static viables and non-viable sampling. There is no question that dynamic/operational (should be called operational really) is the requirement, but it’s not done at MANY locations.
(b) Successfully complete the required competency training appropriate for the type of compounding performed or supervised;

(c) Inspect and approve all ingredients, drug preparation containers, closures, labeling, and any other materials involved in the compounding process;

(d) Review all compounding records for accuracy and conduct in-process and final checks to ensure that safe compounding processes have occurred in the compounding process; and

(e) Ensure proper maintenance, cleanliness, calibration, and use of all equipment used in the compounding process.

(f) Compound batch sizes that the pharmacist has determined are of an appropriate size to maintain product integrity and safety.

(8) A pharmacy technician who compounds sterile preparations must:

(a) Possess the education, training and proficiency as required to properly and safely perform compounding duties undertaken;

(b) Successfully complete the required competency training appropriate for the type of compounding performed by the pharmacy technician;

(c) Respond to in-process and completion checks;

(d) Maintain appropriate records; and

(d) Ensure proper maintenance, cleanliness, and use of all equipment used in the compounding process.

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

OAR 855-045-0620

Microbial Contamination Risk Levels and Beyond-Use-Dates

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, including Immediate-use provisions, are defined, and products must be prepared and managed per current USP standards.

Commented [KF*B48]: Subject to change with Chapter re-writes
Records

(1) In addition to the requirements set forth in 855-045-0580, records for all compounded sterile products (CSPs) must include:

(a) Primary solution;

(b) Container specification (e.g., syringe, pump cassette); and

(c) Infusion rate, when applicable.

(2) Sterile compounding training documentation must include:

(a) Printed name and signature of the person receiving the training;

(b) Name and signature of the person providing the training or evaluating competencies; and

(c) Dates and results of all elements found in OAR 855-045-0610(3).

(3) Records of maintenance and certifications for all equipment, including environmental sampling must be maintained electronically or manually, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board.

(4) Records of cleaning and disinfecting of all compounding areas and equipment must be maintained electronically or manually, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board.

(5) All records, procedures, training, and documentation must be maintained electronically or manually, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board.
## Committee Members

- Laura Abrahamson, RPh – Industry Representative
- Jason Boeshans, RPh – Pharmacist-In-Charge Representative
- Laura Churns, RPh – Industry Representative
- Anna Emoto, RPh – Staff Pharmacist Representative
- Dan Kennedy, RPh – Hospital Representative
- Yolanda Marcotte, CPhT – Technician Representative
- Jill McClellan, RPh – Pharmacist-In-Charge Representative
- Blake Rice, RPh – Former Board of Pharmacy Member Representative
- Elizabeth Scheer, RPh – Pharmacist-In-Charge Representative
- Carrie Senn, RPh – Staff Pharmacist Representative
- Lorri Walmsley, RPh – Industry Representative

### OBOP Staff to Committee

- Marcus Watt, Executive Director
- Karen MacLean, Administrative Director
- Fiona Karbowicz, Pharmacist Consultant

## Agenda Item | Desired Outcome
--- | ---
Welcome | Roll call
 | Introductions
Committee Business | Committee Overview and Purpose
 | The PIC / Community Pharmacy Personnel and Compliance Rules Advisory Committee (RAC) was selected to discuss the language and impacts of the Board’s draft rules. The Board was seeking input related to the policy directives the rule clarifies, as well as the potential fiscal impact. This RAC provides the structure for stakeholder and industry insights.

Pharmacist Consultant Fiona Karbowicz presented an informational set of slides, defining a rule, providing a background of agency promulgation of rules, and outlining the purpose of a RAC. The presentation described the objectives of these Personnel/Compliance rules as well as the context and considerations for the RAC. (see pg. 4-21 of this document)

Committee Dialogue
Committee members shared concerns, opinions and personal experiences related to this topic. They discussed why the rules are and are not necessary. As a way to invoke as much dialogue as possible, members took additional turns to speak, as often the sharing by one member inspired another’s thoughts.

Points shared are provided:

- Staffing concerns and the need to allow a PIC to “run the pharmacy”
- Looking at this from a national perspective, there are no other states where rules such as this exist; there is a hope that these concerns can be addressed
in other ways and there is not a need for this in other states – rule is not necessary

- Concerned about the negative impact on patients, if PICs are allowed to make decisions on the services provided
- Pharmacists feel that they are being put in unsafe working conditions, as they are stuck in the push/pull of business needs vs. patient needs
- There is a shared accountability when decisions are made externally by non-licensed persons; one member suggested this could be looked at from the hospital perspective - hospital administrators are not typically mandated to be a physician
- A new PIC will have lots of questions and needs support from corporate; if the person is a non-pharmacist, he/she is not often qualified to provide the appropriate answer, legally or clinically, etc.
- Per the challenges shared by the Board, related to non-licensed supervisory personnel directing pharmacists, such as inappropriate clinical directives (give an immunization or medication, when it is not clinically warranted) or non-licensed corporate liaison not providing investigatory information requested by Board inspectors, it was suggested that the Board can rely upon current processes for obtaining information and investigations of specific wrong-doing rather than put this rule in place
- Challenges reported that it may be even more difficult to hire PICs and supervisors if these rules are adopted. By requiring Oregon pharmacist licensure, it limits potentially great employees from supervisory positions; a company wants to always hire the most qualified person, and a Supervisor’s skill set is different than a PIC’s; another member shared that her company deems the “best qualified person” to be a licensed pharmacist in all states where they work – maybe the rules can allow a grace period for pharmacist licensure, such as 90 days
- In light of the PIC shortage we currently have, concerns that this language will make this situation worse; another member shared the PIC shortage may be due to the fact that currently PICs have limited autonomy
- A member had been asked to do something illegal by a non-licensed supervisor and there is a general tone that the company doesn’t care about this wrong-doing, they will just pay the fine and move on; there are hotlines that an employee can use for specific circumstances, such as these; another member shared that she worked for a non-pharmacist DM who did not understand how a pharmacy runs – they lost a lot of good employees due to this person and her lack of knowledge
- Concern that the current language is too broad for PIC responsibilities; The PIC responsibilities, as currently written are concerning, particularly from a liability standpoint; other members shared concerns with the PIC language and do not see the direct tie to increased patient safety; Do these rules add more to a PIC’s plate? They are already so busy
- We work in a broken healthcare system – cannot see how the PIC rules will improve patient outcomes
- One member’s spouse got a license in another state because of the professional expectations
- Committee members shared thoughts on the challenges of being a PIC and of being a PIC at 2 locations simultaneously
<table>
<thead>
<tr>
<th>Review of Draft Proposal &amp; Fiscal</th>
</tr>
</thead>
<tbody>
<tr>
<td>With approximately 30 minutes remaining for the meeting, Committee members went around the room providing suggestions for edits and enhancements to the rules, in the event that the Board considers moving forward with proposed rules. The draft with comments and suggested edits is provided. (see pg. 22-25 of this document)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Good of the Order</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrap up and next steps – It was determined that the Committee’s work is not complete. We will attempt to schedule a second meeting prior to the Board’s upcoming August meeting, if that is possible. Administrative Director Karen MacLean will work with member’s availability via Doodle Poll.</td>
</tr>
<tr>
<td>Next meeting - TBD</td>
</tr>
</tbody>
</table>
PIC & COMMUNITY PHARMACY PERSONNEL/COMPLIANCE RULES

OREGON BOARD OF PHARMACY RULES ADVISORY COMMITTEE (RAC) MEETING – JUNE 29, 2018
WHAT IS A RULE?

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

ORS 183.310(9)
WHERE ARE RULES FOUND?

• Oregon Administrative Rules (OAR) - official compilation of rules & regulations having the force of law in Oregon

• Compiled & issued annually by the Secretary of State’s Archives Division

• Monthly updates, including notice of intended rule action, in Oregon Bulletin
  - http://arcweb.sos.state.or.us/pages/rules/bulletin/past.html
WHEN IS A RULE REQUIRED?

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

**Tip:** Statute mandates *what*, and the rule mandates *how* (implementation)
WHEN IS A RULE NOT REQUIRED?

• When the rules for the sections of the legislation are clear enough to administer without rulemaking.

• When the agency merely interprets an existing rule (unless the interpretation changes – this can occur pursuant to contested cases, for example)
May be established and used for rules in which there are issues that may substantially impact the interests of persons or entities ("stakeholders"), who will likely be affected by the proposed rulemaking.
**RULES ADVISORY COMMITTEE - PURPOSE**

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

*A RAC’s role is advisory only.*
PERMANENT RULEMAKING PROCESS

• Agency notifies rules coordinator of rulemaking content and timeline

• Agency provides notices to legislators, “interested parties,” & public, seeking input to rules; May utilize a RAC

• Agency describes fiscal impact on entities, including small businesses

• Agency conducts public hearing and provides opportunity for oral testimony and written comments on proposed rules (rulemaking record)

• Agency considers all input and finalizes rules

• Agency submits final rules to Secretary of State
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.
PROPOSED RULES - OBJECTIVES

- Current edits proposed to Division 019 (Pharmacists) and 041 (Drug Outlets) address Retail/Community Pharmacy Drug Outlet personnel and compliance requirements:
  - Explain that a person who directs the professional activities of PICs must obtain licensure as an Oregon Pharmacist (RPH)
  - Clarify the roles and responsibilities of an Oregon Pharmacist-in-Charge (PIC)
RELATED STATUTES

• **ORS 689.005(30)(k)** The practice of pharmacy means the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy.

• **ORS 689.205** The State Board of Pharmacy shall make, adopt, amend and repeal such rules as may be deemed necessary by the board, from time to time, for the proper administration and enforcement of this chapter. Such rules shall be adopted in accordance with the procedures specified in ORS chapter 183.

https://www.oregonlegislature.gov/bills_laws/ors/ors689.html
CONTEXT / CONSIDERATIONS

• Changes in the practice and industry trends
  • Independent vs. Chain pharmacies

• Increase in the number of “District Area Managers” who are non-pharmacists or non-Oregon licensed pharmacists

• PICs increasingly powerless to practice according to their own professional judgment
COMMITTEE MEMBER
SHARING & DIALOGUE
(2) Each resident community pharmacy that employs a person who (directly supervises) and directs (multiple) PICs shall ensure that the person is an Oregon licensed pharmacist.

*Alternative:*

(2) Each resident community pharmacy that employs a person who directs the professional activities of PICs shall ensure that:

(a) The person is an Oregon licensed pharmacist; and

(b) When a vacancy occurs, the pharmacy will notify the Board within ten business days
RULE DRAFT – PIC LANGUAGE

(1) Each community pharmacy drug outlet (RP) must have an Oregon licensed pharmacist designated as Pharmacist-in-Charge (PIC) who is responsible for the daily operations of the pharmacy. The PIC is responsible for exercising professional judgment and discretion to ensure a pharmacy environment that is safe and effective, and fulfils the responsibilities listed in Division 019.
(4) The PIC is responsible for exercising professional judgment and discretion to ensure a pharmacy environment that is safe and effective, to include:

(a) Assessing pharmacy demand, and workload;

(b) Evaluating pharmacy staffing, inventory, resources, and capacity;

(c) Prioritizing pharmacy tasks, responsibilities, and assignments; and

(d) Modifying pharmacy workflow and services provided.
Identify state agencies, units of local government, and members of the public likely to be economically affected by the rules

Effects on small businesses
*THANK YOU* 
VERY MUCH 

We appreciate your participation in this important work!
General Community Pharmacy

855-041-2105 Personnel

(1) Each community pharmacy drug outlet (RP) must have an Oregon licensed pharmacist designated as Pharmacist-in-Charge (PIC) who is responsible for the daily operations of the pharmacy. The PIC is responsible for exercising professional judgment and discretion to ensure a pharmacy environment that is safe and effective, and fulfills the responsibilities listed in Division 019.

Possibly a hybrid of the follow proposed wording for sub (2)?

(2) Each resident community pharmacy that employs a person who directly / immediately supervises and directs the professional activities of a PIC shall ensure that the person is an Oregon licensed pharmacist.

Alternative

(2) Each resident community pharmacy that employs a person who directly oversees the professional activities of PICs shall ensure that:

(a) The person is an Oregon licensed pharmacist; and

(b) When a vacancy occurs, the pharmacy will notify the Board within ten business days.

Is a vacancy allowed – is there a need to define timeframe? Is the person working to obtain active licensure? Challenge for niche-pharmacies...

Alternative

(2) Each resident community pharmacy that employs a person who directly / immediately supervises and directs the day-to-day professional activities of multiple PICs shall ensure that the person is an Oregon licensed pharmacist or is an individual licensed with the Board and who completes a Board approved training program.

Does it have to be an RPH? Or can it be any licensee (for the Board’s regulatory “tie”?)

Require that the DM (non-licensed and/or OR-licensed) take a PIC Training-type program (would need to be a different class), instead of this licensure requirement. It was noted this may be a staff burden to create a new class.

-lets people know what the Board’s expectations are... terminology/practice of pharmacy elements would need to be identified when teaching non-licensed/non-RPH individual

-class plus the DM’s commitment to the position creates the tie to the Board

-a 3 hour class vs. real-life experience (skepticism was noted)

General question: Is there a ratio/max of number of PICs a DM shall directly supervise?
Pharmacist-in-Charge
855-019-0300

Duties of a Pharmacist-in-Charge

(1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) employed on a regular basis at that location who is responsible for the daily operation of the pharmacy.

(2) In order to be a PIC, a pharmacist must have:

(a) Completed at least one year of pharmacy practice; or

(b) Completed a Board approved PIC training course either before the appointment or within 30 days after the appointment. With the approval of the Board, this course may be employer provided and may qualify for continuing education credit.

(3) A pharmacist may not be designated PIC of more than two pharmacies without prior written approval by the Board. If such approval is given, the pharmacist must comply with the requirements in sub section (4)(e) of this rule. A pharmacist may be designated as a PIC of up to two Oregon licensed pharmacies only upon notification of the second site to the Board in writing within 15 days.

(4) The PIC is responsible for must perform the following the duties and responsibilities:

exercising professional judgment and discretion to ensure a pharmacy environment that is safe and effective, to include:

(a) Assessing pharmacy demand, and workload;

(b) Evaluating pharmacy staffing, inventory, resources, and capacity;

(c) Prioritizing pharmacy tasks, responsibilities, and assignments; and

(d) Modifying pharmacy workflow and services provided.

Alternative

(4) The PIC shall must perform the following the duties and responsibilities:

exercise professional judgment and discretion to ensure a pharmacy environment that is safe and effective, which may include / such as:

(a) Assessing pharmacy demand, and workload;

(b) Evaluating pharmacy staffing, inventory, resources, and capacity;

(c) Prioritizing pharmacy tasks, responsibilities, and assignments; and

(d) Modifying pharmacy workflow and services provided.
Mandate notification to upper management and/or Board when issues arise?

Concerns that PICs will not want to take on this position, thinking that these are new requirements.

If removed, can a-d be articulated by the Board in policy vs. in rule?

(5) The PIC must perform the following duties and responsibilities:

(a) When a change of PIC occurs, both outgoing and incoming PICs must report the change to the Board within 15 days of the occurrence, on a form provided by the Board;

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;

(c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0420-6310;

(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a pharmacist;

(e) A pharmacist designated as PIC for more than one pharmacy shall personally conduct and document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC Compliance Audit Form provided by the Board;

(f) If a discrepancy is noted on a Board inspection, the PIC must submit a plan of correction within 15 days for a Non-Compliance Notification and 30 days of receiving a Deficiency Notice.

(g) The records and forms required by this section must be filed in the pharmacy, made available to the Board for inspection upon request, and must be retained for three years.

(5) The PIC is responsible for ensuring that the following activities are correctly completed:

(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;

(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the Board;

(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the Board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;

(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;
(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs;

(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;

(g) Implementing a *Maintaining the continuous* quality assurance plan program for the pharmacy;

(h) The records and forms required by this section must be filed in the pharmacy, made available to the Board for inspection upon request, and must be retained for three years.

(6) (7) The PIC, *along with other pharmacy and supervisory personnel* licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.

*Strengthens the outlet’s shared responsibility, and the “ownership” by the supervisory personnel*

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155
855-041-1120

Prescription Refills

(1) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions for controlled substances in Schedules III and IV are limited to five refills or six months from date of issue, whichever comes first.

(2) If the practitioner is not available and in the professional judgment of the pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the pharmacist may dispense a sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner shall be promptly notified of the emergency refill.

(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include;

(a) The identity of the responsible pharmacist;
(b) Name of the patient;
(c) Name of the medication;
(d) Date of refill; and
(e) Quantity dispensed.

(4) Refill quantities may be combined into a single filling if the prescription is not for a controlled substance or psychotherapeutic drug and the prescriber is notified of the change.

(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient’s agent. A request specific to each prescription medication is required, unless the requested fill or refill is part of an auto-refill program and is a continuation of therapy.

(6) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may use a program that automatically refills non-controlled prescription medications that have existing refills available and are consistent with the patient’s current medication therapy only when the following conditions are met:

(a) A patient or patient’s agent must enroll each prescription medication in an auto-refill program before a pharmacy can include the prescription medication as part of the auto-refill program; and
(b) The prescription is not a controlled substance; and
(c) The pharmacy must discontinue auto-refill program enrollment when requested by the patient or patient’s agent; and
(d) Pick-up notification to a patient or patient’s agent may be generated upon completion of a prescription refill; and

Oregon Board of Pharmacy

July 10, 2018
(e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription medication is removed from the auto-refill program for that patient.

(7) An automated reminder cannot be used to generate a prescription refill unless the patient or patient’s agent provides authorization for each individual prescription refill. The content of each reminder must include:

(a) Drug name and strength; and

(b) Date of last fill.

(8) Pick-up notification to a patient or patient’s agent may only be generated upon full completion of the prescription refill.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505, 689.515 & 2013 OL Ch. 342
Date: 7/2/2018

Request/Inquiry Type: Temporary exception related to drug shortages

- **Question(s):** Will the Oregon Board of Pharmacy allow a temporary exception to USP 797 beyond use dating for repackaged injectable opioids allowing hospitals to assign a 6 day beyond use date for repackaged injectable opioids when stored at room temperature?

- **Background:**
  - There is currently a nationwide injectable opioid shortage being referred to as “the other opioid crisis.” This shortage is expected to last into 2019.
  - Hospitals are buying whatever dosage form that is available and this often results in purchasing of dosage sizes that are larger package size than needed for a single dose (e.g. hydromorphone 2mg vial when average dose is 0.5mg). As a result, many hospitals have started or are contemplating repackaging these larger doses into smaller doses to avoid waste of a drug that is in critically short supply.
  - Based on USP 797 standards and OAR 855-045-0250, hospitals repackaging opioids are assigning a 30 hour beyond use date for room temperature storage under the medium risk compounded sterile product (CSP) classification. Extending this beyond use dating to 6 days would allow for significantly less waste of expiring product and less burdensome impact on staff repackaging injectable opioids.
  - The request for 6 day beyond use dating at room temperature comes from the latest draft USP 797 guidelines. These guidelines classify CSPs prepared in a cleanroom environment as category 2 CSPs and may be given a 6 day beyond use date if prepared from only sterile starting components.¹ For your reference, the next page of this request includes the Table from the draft standards with inclusion of 6 day room temperature beyond use dating.
  - Oregon hospitals are struggling to continue to supply injectable opioids to patients needing intravenous pain management including surgical patients, oncology patients and hospice patients. This temporary measure would allow for hospitals to continue to provide essential pain management to some of our most vulnerable patients.
Representatives from the following hospitals and health systems discussed this request and indicated their support on 5-22-18:
- Legacy, Providence, Samaritan, Peacehealth, Asante, Salem Health, St. Charles, Willamette Valley Medical Center, Adventist, Tuality, Oregon State Hospital, Kaiser Permanente.

**Discussion:**
- The following table from the draft USP 797 update supports a 6 day BUD for CSPs stored at controlled room temperature
<table>
<thead>
<tr>
<th>Method of Achieving Sterility</th>
<th>Sterility Testing Performed</th>
<th>Preservative Added</th>
<th>Controlled Room Temperature (20°–25°)</th>
<th>Refrigerator (2°–8°)</th>
<th>Freezer (−25° to −10°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aseptically prepared CSPs</td>
<td>No</td>
<td>No</td>
<td>Prepared from one or more nonsterile starting component 4 days</td>
<td>Prepared from one or more nonsterile starting component 7 days</td>
<td>Prepared from one or more nonsterile starting component 45 days</td>
</tr>
<tr>
<td>BUD</td>
<td></td>
<td>Yes</td>
<td>28 days</td>
<td>42 days</td>
<td>45 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>28 days</td>
<td>42 days</td>
<td>45 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes†</td>
<td>42 days</td>
<td>42 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Terminally Sterilized CSPs</td>
<td>No</td>
<td>No</td>
<td>Prepared from only sterile starting components 6 days</td>
<td>Prepared from only sterile starting components 9 days</td>
<td>Prepared from only sterile starting components 45 days</td>
</tr>
<tr>
<td>BUD</td>
<td></td>
<td>Yes</td>
<td>28 days</td>
<td>42 days</td>
<td>45 days</td>
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<td></td>
<td>Yes†</td>
<td>42 days</td>
<td>42 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

* The BUDs specified in the table indicate the days after the Category 2 CSP is prepared beyond which the CSP cannot be used. The BUD is determined from the time the CSP is compounded. One day is equivalent to 24 hours.

* The integrity of the container–closure system with the particular CSP in it must have been demonstrated for 45 days at frozen storage. The container–closure integrity test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

* The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with (51) at the time of preparation. The test must be completed and the results obtained on the specific formulation before any of the CSP is dispensed. The test needs to be conducted only once on each formulation in the category.

• **Related ORS/OARs:**
  Division 45 Sterile and Nonsterile Compounding
  855-045-0250
  Definitions of Risk Levels for Sterile Preparations
  (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.

**Requester’s Contact Info:**
Daniel M. Rackham, Pharm.D., BCPS | Pharmacy Manager
Samaritan Lebanon Community Hospital | 525 N. Santiam HWY | Lebanon, OR 97355
p: 541.451.7551 | f: 541.451.7563 | drackham@samhealth.org
Dear Oregon Board of Pharmacy,

There is currently a nationwide injectable opioid shortage being referred to as “the other opioid crisis.” This shortage is expected to last into 2019. Hospitals are buying whatever dosage form that is available and this often results in purchasing of dosage sizes that are larger package size than needed for a single dose (e.g. hydromorphone 2mg vial when average dose is 0.5mg). As a result, many hospitals have started or are contemplating repackaging these larger doses into smaller doses to avoid waste of a drug that is in critically short supply.

On behalf of the health system pharmacists in Oregon we are requesting a temporary exception to USP 797 beyond use dating for repackaged injectable opioids. Our request is to temporarily allow hospitals to assign a 6 day beyond use date for repackaged injectable opioids when stored at room temperature.

Based on USP 797 standards, hospitals repackaging opioids are assigning a 30 hour beyond use date for room temperature storage under the medium risk compounded sterile product (CSP) classification. Extending this beyond use dating to 6 days would allow for significantly less waste of expiring product and less burdensome impact on staff repackaging injectable opioids.

The request for 6 day beyond use dating at room temperature comes from the latest draft USP 797 guidelines. These guidelines classify CSPs prepared in a cleanroom environment as category 2 CSPs and may be given a 6 day beyond use date if prepared from only sterile starting components. For your reference, the second page of this letter includes the Table from the draft standards with inclusion of 6 day room temperature beyond use dating.

Oregon hospitals are struggling to continue to supply injectable opioids to patients needing intravenous pain management including surgical patients, oncology patients and hospice patients. This temporary measure would allow for hospitals to continue to provide essential pain management to some of our most vulnerable patients.

Thank you for considering this request.

Representatives from the following hospitals and health systems discussed this request and indicated their support on 5-22-18:

- Legacy, Providence, Samaritan, Peacehealth, Asante, Salem Health, St. Charles, Willamette Valley Medical Center, Adventist, Tuality, Oregon State Hospital, Kaiser Permanente.

Sincerely,

Dan Rackham, PharmD, BCPS
Pharmacy Manager, Samaritan Lebanon Community Hospital
President, Oregon Society of Health System Pharmacist 2017-18

Reference
<table>
<thead>
<tr>
<th>Method of Achieving Sterility</th>
<th>Sterility Testing Performed</th>
<th>Preservative Added</th>
<th>Controlled Room Temperature (20°–25°)</th>
<th>Refrigerator (2°–8°)</th>
<th>Freezer (−25° to −10°)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BUD</strong></td>
<td>No</td>
<td>No</td>
<td>Prepared from one or more nonsterile starting component 4 days</td>
<td>Prepared from only sterile starting components 6 days</td>
<td>Yes* 28 days 42 days 45 days</td>
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<tr>
<td></td>
<td>No</td>
<td>Yes</td>
<td>Prepared from one or more nonsterile starting component 7 days</td>
<td>Prepared from only sterile starting components 9 days</td>
<td>No 14 days 28 days 45 days</td>
</tr>
<tr>
<td><strong>Terminally Sterilized CSPs</strong></td>
<td>No</td>
<td>Yes</td>
<td>Prepared from one or more nonsterile starting component 45 days</td>
<td>Prepared from only sterile starting components 45 days</td>
<td>No 28 days 42 days 45 days</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Prepared from one or more nonsterile starting component 45 days</td>
<td>Prepared from only sterile starting components 45 days</td>
<td>Yes* 28 days 42 days 45 days</td>
</tr>
</tbody>
</table>

* The BUDs specified in the table indicate the days after the Category 2 CSP is prepared beyond which the CSP cannot be used. The BUD is determined from the time the CSP is compounded. One day is equivalent to 24 hours.

* The integrity of the container–closure system with the particular CSP in it must have been demonstrated for 45 days at frozen storage. The container–closure integrity test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

* The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with (51) at the time of preparation. The test must be completed and the results obtained on the specific formulation before any of the CSP is dispensed. The test needs to be conducted only once on each formulation in the
Community Question related to the Pharmacy Board’s support of non-prescription syringe access

I have a question and statement regarding the board’s stance on syringes & IDU. Has or did the board consider the safety of the general public and specifically our children before policy of making syringes more available to IDUs?

It would seem that if more syringes are available, the IDUs will be more likely to discard them in public parks where children play? If the number of syringes on the street remain low, then IDUs would be less likely to dispose of them. I have taken my grandchildren to Portland public parks to play only to find used syringes on the playground.

We need to ask ourselves whose health and safety is more important, the general public, our children or a few IDU? Sure we might be solving the problem of spreading disease in the IDU community only to shift it to the larger general community.

Non-prescription syringes sales have been legal in Oregon since 1987 and currently Syringe Service Programs (SSPs) are not available in every county in our state. Pharmacies and pharmacists are important resources and allies in the efforts to prevent infections related to injection drug use. Syringe sales from pharmacies have been found to reduce injection risk behavior and HIV infections among persons who inject drugs (PWIDs) with higher individual syringe coverage strongly associated with safer injection behavior (1-3).

Improper discarding of syringes by PWIDs is often the result of the not having a free disposal options readily accessible or available, not the availability of the syringe itself.

Safety of the public, specifically children

Prompt and proper disposal of non-prescription syringes is a public health objective because re-use of single-use syringes by PWIDs to inject drugs can result in injury from a damaged needle or transmission of blood-borne infections by a contaminated syringe.

Research has demonstrated that the risk of blood-borne infection transmission from syringes improperly discarded in community settings to community members, including children, has been found to be low (4-5). However, when a needlestick injury occurs, the response and treatment protocols presume that the needle is contaminated with blood-borne pathogens and the person must endure an unsettling series of tests, including HIV and hepatitis B and C. An adult, or parent of a child, with a needlestick or sharps-related injury may have to bear the costs of post-injury testing and non-occupational post-exposure prophylaxis (PEP) for HIV, and feelings of anxiety and apprehension during waiting periods, since it takes time for blood test results to indicate infection status.

Proper syringe disposal support strategies

Strategies to reduce improper syringe disposal include

- Dedicated syringe disposal bins located in areas where improper disposal is documented;
- increased SSP sites and hours to provide additional venues for proper disposal;
- Distribution of personal-sized sharps-containers for PWIDs to store used syringes until the syringes can be properly disposed; and
- Educating pharmacists and service providers who work with PWIDs to provide information, tools (such as personal sharps containers) and encouragement to properly dispose of used syringes.

Also, there are community structures in place to address improperly discarded syringes which could be called upon with increased funding to increase efforts to remove syringe litter. For example, the Oregon Housing and Community Services (OHCS) is the state’s housing finance agency and administers programs that provide housing stabilization and ancillary services. The OHCS programs and services are delivered through local partners and syringe collection and disposal for homeless and urban camping is one of the activities that grantees may address. In Portland, the city cited in the public comment, the Homeless/Urban Camping Impact Reduction Program has an online report form and email...
address where a community member can report publicly discarded syringe collection/disposal need. Also, Multnomah County recently installed six new syringe disposal drop boxes to expand proper disposal options with community members given the opportunity to provide input on box locations.

Other examples of ways that communities have responded to improperly discarded syringes include phone numbers where members of the public can report improperly discarded syringes and health department, public works, SSPs or other groups will respond to remove reported syringes. Another example is Eugene in Lane County, where the HIV Alliance provides the public information about what to do in case of a community member is sees or is stuck by a syringe and HIV Alliance will send out a staff person to collect improperly discarded syringes reported to their agency. Lastly, HIV Alliance has also worked with the local parks departments to place tamper-proof syringe collection boxes in areas where there have been improperly discarded syringes.

**Summary**

While improperly discarded syringes is a public health issue that needs to me more effectively addressed, the solution is not to restrict syringe access for PWIDs, but to work for increased, free disposal options and strategies.

**Additional Information and Resources**

Centers for Disease Control and Prevention: [Laws related to the retail sale of syringes/needles](#)

New Jersey legislation requiring the sale of syringes by pharmacies

**Citations**


FDA Statement

Statement by FDA Commissioner Scott Gottlieb, M.D., on formation of a new drug shortages task force and FDA’s efforts to advance long-term solutions to prevent shortages

For Immediate Release
July 12, 2018

Statement

We’ve seen the number of new drug shortages steadily decline since a peak in 2011 owing to the work of the FDA, industry and other groups. Despite these efforts, we continue to see ongoing shortages of medically necessary products. Even shortages of a small number of key drugs can place a serious burden on providers. While we’ve made progress to mitigate individual shortages, we haven’t firmly impacted the underlying structural concerns that give rise to these recurring challenges. When shortages occur, practitioners are forced to ration supplies or substitute alternate drugs that in some cases compromise patient care. We need to pursue more enduring solutions.

We’ve been providing updates and information about the FDA’s efforts to prevent or mitigate drug shortages – both actions to address specific shortages and efforts that target the root causes of drug shortages in general.

At the same time, I believe that more can and must be done across our health care system to achieve more enduring solutions. We’ve recommitted ourselves to expanding our efforts to identify additional actions to prevent and address shortages and look forward to continuing to work with Congress on these efforts.

Lawmakers have recently urged us to develop new proposals for the actions that we believe could have a more enduring impact on solving these vulnerabilities. In that spirit, they’ve asked us to consider whether the FDA or other federal agencies may need additional authorities to help ensure that patients have continued access to their medicine. They have also asked us for recommendations on the policy steps we can implement to address the root causes that give rise to shortages. We are taking up this cause.
Today, I’m announcing the formation of a new Drug Shortages Task Force. It will be led by Keagan Lenihan, the FDA’s associate commissioner for strategic initiatives. I’m charging the shortages task force to delve more deeply into the reasons why some shortages remain a persistent challenge. The charge to this new task force is to look for holistic solutions to addressing the underlying causes for these shortages. The task force will expand upon the work of a group that was created by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). FDASIA gave the FDA new authorities to address drug shortages. This includes broadening the requirements that manufacturers notify us of a permanent discontinuation or temporary interruption in manufacturing, which might lead to a shortage of prescription drugs for serious illnesses. Being notified of these issues has been critically important. It has allowed the FDA to work with manufacturers to address and prevent hundreds of shortages in the past few years. Recently, we submitted our annual drug shortages report to Congress that discusses this important work. However, challenges around drug shortages persist. We must work to find new and creative ways to tackle the issue. We believe lasting solutions to this issue can’t be addressed by the FDA alone. Historically, many drugs in short supply have been low-profit margin generic medicines. Many are sterile, parenteral drugs, which can be challenging to manufacture. The low-profit margins, and the significant cost of manufacturing these complex drugs, has resulted in consolidation in the industry. The only way to produce these low-margin products profitably is to manufacture them at tremendous scale. This has resulted in fewer and fewer manufacturers for certain key products. The result is very little margin for error in this space.

It has also resulted in an under-investment in manufacturing. Manufacturing sterile, injectable drugs is not a trivial endeavor. Unless drug makers are investing in their manufacturing facilities, it can create conditions that give rise to production stoppages in order to fix manufacturing problems. With few manufacturers operating at tremendous scale, if even one of the suppliers faces manufacturing challenges, shortages can occur. I believe long-term solutions must include those that encourage companies to invest in more capacity to make these important medicines, and to produce them with robust manufacturing processes that ensure consistently available quality products. This is one area we’ll explore. But we also need to look more broadly across the entire pharmaceutical industry, health care providers, payors and government regulators for structural solutions that keep these shortages from happening. To ensure we aren’t overlooking any solutions, our task force will include not only senior leaders from the FDA, but also leaders from the Centers for Medicare and Medicaid Services (CMS) and the Department of Veterans Affairs. Collectively, they provide or pay for prescription medicine for millions of Americans.

As we stand up the task force, we intend to establish several dedicated workgroups to look at various aspects of this issue. These will include an examination of the FDA’s current authorities. It will also evaluate the reimbursement policies from CMS and other payors that could be making it difficult for companies to manufacture certain drugs profitably. I also want the task force to explore possible incentives to encourage expansion of manufacturing capacity and enhanced quality. We’ll be looking at whether it makes sense to develop a critical drugs list, or a list of essential drugs. These are medicines where it would be especially important, from a clinical perspective, to ensure
an uninterrupted drug supply. For these medicines, we may want to consider more significant interventions than we currently employ to avert shortages. One possibility might be to look at regulations coupled with additional financial incentives to market these critical access drugs. We want to make sure we aren’t discouraging investment for manufacturing drugs that are more likely to go into shortage, and thus working against our own goals. Among some of the steps that could potentially be considered, and coupled with additional incentives, are requirements for sharing additional key information from industry when they notify the agency about a possible shortage. Another consideration might be to look at whether it could help address shortages to expand the FDA’s authority to require applicants of certain drugs to conduct a risk assessment to identify the vulnerabilities in their drug supply that could cause a shortage, and to establish risk mitigation plans to address those weaknesses proactively.

As it seeks new solutions, the task force will not be operating in a vacuum. Addressing shortages and devising new, practical solutions will require input from the pharmaceutical and health care industries, patient representatives, our federal partners and Congress. We intend to engage the public and hold a meeting with stakeholders in the next several months to provide an opportunity for everyone with a stake in addressing drug shortages to come to the table. We appreciate that lawmakers are also considering this issue. As part of the task force’s work, we’ll consider how additional authorities from Congress might help better address shortages. This engagement will be critical to informing these considerations.

The task force will also be exploring manufacturing issues. The FDA is already taking steps to support new technologies that can improve manufacturing and help reduce the chance that supply disruptions will occur.

Patients expect and deserve high-quality drug products. It is the manufacturer’s responsibility to ensure that its drug products are safe, effective and of high quality. While preventing drug shortages is a top priority for the agency, we also must make sure that quality standards are not compromised. This is why we are committed to working with manufacturers to resolve quality or manufacturing problems in a sustainable way that will help ensure continued patient access to vital safe and effective drugs.

I’ve previously noted that the FDA has implemented an emerging technology program and established an emerging technology team to engage with companies about new production technologies that could, in the long run, prevent drug shortages caused by product quality and manufacturing problems. We recently announced two new initiatives regarding quality metrics, which are used in a variety of industries to monitor the quality control systems and processes that ensure quality standards are met, and to identify opportunities for manufacturing improvements. These scientific and regulatory advances can help address some of the conditions that can give rise to drug shortages.

In the meantime, the FDA’s dedicated groups of employees will continue working diligently behind-the-scenes to anticipate and help mitigate shortages. Our drug shortages staff at the FDA’s Center for Drug Evaluation and Research, who are also U.S. Public Health Service Commissioned Corps officers, worked with manufacturers to prevent 145 drug shortages in 2017. That work was on top of a nearly around-the-clock effort, along with other FDA employees, to cope with the aftermath of the 2017 Atlantic
hurricanes, which initially shut down several important medical product manufacturing facilities in Puerto Rico, exacerbating shortages of IV saline and other fluids. These dedicated Commissioned Corps officers, collaborating with other colleagues in CDER and across the FDA, worked with pharmaceutical companies to address the shortages by temporarily providing discretion to import products from other facilities and to expedite approval of new manufacturing facilities. They also worked to help expedite the review and approval of similar products from other companies. The important work they do cannot be understated. Given the tremendous impact it had on drug shortages over the last year, I’d be remiss if I didn’t mention this year’s hurricane season, which is already upon us. The FDA’s Emergency Operations Center routinely monitors storms, in conjunction with other federal agencies. Part of the FDA’s monitoring is identifying FDA-regulated facilities that could be impacted by any storms. If and when storms hit, that planning enables the agency to begin responding quickly in conjunction with other partners. Staff across the FDA stand ready to work with manufacturers to prevent and mitigate any potential storm-related drug shortages. We look forward to continuing our collaborative efforts with industry, patients, health care professionals, Congress and other stakeholders to address this vital public health issue. Our mission is to ensure that patients have access to the drugs they need. The task force will report regularly on its progress. We’ll keep the public informed about current drug shortages and our efforts to prevent and mitigate new ones. The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

Inquiries

Media

Lyndsay Meyer
240-402-5345

Consumers

888-INFO-FDA

Related Information

- Drug Shortages
- Emerging Technology Program
- Quality Metrics for Drug Manufacturing
• Statement from Douglas Throckmorton, M.D., deputy center director for regulatory programs in FDA’s Center for Drug Evaluation and Research, on the agency’s response to ongoing drug shortages for critical products

• Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA’s work to mitigate shortages of intravenous drugs, shorten supply disruptions and better predict vulnerabilities

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Page Last Updated: 07/12/2018
### Minutes

**Public Health and Pharmacy Formulary Advisory Committee Meeting**  
**July 13, 2018, 8:30am**  
**Portland State Office Building, 800 NE Oregon St. Portland, OR 97232**  
**Conference Room 1A**

#### Committee Members

- Evon Anukam, RPh  
- Kat Chinn, RN MSN  
- Sean Jones, MD  
- Amy Valdez, RPh  
- Amy Burns, Pharm D  
- Mark Helm, MD  
- Helen Turner, DNP

#### OBOP Staff to Committee

- Marcus Watt, Executive Director  
- Rachel Melvin, Executive Support Specialist  
- Fiona Karbowicz, Pharmacist Consultant  
- Brianne Efremoff, Compliance Director

### Agenda Item

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Desired Outcome</th>
</tr>
</thead>
</table>
| Welcome     | Called the meeting to order @ 8:30AM - Roll call – all Committee members present.  
Introductions of public attendees  
Agenda review and approval  
*Motion to approve the agenda was made and unanimously carried (Motion by Helm, seconded by Burns).*  
2.16.18 Minutes review and approval  
*Motion to approve the 2.16.18 Committee Minutes was made and unanimously carried (Motion by Chinn, second by Anukam).* |

### Committee Business

#### Committee Updates:

- The Committee scheduled time with Board Counsel, Tom Cowan. Attorney Cowan explained his role with Board and discussed objectivity and the environment for this Committee. He talked about the formality of the communication for the Committee and that there are public records and meetings laws in Oregon, which allow public transparency. Systematic approach to your communication and mindful of the public record. Tom and Committee members discussed occasions when recusal may and may not be warranted, as well as the best methods for internal and external communications.

- The Committee discussed the creation of a new procedure for approval of minutes, in order to not have to wait until the next meeting, at least three months away. The Committee agreed to meet via phone conference approximately 3 weeks after each meeting (perhaps on Friday mornings) solely for the purpose of approving minutes.

- Rules development update (*this will be a standing agenda item*)
  - Pharmacist Consultant Fiona Karbowicz reported that Division 20 is the landing area for the Committee’s work. The Committee’s first rule is in effect now.
  - As the process develops, the dedicated webpage will be where we house all of the information from this Committee.
  - The Committee discussed the step-by-step process of how their review and recommendations of concepts move through the review and adoption of codified rules by the Board.
Stakeholders may submit concepts for Committee review → Committee recommendations votes are passed along to the Board → Board codifies rules for Formulary addition and votes to send to rulemaking → Stakeholders and public may provide written/verbal testimony → Board adopts final rules, incorporating new items to the Formulary

- High priority items to review at this meeting:
  - none

- Review of Submitted Concepts:
  - **Topical Pain Cream Concept** - submitted 3/18/18
    - This concept contemplates the addition of topical pain creams, general and compounded products, to be added to the Formulary.
    - The Committee discussed concerns related to this concept. Members cited increased (both federal and state) scrutiny on these types of products and of concern was the increased potential for fraud, waste and abuse, particularly when the RPH would be the sole provider (both prescriber and dispenser).
    - Evon asked if we reach out to the sender of the concept after we approve or deny their request. Fiona stated that the Committee’s decision will be responded to the senders.

  - **Emergency Contraception Concepts** - submitted 4/21/18 and 5/5/18
    - Two concepts were received related to the addition of emergency contraception to the Formulary.
    - The Committee discussed the current contraception rules in regards to the product and age restrictions. It was noted that none of the products (such as Plan B or other “me too” products) require ID anymore, some packaging still has mention of age 17, which can still lead to confusion. Committee decisions for recommendation:
      - No age restriction;
      - No mention of gender;
      - No limitations on frequency or quantity.
    - The Committee discussed the potential benefit to patients utilizing a pharmacist for both the OTC and prescription emergency contraception, particularly due to increased “after hours” access, professional consultation, as well as the possibility of insurance coverage.
    - The Committee discussed “stigma” concerns, in light of recent media coverage. It was noted that the Oregon Board of Pharmacy worked to address this in 2005 with the creation of its position statement “Considering Moral and Ethical Objections”. A pharmacy is required to adhere to written policies and procedures that address a pharmacists’ moral, ethical and professional responsibilities, to ensure a patient’s access to care.
    - The Committee discussed whether there was a need to specify an additional mandated education requirement within the recommendation. It was determined that this was not required, but suggested, perhaps with links to additional CE or training made available to pharmacists.
The Committee determined that a specific protocol would not be needed, nor is that the responsibility of a regulatory agency. However, it was recommended that the pharmacy association may consider developing “model” policies and procedures and “model” protocols to assist in these efforts.

Motion to recommend Emergency Contraception, not including abortifacients, no additional required education, and following established core elements to the Protocol list for the Oregon Board of Pharmacy adopt by rule was made and unanimously carried (Motion by Burns, second by Jones).

- Uncontrolled Hypertension Concept – submitted 5/8/18
  - This concept contemplates the addition of anti-hypertensive medications to be added to the Formulary.
  - The Committee members discussed the pros and cons of the concept and the many components and logistical issues. Chair Valdez stated that this might be addressed in the future with the Continuation of Therapy rule where Pharmacists could impact this issue in a positive manner.
  - It was noted that pharmacists can play a critical role in the medication management of hypertension patients and assisting with medication regimen adherence. However, these efforts have the most positive impact when the pharmacist is working as member of a patient’s care team. The Committee discussed the value of increased utilization of Collaborative Drug Therapy Management agreements to care for hypertensive patients, as initiating modifying or discontinuing medications cannot be made on a single blood pressure reading. Additionally, safe care can be provided best when a pharmacist has access to the Electronic Health Record.
  - The Committee stated that the scope of this concept was too broad and it would be willing to address future submissions of smaller, more specific scope related to hypertension.

Motion to not recommend Uncontrolled Hypertension Concept submitted on 5/8/18 to the Protocol list for the Oregon Board of Pharmacy was made and unanimously carried (Motion by Turner, seconded by Chinn).

- Webpage link:  
  https://www.oregon.gov/pharmacy/Pages/PharmacyFormularyAdvisoryCommittee.aspx

Good of the Order
- Wrap up and next steps – The Committee summarized what concepts they recommended and did not recommend.
- Next meeting
  - October 26, 2018
- 2019 tentative meeting schedule
  - January 11, 2019 – room 1D (Note: need to vote for a new Committee Chair)
  - April 12, 2019 or May 3, 2019 – room 1D
  - July 12, 2019 – room TBD
  - October 11 or 25, 2019 – room TBD

Amy Valdez adjourned the meeting at 11:30AM.
<table>
<thead>
<tr>
<th>CONCEPT</th>
<th>Submitted By</th>
<th>Date of Submission</th>
<th>Date of Committee Review</th>
<th>Details</th>
<th>Date of OBOP Review</th>
<th>Attachments</th>
</tr>
</thead>
</table>
| 1. No. 2018-001 Extension of Rx Therapy | staff | January and February 2018 | 16-Feb-18 | - Continuation Period: Appropriate quantity necessary, not to exceed sixty-day supply.  
- Yearly Restriction: Up to two times max in a running twelve month timeframe, per medication  
- Controlled Substance Restriction: Non-controlled medications only  
- Category restriction: None  
- Situation restriction: None  
- Pharmacist prescribing requirements: Follow established core elements, which include: patient assessment, notification of providers upon prescribing, and documentation, among others.  
- Additional considerations: No additional mandated educational requirement is necessary. A pharmacist must use professional judgment and reasonable care when managing prescriptions issued by another pharmacist. | 9-Aug-18 | Y |
| 2. No. 2018-002 Certain Devices | staff | 16-Feb-18 | 16-Feb-18 | 1. Diabetic blood sugar testing supplies  
2. Pen needles  
3. Syringes  
4. Nebulizers and associated supplies (tubing/masks/etc.)  
5. Inhalation spacers  
6. Peak flow meters  
7. International Normalized Ratio (INR) Testing supplies  
8. Enteral nutrition supplies  
9. Ostomy products and supplies | 9-Aug-18 |
| 3. No. 2018-003 OTC and Cough & Cold | staff | 16-Feb-18 | 16-Feb-18 | PSEUDOEPHEDRINE 1. Mandatory PDMP look-up, prior to issuing prescription  
2. Mandatory positive ID and documentation  
3. Quantity MAX:  
   - Max of 3.6g per month or #60 tablets, whichever is less  
   - Yearly restriction: max of three times per year  
4. Age restriction: Only for patients 18 years and older  
INTRANASAL CORTICOSTEROIDS  
BENZONATATE - not to exceed 7-day supply for treatment of cough  
SHORT ACTING B-AGONISTS - Quantity max of 1 MDI or 1 25count box of nebulizer amps per year for cough | 9-Aug-18 | Y |
<p>| 4. No. 2018-004 Substitutions of Non-AB rated drugs | Kristy Butler, RPH | 13-Feb-18 pending | | Notes: ongoing correspondence with RPH licensees at OSPA and OSHP. They will provide concept once finalized. | |
| 5. No. 2018-005 Compounded Topical Pain Creams | Farma Pharmaceuticals, Henry Delu | 20-Mar-18 | 13-Jul-18 | Committee motion AGAINST recommending this to OBOP | n/a | Y |</p>
<table>
<thead>
<tr>
<th>CONCEPT</th>
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</tr>
</thead>
<tbody>
<tr>
<td>6 No. 2018-006 Emergency Contraception</td>
<td>Stephanie Gaston, RPH</td>
<td>21-Apr-18</td>
<td>13-Jul-18</td>
<td>Motion to recommend EC to the protocol list. No age restriction, does not include abortifacents</td>
<td>9-Aug-18</td>
<td></td>
</tr>
<tr>
<td>8 No. 2018-008 Uncontrolled Hypertension</td>
<td>Mariah Alford, RPH</td>
<td>8-May-18</td>
<td>13-Jul-18</td>
<td>Motion to NOT recommend, as submitted.</td>
<td>n/a</td>
<td>Y</td>
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</table>

AUGUST 2018 - B1
These draft rules implement the 2017 HB 2397 signed by Governor Kate Brown on May 18, 2017. The multi-disciplinary Public Health and Pharmacy Formulary Advisory Committee will make recommendations for the Board to adopt by rule of protocols, drugs, and devices fitting for pharmacists to prescribe.

These rules establish a pharmacist’s authority to prescribe drugs and devices, and via protocols recommended by the committee adopted by the Board’s formulary. These rules create the formulary and protocol compendia, per recommendations of the committee. They contemplate this authority for an Oregon licensed pharmacist, practicing in Oregon and the patient assessment must be performed via a face-to-face, in-person interaction. Recognize that participation in prescribing authorities is voluntary, and only a pharmacist is entitled to practice pharmacy, pursuant to ORS 689.005.

These rules describe the Board’s compliance expectations for prescribing from the formulary. Standards defined include (1) education and competency, (2) patient assessment, and determination of inclusion, exclusion and referral criteria (3) collaboration with other healthcare providers, including mandated notification (4) treatment and follow-up care planning, (5) record-keeping, and (6) prohibited practices.

These rules codify the PHPFA Committee recommendations from January 2018, February 2018 and July 2018. Additions to the Formulary and Protocol Compendia are: (1) devices, (2) continuation of therapy, (3) cough and cold symptom management, and (4) emergency contraception.

Sources include: The Joint Commission of Pharmacy Practitioner Pharmacists’ Patient Care Process

See also: Oregon Board of Pharmacy webpage dedicated to these processes for additional background

DIVISION 20
Pharmacist Prescriptive Authority

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.

Note: Using “FDA-approved” here means that some items will be excluded, including compounded drugs, vitamins and supplements

Oregon Board of Pharmacy

August 2018
(2) 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) At a minimum, for 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) Collect subjective and objective information about the patient’s health history and clinical status. The patient assessment shall be performed in a face-to-face, in-person interaction and not through electronic means; and

(c) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the pharmacist’s established drug therapy management protocol; and

(d) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and

(e) 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 formulary drug or device.

(4) The pharmacist shall maintain all records associated with prescribing for a minimum of X 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, provider, and Board upon request.

For Board considerations:

Lines 51-54: How long will these records need to be kept? Staff recommends 10 years.

- Traditional prescription records is 3 years, contraceptive prescribing records is 5 years (due to the 3 year limitation for prescribing without practitioner follow-up), and other medical/billing records may be up to and beyond 10 years
- Records associated with these regulations contemplate the acts of both prescribing and dispensing occurring in a single interaction and location
- Does there need to be a secondary rule in Div 041 for outlet records responsibilities?
Is there a need to address, in rule, the “shared responsibilities” between a pharmacist and the outlet in which they practice pharmacy? (See proposed edit to 855-041-1040, line 262)

- If so, does the Board want to contemplate minimum personnel requirements? (i.e. In order for a pharmacy to provide prescribing services, there shall be minimum of x (RPH/technician)
- Does the Board want to require a specified location (free from distraction, etc.) for prescribing services
- And meaning that for investigatory work, the Board needs a pharmacist to have explicit access to each of their prescribing record/notes (aka they have to be able to “own” their records) but the records shall be stored at the outlet.
  - If so, these may be addressed in the following Prohibited Practices section:

Stat. Auth.: ORS 689.205
Stat. Implemented: 689.645, 689.649

855-020-0120 Prescribing Prohibited Practices

The responsibility and authority to prescribe pursuant to the Formulary and Protocol Compendia is upon the pharmacist. A pharmacist shall not prescribe a drug or device to self or immediate family members.

Stat. Auth.: ORS 689.205
Stat. Implemented: 689.645, 689.649

OAR 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 documented 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;
(c) Syringes;
(d) Nebulizers and associated supplies;
(e) Inhalation spacers;
(f) Peak flow meters;
(g) International Normalized Ratio (INR) testing supplies;

(h) Enteral nutrition supplies; and

(i) Ostomy products and supplies.

(2) Medications (placeholder for adding drugs that may come as the committee continues to meet)

Stat. Auth.: ORS 689.205, 689.649
Stat. Implemented: 689.645, 689.649

OAR 855-020-0300 Protocol Compendium

A pharmacist may prescribe, via 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 sixty (60) day supply, and no more than two extensions in a twelve (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 sixty (60) count quantity per prescription, whichever is less, or a total of three prescriptions in a twelve (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 seven (7) day supply;

(C) Short-acting beta agonists, not to exceed one metered-dose inhaler or one box of nebulizer ampules, per year;

(D) Intrasal corticosteroids.

(b) Emergency Contraception, not including abortifacients
ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A pharmacist licensed to practice pharmacy by the Board has the duty to use that degree of care, skill, diligence and professional judgment that is exercised by an ordinarily careful pharmacist in the same or similar circumstances.

(1) A pharmacist while on duty must ensure that the pharmacy complies with all state and federal laws and rules governing the practice of pharmacy.

(2) Only a pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require the professional judgment of a pharmacist include but are not limited to:

(a) Drug Utilization Review;

(b) Counseling;

(c) Drug Regimen Review;

(d) Medication Therapy Management;

(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;

(f) Practice pursuant to State Drug Therapy Management Protocols;

(g) Prescribing and dispensing a drug or device, as authorized by statute;

(h) Ordering, interpreting and monitoring of a laboratory test;

(i) Oral receipt or transfer of a prescription; and

(j) Final verification of the work performed by those under their supervision.
(3) A pharmacist may not delegate any task listed in OAR 855-019-0200(2), except that a pharmacist may permit an intern to perform the duties of a pharmacist under their direction and supervision, after the intern has successfully completed his or her first academic year, and only after successful completion of coursework corresponding to those duties.

(4) An intern cannot prescribe a drug or device and cannot perform final verification.

(5) A pharmacist who is supervising an intern is responsible for the actions of that intern; however, this does not absolve the intern from responsibility for their own actions.

(6) A pharmacist on duty is responsible for supervising all pharmacy personnel, and ensuring that pharmacy personnel only work within the scope of duties allowed by the Board.

(7) A pharmacist may not permit non-pharmacist personnel to perform any duty they are not licensed and trained to perform.

(8) A pharmacist while on duty is responsible for the security of the pharmacy area including:

(a) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;

(b) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;

(c) Ensuring that only a pharmacist has access to the pharmacy when the pharmacy is closed.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.025, 689.151 & 689.155

Each drug outlet is accountable for establishing, maintaining, and enforcing their written procedures for:

(1) Securing their legend drugs and the area in which they are prepared, compounded, stored or repackaged;

(2) Performing mandatory prospective drug utilization reviews; on all prescriptions both new and refilled;

(3) Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area;
(4) Documenting the identification of the pharmacist responsible for the verification of each dispensed medication;

(5) Ensuring the delivery of each completed prescription to the correct party;

(6) Providing appropriate confidential professional advice concerning medications to patients or their agents;

(7) Prescribing services and maintenance of records for prescribing pharmacist;

(7) (8) Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties and;

(8) (9) Establishing and maintaining a Continuous Quality Assurance Program.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, 689.155 & 689.508
DRAFT Visit Summary

Collect

Patients Name: ____________________________ DOB: ____________________________

Chief Complaint

Subjective Data
☐ On Back

Objective Data
☐ On Back

History of Present Illness
☐ On Back

☐ Allergies
☐ Past Medical History
☐ Social History

☐ On Back

Medications
Post-diagnostic?
☐ No ☐ Yes

Adherence
☐ Past 90 day use

Safety
☐ Relevant Medications

Assess and Evaluate

Per Drug Therapy Management Protocol
☐ Attached
☐ Inclusion Criteria Met
☐ Exclusion Criteria Met
☐ Referral Criteria Met

Resource(s) Used
(e.g. Protocol, Guideline(s), Other Evidence Based Source, etc. (Note: this information shall be referenced in the established Drug Therapy Management Protocol)

Treatment Care Plan

☐ Treatment Goals
☐ Monitoring Parameters

☐ Referral Reason

For ____________________________
Address ____________________________ Date ______________
Rx # ____________________________

Follow-up:
☐ Office/Pharmacy Visit ☐ Phone Call With: ____________________________ Date: ______________
☐ Provider Referral: ____________________________
☐ Notification Sent

☐ Prescribing RPh Printed Name ________________________ RPh Signature ________________________ Date ______________
Joint Commission of Pharmacy Practitioners

The Joint Commission of Pharmacy Practitioners (JCPP) was established in 1977 and serves as a forum on matters of common interest and concern to national organizations of pharmacy practitioners and invited liaison members. JCPP Members are: the Academy of Managed Care Pharmacy, the Accreditation Council for Pharmacy Education, the American Association of Colleges of Pharmacy, the American College of Apothecaries, the American College of Clinical Pharmacy, the American Pharmacists Association, the American Society of Consultant Pharmacists, the American Society of Health-System Pharmacists, the National Alliance of State Pharmacy Associations, the National Association of Boards of Pharmacy, and the National Community Pharmacists Association.

Organizations participating on the Pharmacists’ Patient Care Process Workgroup include:

- Academy of Managed Care Pharmacy
- Accreditation Council for Pharmacy Education
- American Association of Colleges of Pharmacy
- American College of Clinical Pharmacy
- American Pharmacists Association
- American Society of Consultant Pharmacists
- American Society of Health-System Pharmacists
- Food Marketing Institute
- National Association of Chain Drug Stores
- National Alliance of State Pharmacy Associations
- National Community Pharmacists Association

The Pharmacists’ Patient Care Process is supported by the following organizations:

- Academy of Managed Care Pharmacy
- Accreditation Council for Pharmacy Education
- American Association of Colleges of Pharmacy
- American College of Apothecaries
- American College of Clinical Pharmacy
- American Pharmacists Association
- American Society of Consultant Pharmacists
- American Society of Health-System Pharmacists
- Food Marketing Institute
- National Alliance of State Pharmacy Associations
- National Association of Boards of Pharmacy
- National Association of Chain Drug Stores
- National Community Pharmacists Association
Pharmacists’ Patient Care Process

The goal of high quality, cost-effective and accessible health care for patients is achieved through team-based patient-centered care. Pharmacists are essential members of the health care team. The profession of pharmacy is continuing its evolution from a principal focus on medication product distribution to expanded clinically-oriented patient care services. As a result of this professional evolution, the importance of, and need for, a consistent process of care in the delivery of patient care services has been increasingly recognized by the profession at large.

Pharmacists have unique training and expertise in the appropriate use of medications and provide a wide array of patient care services in many different practice settings. These services reduce adverse drug events, improve patient safety, and optimize medication use and health outcomes. Pharmacists contribute to improving patients’ health by providing patient care services as authorized under their scope of practice and facilitated by collaborative practice agreements. The foundation for the pharmacist’s patient care process is embedded within the pharmaceutical care model developed by Hepler and Strand in the 1990s. However, there is variability in how this process is taught and practiced. To promote consistency across the profession, national pharmacy associations used a consensus-based approach to articulate the patient care process for pharmacists to use as a framework for delivering patient care in any practice setting.

The pharmacists’ patient care process described in this document was developed by examining a number of key source documents on pharmaceutical care and medication therapy management.1-6 Patient care process components in each of these resources were catalogued and compared to create the following process that encompasses a contemporary and comprehensive approach to patient-centered care that is delivered in collaboration with other members of the health care team.

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Pharmacists’ Patient Care Process

Pharmacists use a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes. An essential first step is the establishment of a patient–pharmacist relationship that supports engagement and effective communication with patients, families, and caregivers throughout the process. In addition, at the core of the process, pharmacists continually collaborate, document, and communicate with physicians, other pharmacists, and other health care professionals in the provision of safe, effective, and coordinated care. This process is enhanced through the use of interoperable information technology systems that facilitate efficient and effective communication among all individuals involved in patient care. (Figure 1).

Pharmacists’ Patient Care Process

Using principles of evidence-based practice, pharmacists:

A. Collect

The pharmacist assures the collection of necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient. Information may be gathered and verified from multiple sources including existing patient records, the patient, and other health care professionals. This process includes collecting:

- A current medication list and medication use history for prescription and nonprescription medications, herbal products, and other dietary supplements
- Relevant health data that may include medical history, health and wellness information, biometric test results, and physical assessment findings
- Patient lifestyle habits, preferences and beliefs, health and functional goals, and socioeconomic factors that affect access to medications and other aspects of care

Figure 1: Pharmacists’ patient care process
B. Assess
The pharmacist assesses the information collected and analyzes the clinical effects of the patient’s therapy in the context of the patient’s overall health goals in order to identify and prioritize problems and achieve optimal care. This process includes assessing:

- Each medication for appropriateness, effectiveness, safety, and patient adherence
- Health and functional status, risk factors, health data, cultural factors, health literacy, and access to medications or other aspects of care
- Immunization status and the need for preventive care and other health care services, where appropriate

C. Plan
The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective. This process includes establishing a care plan that:

- Addresses medication-related problems and optimizes medication therapy
- Sets goals of therapy for achieving clinical outcomes in the context of the patient’s overall health care goals and access to care
- Engages the patient through education, empowerment, and self-management
- Supports care continuity, including follow-up and transitions of care as appropriate

D. Implement
The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver. During the process of implementing the care plan, the pharmacist:

- Addresses medication- and health-related problems and engages in preventive care strategies, including vaccine administration
- Initiates, modifies, discontinues, or administers medication therapy as authorized
- Provides education and self-management training to the patient or caregiver
- Contributes to coordination of care, including the referral or transition of the patient to another health care professional
- Schedules follow-up care as needed to achieve goals of therapy

E. Follow-up: Monitor and Evaluate
The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed. This process includes the continuous monitoring and evaluation of:

- Medication appropriateness, effectiveness, and safety and patient adherence through available health data, biometric test results, and patient feedback
- Clinical endpoints that contribute to the patient’s overall health
- Outcomes of care, including progress toward or the achievement of goals of therapy
Date: 6/25/2018

Request/Inquiry Type: Waiver

Question(s): Planned Parenthood of Southwestern Oregon requests a renewal of their time-limited 2017 waiver for OAR 855-043-0720(3), Drug Security at their Regional Eugene / Springfield location, Community Health Clinic (CHC-000070) and for their Cottage Grove location (CHC-0000122)

• Background:
This waiver was approved in June 2017 (see pg. 3 for June 2017 Board meeting minutes). OBOP requested a 1-year follow-up response from PPSW-Oregon, with the log utilized to document access to the room, including dates/times of each person entering and the reason, as well as a report summarizing the information provided by the log’s data.
  o Log is included on pg. 4 of this document
  o In the past year, there were no recorded needs of after-hours access to the room

• Discussion:
  o Location has a large storage area that stores birth control, office supplies and medical waste.
  o Request for certain non-licensed individuals to have access to the large storage area in the absence of a licensed staff member. Often have shipments that need to be counted and stored at the end of shift; or need to store our medical waste in a locked area.
  o Request an exception for only two individuals, and like last time, this waiver is only requested for our Eugene-Springfield Clinic Site. Please see the names and titles of those individuals below.
    ▪ Corilynn Dodson-Specialty Services Coordinator
    ▪ Yezenia Ramirez-Health Center Manager
  o To note: This room access does not have or house controlled substances; those are in a separate safe with a restricted access system.

• Related ORS/OARs:
OAR 855-043-0720 Security
(1)All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.
(2) Only a Physician, Clinical Nurse Specialist, Nurse Practitioner, or Registered Nurse shall have a key to the drug cabinet or drug room. In their absence, the drug cabinet or drug room must remain locked.

(3) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

_Requester’s Contact Info:_
Sera R. Miller  
Quality Improvement, Compliance & Training Manager  
Corporate Compliance Officer  
Planned Parenthood of Southwestern Oregon  
3579 Franklin Boulevard, Eugene, OR 97403  
P: 541.344.2632 ext.1065 | Sera.Miller@ppsworegon.org
Waiver Requests – Planned Parenthood of Southwestern Oregon

Pharmacist Consultant, Fiona Karbowicz reviewed the waiver request from Planned Parenthood of Southwestern Oregon regarding drug security per OAR 855-043-0720(3). This request would allow access for additional staff such as the facility director after hours, during an emergency at the central clinic. Board Member, Christine Chute wanted to know why staff would need access to this room where drugs are stored and Fiona stated that their server is also in that room and that this request isn’t for IT related situations but for true emergency situations. Executive Director, Marc Watt stated that due to the nature of their business, they are sometimes targeted and officials such as law enforcement need to inspect the facility/building for threats and that it would be uncommon that these particular staff would actually access the room.

Board Members asked a variety of questions: could the clinic track who’s going in and out of that room and when; could they provide the Board with a picture of the room so they could see the layout; what kind of drugs are currently stored in the room and why they couldn’t install a locked cabinet or relocate the server and are these people are licensed with other boards. Fiona stated they are storing over the counter drugs, birth control, etc., and that relocating and adding a locked cabinet is not an option and that it’s just storage, not where they distribute. She went on to say that theft is the potential issue, but that as a licensee, they have to be compliant and it’s their duty to report a loss if there is a security breach. Fiona believes the room is small and locked all of the time. The conversation ended with the Board Members agreeing that they would like to see a report in one year to see if the room was accessed.

MOTION
Motion to approve Planned Parenthood request for five years with a report on after hours access in a year was made and unanimously carried. (Motion by Vipperman, seconded by Armstrong).

Source: June 2017 Board Meeting Minutes
After-Hours Inventory Room Log  
(RHEC ONLY)

Please fill out this document if access to the Inventory room is needed outside of business hours, without a licensed provider onsite.

**Example:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Person</th>
<th>Time-In</th>
<th>Time-Out</th>
<th>Reason why needed after-hours access</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/12/2017</td>
<td>Jane Doe</td>
<td>7:02 PM</td>
<td>7:22 PM</td>
<td>Electrical Panel needed Maintenance</td>
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</tbody>
</table>

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<tr>
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Please See Compliance Officer Sera Miller for Additional Log Copies if needed.
If this log is FULL, please give to Sera Miller
June 30, 2017

Sera Miller via e-mail & mail
Planned Parenthood of Southwestern Oregon
3579 Franklin Boulevard
Eugene, OR 97403

Re: Drug Security Waiver request – OAR 855-043-0720 (3)

Dear Ms. Miller,

At the Oregon Board of Pharmacy’s June 8, 2017 meeting, the Board reviewed your request to waive the drug access requirement in OAR 855-043-0720 (3).

The Board approved your request for Kelly Hall Regional Health Center Director and Afrika Mucha Facilities and Operations Manager to have access to the secure drug room under the following conditions:

- Access is limited to after-hours only
- Create and maintain a log of the time & date of these person entering and reason
- Report to the Board with the above log and the number of times accessed after-hours under this waiver by June 30, 2018.
- Email your report and information to: Karen.S.MacLean@state.or.us

Please keep a copy of this letter with your licensing records and available for Board inspectors if needed.

Sincerely,

Karen S. MacLean,
Administrative Director

Cc: Brianne Efremoff, Compliance Director
Board Meeting Correspondence File
CHC-0000067 Licensing File
**Date:** 5.17.2018  

**Request/Inquiry Type:** TCVP initiation  

**Question(s):** Columbia Memorial Hospital Pharmacy (IP-0000112) requests permission to begin a TCVP program.

- **Discussion:**
  I am hoping to gain approval from the Board to operate a TCVP at our facility. It would only occur in the inpatient pharmacy, and only apply to our Pyxis fill (non-patient-specific) and our surgical tray restocking. We do not perform cart-fills. Attached to this email is the CMH TCVP policy (including a list of high risk medications), Training material (which will be reviewed with technicians in a lecture style format, including a test), an initial validation form, and a quality assurance check form.

- **Related ORS/OARs:**
  
  855-041-5100  
  Definitions

  (1) “Error” in Automated Distribution Cabinet (ADC) is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item counts as one error.

  (2) “Error” in a unit of use cart is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date. All errors in any single dose count as one error.

  (3) “Line Item” is a checking unit for ADC restocking (example: one specific drug and dose, regardless of quantity).

  (4) “Technician Checker” is an Oregon certified technician who has completed the TCVP validation process and is currently authorized to check another technician’s work.

  (5) “Technician Checking Validation Program (TCVP)” is a program that uses a technician checker to check functions completed by another technician.

  (6) “Unit Dose” is the physical quantity of a drug product designed to be administered to a patient specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged, oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed IV products.

  **NOTE:** Technician Checking Validation Program (TCVP) The TCVP is a tool to allow the re-direction of a pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients. The development of individualized training programs is the responsibility of each pharmacy in order to tailor the program to the patient population and medication distribution system of the institution. Assessment questions must be tailored to the site and be changed periodically as appropriate. It is the responsibility of the pharmacist-in-charge to ensure that all training is completed and documented prior to a technician performing as a technician checker.

  855-041-5120  
  Hospital and Pharmacist in Charge Requirements
(1) Only a hospital pharmacy may apply to participate in a TCVP. To participate in the TCVP, the hospital pharmacy must meet the following requirements:

(a) The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-risk medications that are excluded from the TCVP. The policies and procedures for the TCVP must be available in the pharmacy for board inspectors.

(b) The hospital pharmacy must obtain approval from the appropriate committee before the TCVP can be implemented;

(c) The hospital pharmacy must have a drug distribution system that is structured to allow for one additional check of the distributed medications by a licensed nurse or other licensed health care professional with authority to administer medications after the delivery of checked medications; and

(d) The Pharmacist-in-Charge is responsible for the TCVP and will document any error, or irregularity in the quality assurance documentation records.

(2) A hospital may not operate a TCVP without prior written approval from the Oregon Board of Pharmacy. To apply for approval, the hospital must submit the following to the Board:

(a) Copies of written training material that will be used to train technicians as technician checkers;

(b) Copies of quality assurance documentation records and forms that will be used to evaluate the technician checkers and the proposed TCVP;

(c) Copies of the policy and procedures for the proposed TCVP; and

(d) A description of how the proposed TCVP will improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients.

(e) Other items as requested by the Board.

855-041-5130

Technician Eligibility and Training

(1) Only Oregon certified technicians who undergo specific training may work as technician checkers. The training must include the following:

(a) A minimum of one year of drug distribution experience;

(b) Didactic lecture or equivalent training with a self-learning packet;

(c) Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a pharmacist; and

(d) Initial Validation Process as described in OAR 855-041-5140(1).

(2) The practical training sessions must include:

(a) The trainee observing a technician checker or pharmacist performing the checking process that the trainee is learning;

(b) The trainee performing the initial check with a pharmacist verifying all doses;

(c) The trainee completing the validation process with a pharmacist verifying all doses;

(d) The introduction of artificial errors into a live or simulated environment, to monitor the ability of the technician to catch errors. Artificial errors introduced into the live environment, which are not corrected by the technician, must be removed.
(e) The pharmacist must document and notify a technician checker of any errors found during training.

(3) If at any time a TCVP technician loses his or her validation the technician must be retrained and revalidated before acting as a technician checker.

855-041-5140
Initial Validation Process and Quality Assurance Process

(1) Initial Validation Process: The initial process to validate a trainee’s ability to accurately check another technician’s work must include:

(a) Unit of Use: For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a 99.8% accuracy rate in 1500 total doses, divided among five separate training checks. A trainee who makes more than three errors in 1500 doses fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.

(A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications after the trainee has checked them. The pharmacist must document any errors in the unit of use cart and discuss them with the trainee.

(B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist coordinating the training check will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.

(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.

(b) ADC or non-emergent trays and kits: For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.

(A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent tray or kit medications after the trainee has checked them. The pharmacist must document any errors and discuss them with the trainee.

(B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.

(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.

(2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of technician checkers must include:

(a) Quality checks conducted in the same manner as the applicable initial validation process described in section one of this rule, except that the quality check sample must consist of at least 300 doses for technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-emergent trays and kits.

(b) The quality checks must occur on random and unannounced dates and times.

(c) A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.
(d) The results of each quality check must be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation must be retained in the quality assurance file.

(3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.

(4) A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.

(5) A description of the quality assurance process must be included in the hospital’s and the pharmacy’s quality assurance program and error reporting system.

855-041-5150
Checking Procedure

(1) A technician checker must use the following procedure when checking another technician’s work:

(a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent trays and kits.

(b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.

(c) If the technician checker discovers a filling error the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction. A pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or kit, or medication corrections filled by a technician checker.

(d) If a technician checker is not available, then all doses must be checked by a pharmacist.

(2) This checking process continues until all doses have been checked and determined to be correct.

855-041-5160
Eligible Specialized Functions

(1) The following specialized functions are eligible for participation in the TCVP:

(a) Cart fill;

(b) ADC batch replacement; and

(c) Non-Emergent kits and trays.

(2) Upon written request, the Board may permit additional specialized functions if to do so will further public health or safety. A waiver granted under this section shall be effective only when issued in writing and approved by the Board.

855-041-5170
Records

(1) Unless specified otherwise, all records and documentation required by these rules must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.
(2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:

(a) Technician checker training documents;

(b) List of high risk medications;

(c) Documentation of any errors, irregularities and results of each initial validation check.

(d) Documentation of quality assurance and forms used to evaluate the technician checker including:

(A) Total number of doses or line item checks;

(B) Description of errors;

(C) Total number of errors; and

(D) Percent error rate.

(e) Documentation of the initial validation check.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
History:
BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

Requester’s Contact Info:
Nate Nerenberg, PharmD, BCPS
Pharmacy Manager
Inpatient Pharmacy Services
Columbia Memorial Hospital
2111 Exchange Street
Astoria OR 97103
Office: (503) 338-4011
Cell: (503) 338-9391
Fax: (503) 338-7577
**SCOPE:**

Pharmacy

**GENERAL POLICY STATEMENT:**

The Technician Checker Validation Program (TCVP) allows for trained pharmacy technicians to verify the work of another technician in the processes of refilling automated dispensing cabinets (ADCs) such as Pyxis, restocking surgical trays, and other non-emergent kits and trays. The main reason for the program is to allow the pharmacist more time for direct patient care activities, medication reconciliation, and clinical rounding, that will thus enhance patient care and safety.

**PURPOSE:**

To outline the appropriate procedure for the management and administration of the technician checker validation program as delineated by the Oregon Board of Pharmacy rules and regulations.

**DEFINITIONS:**

None

**PROCEDURE:**

*Pharmacy Technician Eligibility and Training*

Only Oregon certified technicians who undergo specific training may work as technician checkers. The training must include the following:

- A minimum of one year of drug distribution experience;
- Didactic lecture or equivalent training with a self-learning packet;
- Practical sessions that consist of individual training in checking an ADC that is provided by a pharmacist; and the Initial Validation Process as described below.
- The practical training sessions must include:
  - The trainee observing a technician checker or pharmacist performing the checking process that the trainee is learning;
  - The trainee performing the initial check with a pharmacist verifying all doses;
  - The trainee completing the validation process with a pharmacist verifying all doses;
  - The introduction of artificial errors into a live or simulated environment, to monitor the ability of the technician to catch errors. Artificial errors introduced into the live environment, which are
not corrected by the technician, must be removed. The pharmacist must document and notify a technician checker of any errors found during training. If at any time a TCVP technician loses his or her validation the technician must be retrained and revalidated before acting as a technician checker.

Initial Validation Process
The initial process to validate a trainee’s ability to accurately check another technician’s work must include the following:
- For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.
- In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent tray or kit medications after the trainee has checked them. The pharmacist must document any errors and discuss them with the trainee.
- In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.
- The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.

Quality Assurance Process
The Quality Assurance Process that ensures ongoing competency of technician checkers must include the following:
- Quality checks conducted in the same manner as the applicable initial validation process described above, except that the quality check sample must consist of at least 100 line items for technicians checking ADC or non-emergent trays and kits.
- The quality checks must occur on random and unannounced dates and times.
- A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.
- The results of each quality check must be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation must be retained in the quality assurance file.
- Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.
- A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.
- A description of the quality assurance process must be included in the hospital’s and the pharmacy’s quality assurance program and error reporting system.
**Checking Procedure**

A technician checker must use the following procedure when checking another technician’s work:
- A pharmacy technician fills the medication for the ADC restocking batch or non-emergent trays and kits.
- A technician checker must check the accuracy of ADC or non-emergent trays and kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.
- If the technician checker discovers a filling error the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction. A pharmacist or another technician checker must check any ADC or non-emergent tray or kit, or medication corrections filled by a technician checker.
- A technician checker is not permitted to check emergent kits and trays, such as code carts, rapid sequence intubation kits, and other kits used in emergency situations.
- A technician checking is not permitted to check any kits, trays, or batch fills that contain any of the drugs on the list of “high risk” medications contained within this policy.

**Records**

The Pharmacist-in-Charge is responsible for the TCVP and will document any error or irregularity in the quality assurance documentation records. Unless specified otherwise, all records and documentation required by the TCVP must be retained for three years and made available to the Oregon Board of Pharmacy for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:
- Technician checker training documents;
- List of high risk medications;
- Documentation of any errors, irregularities and results of each initial validation check.
- Documentation of quality assurance and forms used to evaluate the technician checker including:
  - Total number of doses or line item checks;
  - Description of errors;
  - Total number of errors; and
  - Percent error rate
- Documentation of the initial validation check.

**High Risk Medications**

A certain number of high risk medications will be excluded from the TCVP program, and when they are included in a Pyxis batch fill or non-emergent tray or kit, a technician checker may not perform the duties of a technician checker for these medications. In these cases, a pharmacist must still perform the checking process before the drug can leave the pharmacy.
The following is a list of high risk medications:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Medication</th>
<th>Medication</th>
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<tbody>
<tr>
<td>Abatacept</td>
<td>Doxorubicin</td>
<td>Obinutuzumab</td>
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<td>Ado-Trastuzumab</td>
<td>Elotuzumab</td>
<td>Omalizumab</td>
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<td>Adenosine</td>
<td>Eribulin</td>
<td>Oxaliplatin</td>
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<td>Albumin</td>
<td>Etoposide</td>
<td>Paclitaxel</td>
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<tr>
<td>Alteplase</td>
<td>Ferrumoxytol</td>
<td>Paclitaxel-Protein Bound</td>
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<td>Filgrastim</td>
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<td>Fluorouracil</td>
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<td>Fosaprepitant</td>
<td>Pemetrexed</td>
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<td>Rivaroxaban</td>
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<td>Insulin Glargine</td>
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<td>Insulin Lispro</td>
<td>Rhogam</td>
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<td>Bortezomib</td>
<td>Insulin 70/30</td>
<td>Rituximab</td>
</tr>
<tr>
<td>Carboplatin</td>
<td>Insulin Regular (Human)</td>
<td>Sodium Ferric Gluconate</td>
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<td>Cisplatin</td>
<td>Irinotecan</td>
<td>Tacrolimus</td>
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<td>Valrubicin</td>
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<td>Dextrazoxane</td>
<td>Methotrexate</td>
<td>Vedolizumab</td>
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<td>Digoxin</td>
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<td>Vinblastine</td>
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<td>Dobutamine</td>
<td>Natalizumab</td>
<td>Vincristine</td>
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<td>Docetaxel</td>
<td>Neostigmine</td>
<td>Warfarin</td>
</tr>
<tr>
<td>Dopamine</td>
<td>Nivolumab</td>
<td>Zoledronic Acid</td>
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</table>

REFERENCES:

Oregon Administrative Rules 855-041-5120; 5130; 5140; 5150; 5160; 5170

KEY WORDS:

Pharmacy, technician, checker, validation, program, tech-check-tech, Pyxis, filling, medication

DEPARTMENT: PHARMACY/MEDICATION MANAGEMENT
EFFECTIVE: 5/2018
APPROVED BY: Pending
Reviewed/Revised: 5/18
CMH Technician Checker Validation Program Training

Technician Eligibility

In order to participate in the technician checker validation program (TCVP), otherwise known as “tech-check-tech”, the following requirements must be met:

Only Oregon certified technicians who undergo specific training may work as technician checkers. These technicians must also have at least one year of drug distribution experience, have undergone a didactic lecture or equivalent training with a self-learning packet, and completed practical sessions provided by a pharmacist and consisting of individual training in checking fill for an ADC. It is also necessary to undergo an initial validation process and several regularly scheduled quality assurance checks, which will be discussed later in the training.

Training

As part of the training process, you will need to observe a pharmacist or technician checker performing the checking process, perform the checking process under pharmacist supervision, and complete initial validation before being allowed to perform duties as a technician checker. Please note that artificial errors will be periodically introduced into the system as part of the training and ongoing quality checks.

The following steps will guide you through the training process:

Step #1 - Observe a technician checker or pharmacist performing the checking process.

Date completed________ Technician Signature_________________ Pharmacist Signature____________

Step #2 - The trainee performs the initial check with a pharmacist verifying all doses.

Date completed________ Technician Signature_________________ Pharmacist Signature____________

Step #3 - The trainee must repeat Step #2 until the initial validation process is complete, making sure a pharmacist verifies all doses, and documents/discusses errors with the trainee.

Date completed________ Technician Signature_________________ Pharmacist Signature____________

Please note that if at any time a TCVP technician loses his or her validation the technician must be retrained and revalidated before acting as a technician checker.
**Initial Validation Process**

For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.

In each initial validation check, a pharmacist will check the accuracy of all ADC or non-emergent tray or kit medications after you have checked them. The pharmacist will document errors and discuss them with you.

In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.

The pharmacist will then document the results of each initial validation check and retain the results in the CMH – TVCP folder in the initial validation section.

**Quality Assurance Process**

Quality Assurance checks will be conducted in the same manner as the applicable initial validation process described previous, except that the quality check sample will only consist of at least 100 line items for technicians checking ADC or non-emergent trays and kits.

Oregon Board of Pharmacy rules state that the quality checks must occur on random and unannounced dates and times.

A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.

The results of each quality check will be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation will be retained in the CMH – TVCP folder in the quality assurance section.

**Timing and Frequency of the Quality Assurance Process**

A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.

A technician checker who does not perform TCVP duties for more than six months must undergo the initial validation process again before being allowed to perform the duties of a technician checker.
Checking Procedure

A technician checker must use the following procedure when checking another technician’s work:

First, a pharmacy technician fills the medication for the ADC restocking batch or replenishes the supply of non-emergent trays and kits.

Second, a technician checker must check the accuracy of ADC restocking batches or replenished non-emergent trays and kits. As part of this checking process, the technician checker will review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.

If during the checking process the technician checker discovers a filling error, then the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction.

A pharmacist or another technician checker must check ADC restocking batches or replenished non-emergent trays or kits, or medication corrections filled by a technician checker.

At CMH currently, the technician checker may ONLY check ADC restocking batches or replenished non-emergent trays or kits (such as our surgical tray or bronchoscopy kit).

High Risk Medications

The following is a list of high risk medications that MUST NOT be checked by a technician checker. In the event that they are part of a Pyxis batch fill, the drugs on this list may not leave the pharmacy until being verified by a licensed pharmacist only.

The following is a list of high risk medications:

TCVP Quiz

Question #1
True or False? The technician checker may check code carts and RSI kits.

Question #2
If you are checking a Pyxis batch fill and find an error what should you do?
A. Fix the error yourself and let the other tech restock the Pyxis.
B. Notify the technician that pulled Pyxis to please fix the error then have them restock Pyxis.
C. Notify the technician to please fix the error, document the error, perform another check, and then they may refill the Pyxis.
D. Remove the error, have them refill the Pyxis, and leave the error in pharmacy for the pharmacist to clear up.

Question #3
True or False? If you make several errors during a quality check, but those errors are all corrected before filling Pyxis, it is not necessary to perform another quality check.

Question #4
What type of error is most likely to occur?
A. IV lidocaine is pulled instead of oxycodone tablets.
B. Tums are pulled instead of ceftriaxone advantage vials.
C. Metoprolol Succinate is pulled instead of Metoprolol Tartrate.
D. 1 liter bags of NS are pulled instead of furosemide tablets.

Question #5
Which of the following don’t need to happen before you can perform the duties of a Technician Checker?
A. You must complete the technician training
B. You must complete the initial validation process
C. You must have at least one year of drug distribution experience and be an Oregon licensed tech.
D. You must have passed the quality assurance checks for at least three months.

Question #6
True or False? If you are the only technician in the pharmacy, you are allowed as a pharmacy checker to pull the Pyxis, check it, and then reload the Pyxis as long as you get pharmacist approval.
Question #7
True or False? If an ED provider or nurse calls the pharmacy asking for an amlodipine 5mg tablet, you can show the tablet to a technician checker and have them verify it before bringing it to the ED.

Question #8
Which of the following duties may not be performed by a technician checker?
A. Checking a Pyxis fill containing insulin products.
B. Checking a Pyxis fill containing chemotherapy agents.
C. Checking a Pyxis fill containing heparin.
D. All of the above.

Question #9
You have reached the point in your quality assurance checks that you are now only required to have one every six months, but you notice that it has now been six months and two days since your last one. What is the appropriate course of action?
A. Notify the pharmacist, and have them perform a quality assurance check immediately before continuing your duties as a technician checker.
B. Stop performing your duties as a technician checker until you complete the initial validation process again.
C. Stop performing your duties as a technician checker and notify the board of pharmacy in writing within 10 days.
D. You are allowed a one-month grace period with your first lapse in quality checks, so you may continue your duties as a technician checker as long as you get your next check done within the month.

Question #10
True or False? Both the technician checking the Pyxis batch fill AND the technician pulling the Pyxis batch fill must be certified Technician Checkers in order for the batch fill to be delivered to Pyxis.
CMH Technician Checking Validation Program (TCVP): Quality Assurance Check

Technician Checker: ________________ Evaluator: ________________ Date: __________

Quality Assurance Checks:

Check #1:

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<th>Total Line Items (must add to &gt;100):</th>
<th>Date:</th>
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<tr>
<td>#2</td>
<td>Technician Found Error? Y or N</td>
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<tr>
<td>#3</td>
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Other errors (if any)?

Errors were corrected before loading into Pyxis? ☐  Pharmacist Signature:

Check #2:

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<th>Errors Introduced:</th>
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Other errors (if any)?

Errors were corrected before loading into Pyxis? ☐  Pharmacist Signature:

Check #3:

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<td>#1</td>
<td>Technician Found Error? Y or N</td>
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Other errors (if any)?

Errors were corrected before loading into Pyxis? ☐  Pharmacist Signature:

Check #4:

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Other errors (if any)?

Errors were corrected before loading into Pyxis? ☐  Pharmacist Signature:

Check #5:

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<tr>
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Other errors (if any)?

Errors were corrected before loading into Pyxis? ☐  Pharmacist Signature:
# CMH Technician Checking Validation Program (TCVP): Initial Validation Process

**Trainee:** ______________________  **Evaluator:** ______________________  **Date:** ______________

## Validation Checks:

### Check #1:

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Other errors (if any)?

Errors were corrected before loading into Pyxis? □  **Pharmacist Signature:**

### Check #2:

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<th>Errors Introduced:</th>
<th>Total line items (must add to &gt;500):</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#2</td>
<td></td>
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</tr>
<tr>
<td>#3</td>
<td></td>
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</tr>
</tbody>
</table>

Other errors (if any)?

Errors were corrected before loading into Pyxis? □  **Pharmacist Signature:**

### Check #3:

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<th>Date:</th>
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</thead>
<tbody>
<tr>
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<td>#2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#3</td>
<td></td>
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</tr>
</tbody>
</table>

Other errors (if any)?

Errors were corrected before loading into Pyxis? □  **Pharmacist Signature:**

### Check #4:

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<th>Total line items (must add to &gt;500):</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>#2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other errors (if any)?

Errors were corrected before loading into Pyxis? □  **Pharmacist Signature:**

### Check #5:

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<tr>
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<th>Total line items (must add to &gt;500):</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other errors (if any)?

Errors were corrected before loading into Pyxis? □  **Pharmacist Signature:**
Agency: Pharmacy, Board of

Mission Statement:
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.

<table>
<thead>
<tr>
<th>Legislatively Approved KPMs</th>
<th>Metrics</th>
<th>Agency Request</th>
<th>Last Reported Result</th>
<th>Target 2018</th>
<th>Target 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Percent of inspected pharmacies that are in compliance annually.</td>
<td>Approved</td>
<td>79%</td>
<td>80%</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>2. Percent of audited pharmacists who complete continuing education on time.</td>
<td>Approved</td>
<td>97%</td>
<td>0%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>3. Percent of pharmacies inspected annually.</td>
<td>Approved</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>4. Average number of days to complete an investigation from complaint to board presentation.</td>
<td>Approved</td>
<td>98</td>
<td>100</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>5. CUSTOMER SERVICE - Percent of Customers Rating Their Satisfaction With the Agency’s Customer Service as “Good” or “Excellent” : Overall Customer Service, Timeliness, Accuracy, Helpfulness, Expertise, and Availability of Information.</td>
<td>Timeliness</td>
<td>Approved</td>
<td>90%</td>
<td>90%</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>Expertise</td>
<td>Approved</td>
<td>94%</td>
<td>90%</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>Accuracy</td>
<td>93%</td>
<td>90%</td>
<td>90%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Helpfulness</td>
<td>92%</td>
<td>90%</td>
<td>90%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Overall</td>
<td>93%</td>
<td>90%</td>
<td>90%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Availability of Information</td>
<td>Approved</td>
<td>90%</td>
<td>90%</td>
<td>90%</td>
</tr>
<tr>
<td>6. Board Best Practices - Percent of total best practices met by the Board.</td>
<td>Approved</td>
<td>99%</td>
<td>100%</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

LFO Recommendation:
For KPM #2, LFO recommends the agency reports information only in odd number years when pharmacists renew their license and are audited.

For the remaining KPMs, LFO recommends approval of KPM and targets as presented.

SubCommittee Action:
Approved LFO recommendation.
<table>
<thead>
<tr>
<th>KPM #</th>
<th>Approved Key Performance Measures (KPMs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Percent of inspected pharmacies that are in compliance annually.</td>
</tr>
<tr>
<td>2</td>
<td>Percent of audited pharmacists who complete continuing education on time.</td>
</tr>
<tr>
<td>3</td>
<td>Percent of pharmacies inspected annually.</td>
</tr>
<tr>
<td>4</td>
<td>Average number of days to complete an investigation from complaint to board presentation.</td>
</tr>
<tr>
<td>5</td>
<td>CUSTOMER SERVICE - Percent of Customers Rating Their Satisfaction With the Agency’s Customer Service as “Good” or “Excellent” : Overall Customer Service, Timeliness, Accuracy, Helpfulness, Expertise, and Availability of Information.</td>
</tr>
<tr>
<td>6</td>
<td>Board Best Practices - Percent of total best practices met by the Board.</td>
</tr>
</tbody>
</table>

Performance Summary

<table>
<thead>
<tr>
<th></th>
<th>Green</th>
<th>Yellow</th>
<th>Red</th>
</tr>
</thead>
<tbody>
<tr>
<td>= Target to -5%</td>
<td>83.33%</td>
<td>0%</td>
<td>16.67%</td>
</tr>
</tbody>
</table>

Summary Stats:
KPM #1  Percent of inspected pharmacies that are in compliance annually. -
Data Collection Period: Feb 01 - Jan 31

* Upward Trend = positive result

<table>
<thead>
<tr>
<th>Report Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual</td>
<td>82%</td>
<td>83%</td>
<td>85%</td>
<td>79%</td>
<td>97%</td>
</tr>
<tr>
<td>Target</td>
<td>75%</td>
<td>75%</td>
<td>75%</td>
<td>75%</td>
<td>80%</td>
</tr>
</tbody>
</table>

How Are We Doing
The Board's inspection year runs February 1 through January 31 annually. Outlets are required to complete their Annual Self Inspection Report prior to February 1 in order for the Inspectors to be able to conduct a thorough inspection. This form needs to be completed and available for inspection by the Board at all times. The purpose of the self-inspection is to ensure the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy. Newly assigned PICs are required to complete a self-inspection of their pharmacy within 15 days of becoming the PIC.

This report includes results from February 1, 2016 - January 31, 2017, the Board completed 924 pharmacy inspections. This is 100% of the retail and institutional pharmacies licensed and located in Oregon. Upon inspection, 83% or 763 passed, there were 136 Deficiency Notices issued, however after correcting deficiencies noted during inspection, 97% were in compliance. Outlets have 30 days to correct deficiencies and report back to the Board. During this period, 25 received notices of Non-Compliance because they did not correct deficiencies in a timely manner.

Factors Affecting Results
The Board's axiom is "Compliance through Education" and Inspectors strive to educate pharmacists during the inspection process. Where there are deficiencies, outlets are advised what needs to be corrected. The Self Inspection Report cites to the specific laws and rules Inspectors are evaluating to check compliance. The Board allows time for outlets to achieve compliance with newer laws and rules upon implementation. However, some outlets are not always as quick to change or comply. We continue to work with these outlets to achieve compliance and maintain public safety.
KPM #2 Percent of audited pharmacists who complete continuing education on time.

Data Collection Period: Jan 01 - Dec 31

* Upward Trend = positive result

<table>
<thead>
<tr>
<th>Report Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual</td>
<td>95%</td>
<td>95%</td>
<td>97%</td>
<td>No Data</td>
<td>No Data</td>
</tr>
<tr>
<td>Target</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>TBD</td>
<td>100%</td>
</tr>
</tbody>
</table>

**How Are We Doing**

The Board is currently in the process of conducting the 2017 pharmacist continuing education audit. In 2015, the Board moved to biennial licensure for pharmacists and the renewal period ended June 30, 2017. We increased the number of individuals audited from 10 to 20% for this year. Therefore, we are auditing 1389 out of 7257 pharmacists licensed in Oregon. The audit notice was emailed to licensees in August 19th with a due date of October 11th. At this time we have logged and acknowledged the 1111 or 79% responses received. In October, staff will begin reviewing individual's responses for completeness. Due to our transition to biennial licensure, this is the first year that pharmacists were required to submit 30 hours of continuing pharmacy education. This is to include a minimum of at least two hours earned in the area of pharmacy and drug law and a minimum of two hours earned in the area of patient safety or medication error prevention. The remaining 26 hours may be earned in the area the individual practices in, therapeutics, pain management, cultural competency or pharmacy and drug law or other aspects of health care. When the audit is complete, we will update the actual number of pharmacists that completed their continuing education on time to complete reporting on this measure.

**Factors Affecting Results**

The 2017 audit is not complete yet.
**Percent of pharmacies inspected annually.**

Data Collection Period: Feb 01 - Jan 31

* Upward Trend = positive result

<table>
<thead>
<tr>
<th>Report Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Target</td>
<td>95%</td>
<td>95%</td>
<td>95%</td>
<td>95%</td>
<td>100%</td>
</tr>
</tbody>
</table>

**How Are We Doing**

For the reporting period February 1, 2016 - January 31, 2017, the Board completed 100% inspections of retail and institutional pharmacy outlets licensed and located in Oregon. The Board is seeing a greater need to inspect additional drug outlets and staff works to incorporate these into the inspection schedule.

**Factors Affecting Results**

While we have achieved 100% of the primary inspections required, we are limited in expanding inspections to other categories unless there is a complaint or identified compliance issue reported.
**KPM #4** Average number of days to complete an investigation from complaint to board presentation.

Data Collection Period: Jan 01 - Dec 31

* Upward Trend = negative result

<table>
<thead>
<tr>
<th>Report Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of days to process complete investigation from complaint to Board presentation.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual</td>
<td>71</td>
<td>97</td>
<td>107</td>
<td>98</td>
<td>93</td>
</tr>
<tr>
<td>Target</td>
<td>75</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

**How Are We Doing**

The Board investigates more than just consumer complaints that become cases. We do not have a backlog at this point. We are continually working on cases which includes complaints, Board initiated cases, cases initiated because of inspection deficiencies, inspection notices of non-compliance, license application cases etc. Cases of drug diversion, theft or impairment always take priority for public's safety and may delay complaints from immediate investigation. For the calendar year January 1, 2016 - December 31, 2016, Board staff investigated 585 cases, of those 272 were specifically complaints which were on average reported to the Board within 92 days.

**Factors Affecting Results**

The Board meets six times a year for two to three days each to conduct case deliberation and general business. Depending on the date a complaint/case is initiated and the deadlines for submitting investigated cases for the next Board meeting, there may be a delay in how quickly the Board receives a complaint/case for review. The Board strives to meet the statutory reporting requirement of 120 days (ORS 676.165(4).
# Customer Service: Percent of Customers Rating Their Satisfaction as "Good" or "Excellent"

Data Collection Period: Jan 01 - Dec 31

<table>
<thead>
<tr>
<th>Report Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Timeliness</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual</td>
<td>90%</td>
<td>86%</td>
<td>90%</td>
<td>90%</td>
<td>83%</td>
</tr>
<tr>
<td>Target</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
</tr>
<tr>
<td><strong>Expertise</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual</td>
<td>95%</td>
<td>94%</td>
<td>96%</td>
<td>94%</td>
<td>95%</td>
</tr>
<tr>
<td>Target</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual</td>
<td>92%</td>
<td>91%</td>
<td>94%</td>
<td>93%</td>
<td>92%</td>
</tr>
<tr>
<td>Target</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
</tr>
<tr>
<td><strong>Helpfulness</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual</td>
<td>93%</td>
<td>92%</td>
<td>92%</td>
<td>92%</td>
<td>90%</td>
</tr>
<tr>
<td>Target</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual</td>
<td>93%</td>
<td>93%</td>
<td>93%</td>
<td>93%</td>
<td>91%</td>
</tr>
<tr>
<td>Target</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
</tr>
<tr>
<td><strong>Availability of Information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual</td>
<td>88%</td>
<td>94%</td>
<td>87%</td>
<td>90%</td>
<td>82%</td>
</tr>
<tr>
<td>Target</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
<td>85%</td>
</tr>
</tbody>
</table>
The Board utilized three surveys via the SurveyMonkey Customer Service Survey to Board customers that obtained a new license between the dates of January 1, 2016 and December 31, 2016. We emailed the survey link to 2827 new licensees. 38 email addresses came back to us as undeliverable. Of the 2789 remaining licensees that provided valid email addresses, 587 individuals responded to the surveys. This represents an overall response rate of 21.05%. This is a 9.67% increase from the 2015 overall response rate.

Customer Service is a priority for the Board and staff. We strive to provide excellent customer service daily and the Director reviews survey results monthly and provides feedback to the staff at staff meetings.

Factors Affecting Results
The number of significant rule changes implemented in 2015 added to the time it takes to process new applications and renewals which is reflected in the decreased percentages.
**KPM #6 Board Best Practices - Percent of total best practices met by the Board.**

Data Collection Period: Jan 01 - Dec 31

* Upward Trend = positive result

### Report Year

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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<tr>
<td>Actual</td>
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<td>100%</td>
<td>100%</td>
<td>99%</td>
<td>100%</td>
</tr>
<tr>
<td>Target</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

**How Are We Doing**

At the Board’s Annual Business Meeting each June, the Board reviews the Best Practices Self-Assessment criteria and scores. This year the Board scored 100% on the best practices criteria. The Board and staff are always looking at ways to do things better and more efficiently.

**Factors Affecting Results**

The Board and its Officers are very active. They are committed to excellence and ensuring the Board and agency are run effectively through the work of the Executive Director and staff.
Appendix A
Best Practices Self-Assessment Guidance

Annually, board members are to self-evaluate their adherence to a set of best practices and report the percent of total best practices met by the board (percent of yes responses in the table below) in the Annual Performance Progress Report as specified in the agency Budget Instructions.

Recommended Assessment Process
1. Select a neutral party to facilitate the self-evaluation (recommended, not required).
2. Individual board members complete the score card shown below.
3. Tabulate the results for all board members (can be done by neutral party in advance).
4. Discuss the results—particularly the results for those areas where there are disparate responses or where the group agrees that they are not adhering to a best practice.
5. Record the group’s joint response to each best practice on a new score card. If consensus is not achieved, the board or commission should record the response as “no.”

Best Practices Assessment Score Card

<table>
<thead>
<tr>
<th>Best Practices/Criteria</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Executive Director’s performance expectations are current.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Executive Director’s receives annual performance feedback.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. The agency’s mission and high-level goals are current and applicable.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. The board reviews the Annual Performance Progress Report.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. The board is appropriately involved in review of agency’s key communications.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. The board is appropriately involved in policy-making activities.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. The agency’s policy option packages are aligned with their mission and goals.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. The board reviews all proposed budgets.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. The board periodically reviews key financial information and audit findings.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. The board is appropriately accounting for resources.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. The agency adheres to accounting rules and other relevant financial controls.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Board members act in accordance with their roles as public representatives.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. The board coordinates with others where responsibilities and interests overlap.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. The board members identify and attend appropriate training sessions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. The board reviews its management practices to ensure best practices are utilized.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Others [The board may add additional best practices; however, they are not to be counted when calculating the percentage adherence to best practices.]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Number

Percentage of Total

Analyzing Assessment Results and Defining Next Steps
Once the above table has been completed, the board will want to prepare responses to the following questions. Responses should be integrated into the Annual Performance Progress Report, which is due from agencies on September 30th of each year.

- How are we doing?
- How do we compare to others and/or to our target? (Once this data is available.)
- What factors are affecting our results?
- What needs to be done to improve future performance?
<table>
<thead>
<tr>
<th>Budget Objects</th>
<th>REVENUE</th>
<th>SERVICES AND SUPPLIES</th>
<th>PERSONAL SERVICES</th>
<th>TOTAL REVENUE &amp; TRANSFERS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LAB ORBITS BUDGET</td>
<td>Rstars Financial Plan</td>
<td>EBoard or Adj Budget or Salary Pot</td>
<td>Adjusted Financial Plan</td>
</tr>
<tr>
<td>0205 Other Business Licenses</td>
<td>4,431,667</td>
<td>4,431,667</td>
<td>4,431,667</td>
<td>1,850,923</td>
</tr>
<tr>
<td>0210 Other NonBusiness Licenses and Fees</td>
<td>505,552</td>
<td>505,552</td>
<td>505,552</td>
<td>83,578</td>
</tr>
<tr>
<td>0505 Fines and Forfeits</td>
<td>420,000</td>
<td>420,000</td>
<td>420,000</td>
<td>214,045</td>
</tr>
<tr>
<td>0605 Interest and Investments</td>
<td>48,000</td>
<td>48,000</td>
<td>48,000</td>
<td>65,468</td>
</tr>
<tr>
<td>0975 Other Revenue</td>
<td>39,700</td>
<td>39,700</td>
<td>39,700</td>
<td>41,809</td>
</tr>
<tr>
<td><strong>SubTotal Revenue</strong></td>
<td>5,444,919</td>
<td>5,444,919</td>
<td>0</td>
<td>2,255,843</td>
</tr>
<tr>
<td>2443 Transfer out to OHA--Workforce Data program</td>
<td>(409,357)</td>
<td>(409,357)</td>
<td></td>
<td>23,388</td>
</tr>
<tr>
<td><strong>SubTotal Transfers</strong></td>
<td>(409,357)</td>
<td>(409,357)</td>
<td>0</td>
<td>(409,357)</td>
</tr>
<tr>
<td><strong>TOTAL REVENUE &amp; TRANSFERS</strong></td>
<td>5,035,562</td>
<td>5,035,562</td>
<td>0</td>
<td>2,232,455</td>
</tr>
</tbody>
</table>

**PERSONAL SERVICES**

<table>
<thead>
<tr>
<th>LAB</th>
<th>SP</th>
<th>S&amp;S</th>
</tr>
</thead>
<tbody>
<tr>
<td>3110 Regular Employees</td>
<td>3,191,268</td>
<td>3,191,268</td>
</tr>
<tr>
<td>3160 Temporary Appointments</td>
<td>25,222</td>
<td>25,222</td>
</tr>
<tr>
<td>3170 Overtime Payments</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3190 All Other Differential Q/Class Leav</td>
<td>183,457</td>
<td>183,457</td>
</tr>
<tr>
<td>3210 Employment Relations Board Assess</td>
<td>1,083</td>
<td>1,083</td>
</tr>
<tr>
<td>3220 Public Employees Retirement Contri</td>
<td>504,012</td>
<td>504,012</td>
</tr>
<tr>
<td>3221 Pension Bond Contribution</td>
<td>195,224</td>
<td>195,224</td>
</tr>
<tr>
<td>3230 Social Security Taxes</td>
<td>256,020</td>
<td>256,020</td>
</tr>
<tr>
<td>3240 Unemployment Assessment</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3250 Workers’ Compensation Assessment</td>
<td>1,380</td>
<td>1,380</td>
</tr>
<tr>
<td>3260 Mass Transit Tax</td>
<td>20,334</td>
<td>20,334</td>
</tr>
<tr>
<td>3270 Flexible Benefits</td>
<td>666,720</td>
<td>666,720</td>
</tr>
<tr>
<td>3455 Vacancy Savings-ORBITS only</td>
<td>(169,448)</td>
<td>(169,448)</td>
</tr>
<tr>
<td>3465 Reconciliation Adjustment-ORBITS only</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3470 Undistributed Personal Services-ORBITS</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3991 PERS Policy Adjustment-ORBITS</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**SERVICES AND SUPPLIES**

| Proj | SubTotal Personal Services | 4,875,272 | 4,875,272 | 129,211 | 5,004,482 | 2,041,903 | 2,982,580 | 44% |

**SPECIAL PAYMENTS**

<table>
<thead>
<tr>
<th>LAB</th>
<th>PS</th>
<th>S&amp;S</th>
<th>SP</th>
</tr>
</thead>
<tbody>
<tr>
<td>4110 InState Travel</td>
<td>102,270</td>
<td>102,270</td>
<td>36,530</td>
</tr>
<tr>
<td>4125 Out of State Travel</td>
<td>15,724</td>
<td>15,724</td>
<td>1,526</td>
</tr>
<tr>
<td>4150 Employee Training</td>
<td>52,335</td>
<td>52,335</td>
<td>7,623</td>
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<tr>
<td>4175 Office Expenses</td>
<td>123,883</td>
<td>123,883</td>
<td>24,029</td>
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<tr>
<td>4200 Telecommunications</td>
<td>43,879</td>
<td>43,879</td>
<td>16,906</td>
</tr>
<tr>
<td>4225 State Govt. Service Chgs.</td>
<td>119,969</td>
<td>119,969</td>
<td>57,794</td>
</tr>
<tr>
<td>4250 Data Processing</td>
<td>73,694</td>
<td>73,694</td>
<td>23,558</td>
</tr>
<tr>
<td>4275 Publicity &amp; Publications</td>
<td>37,712</td>
<td>37,712</td>
<td>4,682</td>
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<tr>
<td>4300 Professional Services</td>
<td>402,408</td>
<td>402,408</td>
<td>121,313</td>
</tr>
<tr>
<td>4315 IT Professional Services</td>
<td>353,340</td>
<td>353,340</td>
<td>10,500</td>
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<tr>
<td>4325 Attorney General</td>
<td>326,595</td>
<td>326,595</td>
<td>206,099</td>
</tr>
<tr>
<td>4375 Employee Recruitment &amp; Develop</td>
<td>207</td>
<td>207</td>
<td>-</td>
</tr>
<tr>
<td>4400 Dues &amp; Subscriptions</td>
<td>4,583</td>
<td>4,583</td>
<td>2,855</td>
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<td>4425 Facilities Rent &amp; Taxes</td>
<td>219,519</td>
<td>219,519</td>
<td>71,240</td>
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<tr>
<td>4475 Facilities Maintenance</td>
<td>51</td>
<td>51</td>
<td>70</td>
</tr>
<tr>
<td>4525 Medical Supplies and Services</td>
<td>1,110</td>
<td>1,110</td>
<td>1,989</td>
</tr>
<tr>
<td>4575 Agency Program Related S&amp;S</td>
<td>229,434</td>
<td>229,434</td>
<td>63,209</td>
</tr>
<tr>
<td>4650 Other Services &amp; Supplies</td>
<td>278,652</td>
<td>278,652</td>
<td>124,473</td>
</tr>
<tr>
<td>4700 Expendible Property</td>
<td>10,499</td>
<td>10,499</td>
<td>689</td>
</tr>
<tr>
<td>4715 IT Expendible Property</td>
<td>43,976</td>
<td>43,976</td>
<td>5,354</td>
</tr>
<tr>
<td>5550 Data Processing Software</td>
<td>-</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>5600 Data Processing Hardware</td>
<td>8,296</td>
<td>8,296</td>
<td>-</td>
</tr>
</tbody>
</table>

**SubTotal Services and Supplies** | 2,448,136 | 2,448,136 | - | 2,448,136 | 778,621 | 1,669,515 | 32% |

**Total Expenditures Budget** | 7,335,399 | 7,335,399 | 129,211 | 7,464,610 | 2,820,524 | 4,644,086 | 38% | 7,057,070 |

<table>
<thead>
<tr>
<th>LAB % PS</th>
<th>66%</th>
<th>LAB % S&amp;S</th>
<th>33%</th>
<th>LAB % SP</th>
<th>0%</th>
</tr>
</thead>
</table>

**AY17 Ending Cash Balance**

<table>
<thead>
<tr>
<th>Revenue less Expenditures</th>
<th>Actuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Revenue &amp; Transfers</td>
<td>2,232,455</td>
</tr>
<tr>
<td>Total Expenditures</td>
<td>(2,820,524)</td>
</tr>
<tr>
<td>Total Revenues &amp; Transfers less Expenditures</td>
<td>(588,069)</td>
</tr>
</tbody>
</table>

**AY19 Cash Balance after the Fiscal Month Closed**

<table>
<thead>
<tr>
<th>Cash</th>
<th>4,206,861</th>
</tr>
</thead>
</table>

**AY19 Estimated Cash Balance**

| Cash Balance Contingency (Months) | (1.43) |
## BOARD OF PHARMACY

### AUGUST 2018 - J

### AY19 CASH FLOW - May 2018

#### OF Appn 30235

<table>
<thead>
<tr>
<th>Budget Object</th>
<th>REVENUE &amp; EXPENDITURES</th>
<th>EXPENDITURES</th>
<th>Adjusted Transfers</th>
<th>ACTUALS</th>
<th>Unobligated Balance</th>
<th>% Expended</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>LAB Revenue/Budget</td>
<td>4,413,667</td>
<td>4,413,667</td>
<td>2,022,733</td>
<td>2,408,935</td>
<td>46%</td>
</tr>
<tr>
<td>-</td>
<td>Other Business Licenses</td>
<td>4,431,667</td>
<td>4,431,667</td>
<td>2,022,733</td>
<td>2,408,935</td>
<td>46%</td>
</tr>
<tr>
<td>-</td>
<td>Total Revenue</td>
<td>8,845,334</td>
<td>8,845,334</td>
<td>4,045,467</td>
<td>4,817,870</td>
<td>54%</td>
</tr>
</tbody>
</table>

#### PERSONAL SERVICES

| 3110 | Supervisor | 3,191,268 | 104,724 | 3,295,992 | 1,467,787 | 1,850,205 | 44% |
|      | Board Member Stipends | 25,222 | 25,222 | 25,222 | 25,222 | 25,222 | 0% |
|      | Overtime Payments | 0 | 0 | 283 | 283 | 0 | 0% |
|      | Total PERSONAL SERVICES | 3,216,490 | 104,724 | 3,321,212 | 1,495,069 | 1,850,205 | 44% |

#### SERVICES AND SUPPLIES

| 4100 | InState Travel | 102,270 | 102,270 | 38,896 | 63,374 | 38% |
|      | Out of State Travel | 15,724 | 15,724 | 1,902 | 13,822 | 12% |
|      | Employee Training | 52,335 | 52,335 | 8,296 | 43,939 | 16% |
|      | Not For Profit | 121,683 | 121,683 | 37,738 | 84,146 | 30% |
|      | Telecommunications | 45,879 | 45,879 | 45,879 | 45,879 | 100% |
|      | Total NOT FOR PROFIT | 174,317 | 174,317 | 74,515 | 174,317 | 100% |
|      | Total SERVICES AND SUPPLIES | 246,602 | 104,724 | 351,326 | 224,415 | 325,465 | 47% |

#### PERSONAL SERVICES

| 3455 | 3455 | 11,991 | 0 | 11,991 | 0 | 0% |

#### Total Expenditure Budget

| 7,335,399 | 7,335,399 | 126,211 | 7,461,610 | 2,092,419 | 4,372,191 | 41% |

#### LAB % PS

| 66% | 67% | Target 100% |

#### LAB % S&S

| 33% | 33% | 33% |

#### LAB % SP

| 0% | 0% | 0% |

### Other Special Payments

| 6085 | Special Payments to CPIA-ORBITS | 11,991 | 11,991 | 11,991 | 11,991 | 11,991 | 11,991 |

#### Total Expenditure from Budget

| 7,335,399 | 7,335,399 | 126,211 | 7,461,610 | 2,092,419 | 4,372,191 | 41% |

### Cash Balance

| 3215 | 3215 | 0 | 0 | 0 | 0 | 0% |

### Auxiliary Account Expenditures

| 8,296 | 8,296 | 0 | 8,296 | 0 | 0% |

### Undistributed Personal Services-ORBITS

| (169,448) | (169,448) | 0 | (169,448) | 0 | 0% |

### Total Transfers from Budget

| 7,448,136 | 7,448,136 | 844,612 | 8,292,748 | 2,092,419 | 4,372,191 | 41% |

### AY19 Ending Cash Balance

| 4,147,271 | 4,272,191 | 0 | 4,272,191 | 0 | 0% |

### Revenue less Expenditures

| 4,272,191 | 4,272,191 | 0 | 4,272,191 | 0 | 0% |

### Total Expenditure from Budget

| 7,335,399 | 7,335,399 | 126,211 | 7,461,610 | 2,092,419 | 4,372,191 | 41% |

### Total Budgeted Expenditure

| 8,296 | 8,296 | 0 | 8,296 | 0 | 0% |

### Total Expenditure from Budget

| 7,335,399 | 7,335,399 | 126,211 | 7,461,610 | 2,092,419 | 4,372,191 | 41% |

### Total Budgeted Expenditure

| 8,296 | 8,296 | 0 | 8,296 | 0 | 0% |

### Total Expenditure

| 7,448,136 | 7,448,136 | 844,612 | 8,292,748 | 2,092,419 | 4,372,191 | 41% |

### AY19 Cash Balance after the Fiscal Month Closed

| 4,147,271 | 4,272,191 | 0 | 4,272,191 | 0 | 0% |

### Budgeted Revenue

| 4,272,191 | 4,272,191 | 0 | 4,272,191 | 0 | 0% |

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

| 0 | 0 | 0 | 0 | 0 | 0% |

### Budgeted Expenditures not yet spent

| 3,092,419 | 3,092,419 | 0 | 3,092,419 | 0 | 0% |

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

| 0 | 0 | 0 | 0 | 0 | 0% |

### Budgeted Expenditures not yet spent

| (3,092,419) | (3,092,419) | 0 | (3,092,419) | 0 | 0% |

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

| 0 | 0 | 0 | 0 | 0 | 0% |

### Budgeted Expenditures not yet spent

| (3,092,419) | (3,092,419) | 0 | (3,092,419) | 0 | 0% |

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

| 0 | 0 | 0 | 0 | 0 | 0% |

### Budgeted Expenditures not yet spent

| (3,092,419) | (3,092,419) | 0 | (3,092,419) | 0 | 0% |

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

| 0 | 0 | 0 | 0 | 0 | 0% |

### Budgeted Expenditures not yet spent

| (3,092,419) | (3,092,419) | 0 | (3,092,419) | 0 | 0% |

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

| 0 | 0 | 0 | 0 | 0 | 0% |

### Budgeted Expenditures not yet spent

| (3,092,419) | (3,092,419) | 0 | (3,092,419) | 0 | 0% |

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

| 0 | 0 | 0 | 0 | 0 | 0% |

### Budgeted Expenditures not yet spent

<p>| (3,092,419) | (3,092,419) | 0 | (3,092,419) | 0 | 0% |</p>
<table>
<thead>
<tr>
<th>Item</th>
<th>Budgeted Revenues</th>
<th>Actuals</th>
<th>Budgeted Expenditures</th>
<th>Adjusted Financial Plan</th>
<th>Actuals To Date</th>
<th>Unobligated Balance</th>
<th>% Expended</th>
</tr>
</thead>
<tbody>
<tr>
<td>0205</td>
<td>Other Business Licenses</td>
<td>4,431,667</td>
<td>4,431,667</td>
<td>4,431,667</td>
<td>2,149,774</td>
<td>2,281,894</td>
<td>49%</td>
</tr>
<tr>
<td>0210</td>
<td>Other Nonbusiness Licenses and Fees</td>
<td>505,352</td>
<td>505,352</td>
<td>505,352</td>
<td>123,978</td>
<td>381,374</td>
<td>25%</td>
</tr>
<tr>
<td>0505</td>
<td>Fines and forfeits</td>
<td>420,000</td>
<td>420,000</td>
<td>420,000</td>
<td>234,247</td>
<td>185,753</td>
<td>56%</td>
</tr>
<tr>
<td>0605</td>
<td>Interest and Investments</td>
<td>48,000</td>
<td>48,000</td>
<td>48,000</td>
<td>80,997</td>
<td>32,153</td>
<td>67%</td>
</tr>
<tr>
<td>0975</td>
<td>Other Revenue</td>
<td>39,700</td>
<td>39,700</td>
<td>39,700</td>
<td>53,697</td>
<td>(14,197)</td>
<td>16%</td>
</tr>
</tbody>
</table>

SubTotal Revenues 5,035,562 5,035,562 0 5,035,562 2,613,536 2,420,224 52%

<table>
<thead>
<tr>
<th>Item</th>
<th>Budget</th>
<th>Actuals</th>
<th>Budget</th>
<th>Actuals</th>
<th>Budget</th>
<th>Actuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>4100</td>
<td>In State Travel</td>
<td>102,270</td>
<td>102,270</td>
<td>102,270</td>
<td>47,945</td>
<td>54,325</td>
</tr>
<tr>
<td>4125</td>
<td>Out of State Travel</td>
<td>15,724</td>
<td>15,724</td>
<td>15,724</td>
<td>4,751</td>
<td>10,973</td>
</tr>
<tr>
<td>4150</td>
<td>Employee Training</td>
<td>52,335</td>
<td>52,335</td>
<td>52,335</td>
<td>10,352</td>
<td>42,983</td>
</tr>
<tr>
<td>4175</td>
<td>Office Expenses</td>
<td>121,683</td>
<td>121,683</td>
<td>121,683</td>
<td>36,248</td>
<td>85,435</td>
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<tr>
<td>4200</td>
<td>Telecommunications</td>
<td>45,879</td>
<td>45,879</td>
<td>45,879</td>
<td>22,818</td>
<td>23,061</td>
</tr>
<tr>
<td>4225</td>
<td>Data Div. Service Chgs.</td>
<td>116,999</td>
<td>116,999</td>
<td>116,999</td>
<td>60,672</td>
<td>56,327</td>
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<tr>
<td>4250</td>
<td>Travel &amp; Lodging</td>
<td>119,457</td>
<td>119,457</td>
<td>119,457</td>
<td>42,818</td>
<td>76,639</td>
</tr>
<tr>
<td>4275</td>
<td>Pubs &amp; Publications</td>
<td>37,712</td>
<td>37,712</td>
<td>37,712</td>
<td>5,074</td>
<td>32,638</td>
</tr>
<tr>
<td>4300</td>
<td>Professional Services</td>
<td>404,408</td>
<td>404,408</td>
<td>404,408</td>
<td>152,127</td>
<td>252,281</td>
</tr>
<tr>
<td>4315</td>
<td>IT Professional Services</td>
<td>355,340</td>
<td>355,340</td>
<td>355,340</td>
<td>25,050</td>
<td>330,290</td>
</tr>
<tr>
<td>4325</td>
<td>Data Processing</td>
<td>326,595</td>
<td>326,595</td>
<td>326,595</td>
<td>206,511</td>
<td>120,084</td>
</tr>
<tr>
<td>4375</td>
<td>Employee Recruitment &amp; Devel.</td>
<td>207</td>
<td>207</td>
<td>207</td>
<td>207</td>
<td>0</td>
</tr>
<tr>
<td>4400</td>
<td>Dues &amp; Subscriptions</td>
<td>4,563</td>
<td>4,563</td>
<td>4,563</td>
<td>4,352</td>
<td>211</td>
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<tr>
<td>4425</td>
<td>Facilities Rent &amp; Taxes</td>
<td>219,519</td>
<td>219,519</td>
<td>219,519</td>
<td>94,087</td>
<td>125,432</td>
</tr>
<tr>
<td>4475</td>
<td>Facilities Maintenance</td>
<td>51</td>
<td>51</td>
<td>51</td>
<td>70</td>
<td>(19)</td>
</tr>
<tr>
<td>4525</td>
<td>Medical Supplies &amp; Services</td>
<td>1,110</td>
<td>1,110</td>
<td>1,110</td>
<td>2,387</td>
<td>(1,277)</td>
</tr>
<tr>
<td>4575</td>
<td>Agency Program Related SAS</td>
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<td>229,434</td>
<td>229,434</td>
<td>90,615</td>
<td>138,819</td>
</tr>
<tr>
<td>4650</td>
<td>Other Services &amp; Supplies</td>
<td>278,652</td>
<td>278,652</td>
<td>278,652</td>
<td>131,890</td>
<td>146,762</td>
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<tr>
<td>4700</td>
<td>Employable Property</td>
<td>10,499</td>
<td>10,499</td>
<td>10,499</td>
<td>689</td>
<td>9,810</td>
</tr>
<tr>
<td>4715</td>
<td>IT Employable Property</td>
<td>43,976</td>
<td>43,976</td>
<td>43,976</td>
<td>3,864</td>
<td>40,112</td>
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<tr>
<td>5500</td>
<td>Data Processing Software</td>
<td>8,296</td>
<td>8,296</td>
<td>8,296</td>
<td>8,296</td>
<td>0</td>
</tr>
<tr>
<td>5600</td>
<td>Data Processing Hardware</td>
<td>4,352</td>
<td>4,352</td>
<td>4,352</td>
<td>4,352</td>
<td>0</td>
</tr>
</tbody>
</table>

SubTotal Subservices 2,446,136 2,446,136 2,446,136 992,099 1,454,037 38% $ 1,520,037

<table>
<thead>
<tr>
<th>Item</th>
<th>Budget</th>
<th>Actuals</th>
<th>Budget</th>
<th>Actuals</th>
<th>Budget</th>
<th>Actuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>6085</td>
<td>Other Special Payments</td>
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<td>11,991</td>
<td>11,991</td>
<td>11,991</td>
<td>0</td>
</tr>
<tr>
<td>6445</td>
<td>Special Payments to OHA-PMP</td>
<td>11,991</td>
<td>11,991</td>
<td>11,991</td>
<td>11,991</td>
<td>0</td>
</tr>
</tbody>
</table>

SubTotal Transfers 11,991 11,991 0 11,991 0 11,991 $ 11,991

Total Expenditures Budget 7,335,399 7,335,399 126,211 7,461,610 2,382,100 4,081,510 45% $ 4,081,510

<table>
<thead>
<tr>
<th>Item</th>
<th>LAB % PS</th>
<th>LAB % SS</th>
<th>LAB % SF</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015 Ending Cash Balance</td>
<td>66%</td>
<td>33%</td>
<td>0%</td>
</tr>
<tr>
<td>Cash</td>
<td>4,081,510</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

AY19 Ending Cash Balance

Revenue less Expenditures

<table>
<thead>
<tr>
<th>Item</th>
<th>Budget</th>
<th>Actuals</th>
<th>Budget</th>
<th>Actuals</th>
<th>Budget</th>
<th>Actuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>Total Revenue &amp; Transfers</td>
<td>2,613,536</td>
<td>2,613,536</td>
<td>2,613,536</td>
<td>1,520,037</td>
<td>0</td>
</tr>
</tbody>
</table>

AY19 Cash Balance after the Fiscal Month Closed 4,081,510

Budgeted Revenues not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be made 0
Revenue received is more than budgeted so zero is not yet received

AY19 Estimated Cash Balance 4,081,510

Cash Balance Contingency (Months) (10.15)
## Revenue Estimate Report - Other Funds

**Biennium: 2019-21**

<table>
<thead>
<tr>
<th>Other Funds Revenue Source</th>
<th>2017-19 Leg Adopted</th>
<th>CURRENT2017-19 Rate</th>
<th>2017-19 Projected (Actuals + Estimate for remainder of biennium)</th>
<th>2019-21 PROPOSED AY19 Rate</th>
<th>2019-21 Number of Units</th>
<th>2019-21 Estimate - Proposed</th>
<th>Methodology</th>
<th>Comments**</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANIMAL EUTHANASIA</td>
<td>$4,431,667.00</td>
<td>$4,765,240.00</td>
<td>$7,146,250.00</td>
<td></td>
<td></td>
<td></td>
<td>Business License Fees</td>
<td></td>
</tr>
<tr>
<td>CERTIFIED PHARMACY TECHNICIAN</td>
<td>50 $2,400.00</td>
<td>75 $350,168.00</td>
<td>$689,400.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td>renews in even yrs April/June</td>
</tr>
<tr>
<td>CHARITABLE PHARMACY</td>
<td>75 $1,800.00</td>
<td>75 $18,750.00</td>
<td>$29,000.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td></td>
</tr>
<tr>
<td>COMMUNITY HEALTH CLINIC</td>
<td>75 $4,200.00</td>
<td>225</td>
<td>$10,800.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td></td>
</tr>
<tr>
<td>CONTROLLED SUBSTANCE</td>
<td>50 $199,500.00</td>
<td>100</td>
<td>$404,200.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td></td>
</tr>
<tr>
<td>DISPENSING PRACTITIONER DRUG OUTLET</td>
<td>100 $1,300.00</td>
<td>100</td>
<td>$7,000.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td></td>
</tr>
<tr>
<td>DRUG DISTRIBUTION AGENT</td>
<td>400 $206,400.00</td>
<td>400</td>
<td>$206,400.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td></td>
</tr>
<tr>
<td>DRUG ROOM &amp; Correctional</td>
<td>75 $12,000.00</td>
<td>100</td>
<td>$16,000.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td>includes Correction Facilities, Hospital and other drug rooms</td>
</tr>
<tr>
<td>GASES-MEDICAL CLASS C</td>
<td>50 $44,000.00</td>
<td>75 $440</td>
<td>$69,300.00</td>
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<td></td>
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<td>annual</td>
<td></td>
</tr>
<tr>
<td>INSTITUTIONAL PHARMACY</td>
<td>175 $50,750.00</td>
<td>225</td>
<td>$69,300.00</td>
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<td></td>
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<td>annual</td>
<td></td>
</tr>
<tr>
<td>INTERN LICENSE/2 YEAR*</td>
<td>50 $44,350.00</td>
<td>100</td>
<td>$88,700.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td>*may not renew more than twice, unless authorized</td>
</tr>
<tr>
<td>MANUFACTURER</td>
<td>400 $830,400.00</td>
<td>525</td>
<td>$1,089,900.00</td>
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<td></td>
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<td>annual</td>
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</tr>
<tr>
<td>NAPLEX</td>
<td>50 $27,967.50</td>
<td>50 $390</td>
<td>$35,000.00</td>
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<td>annual</td>
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</tr>
<tr>
<td>NONPRESCRIPTION A</td>
<td>50 $249,700.00</td>
<td>75 $2550</td>
<td>$382,500.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td></td>
</tr>
<tr>
<td>NONPRESCRIPTION B</td>
<td>50 $8,000.00</td>
<td>75 $80</td>
<td>$12,000.00</td>
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<td></td>
<td></td>
<td>annual</td>
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</tr>
<tr>
<td>NONPRESCRIPTION D</td>
<td>100 $200.00</td>
<td>100</td>
<td>$200.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td></td>
</tr>
<tr>
<td>PHARMACIST LICENSE</td>
<td>120 $1,005,905.00</td>
<td>250</td>
<td>$1,982,500.00</td>
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<td></td>
<td></td>
<td>biennial</td>
<td>renews in odd yrs April/June</td>
</tr>
<tr>
<td>PRECURSOR</td>
<td>50 $1,000.00</td>
<td>75 $16</td>
<td>$2,400.00</td>
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<td>annual</td>
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</tr>
<tr>
<td>PRESCRIPTION DRUG MONITORING FEE</td>
<td>50 $388,800.00</td>
<td>50 $7930</td>
<td>$396,500.00</td>
<td></td>
<td></td>
<td></td>
<td>biennial</td>
<td>paid with pharmacist renewal in odd yrs</td>
</tr>
<tr>
<td>PROPHYLACTIC MGF</td>
<td>50 $1,300.00</td>
<td>50 $13</td>
<td>$1,300.00</td>
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<td>annual</td>
<td></td>
</tr>
<tr>
<td>RECIPROCITY</td>
<td>200 $126,000.00</td>
<td>200</td>
<td>$126,000.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td>includes Remote Distribution Facilities and Remote Dispensing Machines</td>
</tr>
<tr>
<td>REMOTE DISPENSING/Distribution</td>
<td>100 $1,000.00</td>
<td>120</td>
<td>5 $1,200.00</td>
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<td>annual</td>
<td></td>
</tr>
<tr>
<td>RETAIL PHARMACY</td>
<td>175 $474,950.00</td>
<td>225</td>
<td>$636,750.00</td>
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<td></td>
<td>annual</td>
<td>includes Home Dialysis,</td>
</tr>
<tr>
<td>SUPERVISING PHYSICIAN DISPENSING OUTLET</td>
<td>175 $12,950.00</td>
<td>175</td>
<td>$15,400.00</td>
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<td></td>
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<td>annual</td>
<td></td>
</tr>
<tr>
<td>TECHNICIANS</td>
<td>50 $95,100.00</td>
<td>100</td>
<td>$108,600.00</td>
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<td></td>
<td>annual</td>
<td>2 yr license, not renewable</td>
</tr>
<tr>
<td>WHOLESALER</td>
<td>400 $581,600.00</td>
<td>525</td>
<td>$763,350.00</td>
<td></td>
<td></td>
<td></td>
<td>annual</td>
<td></td>
</tr>
</tbody>
</table>