Oregon Board of Pharmacy

BOARD MEETING AGENDA

Meeting Location:
Portland State Office Building
800 NE Oregon Street, Portland, OR 97232
February 6-7, 2019
(Updated 2.1.19)

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, February 6, 2019 @ 8:30AM – Conference Room 1A
Thursday, February 7, 2019 @ 8:30AM – Conference Room 1A
≈ If special accommodations are needed for you to attend or participate in this Board Meeting, please contact Loretta Glenn at: (971) 673-0001. ≈

WEDNESDAY, FEBRUARY 6, 2019

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

A. Roll Call
B. Introduction of new Executive Director Joseph Schnabel, Pharm.D., R.Ph. BCPS
C. Agenda Review and Approval *Action Necessary*

II. Contested Case Deliberation pursuant to ORS 192.690(1) - **Not Open to the Public**

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

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

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

THURSDAY, FEBRUARY 7, 2019

8:30AM

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

A. Roll Call
B. Introduction of new Executive Director Joseph Schnabel, Pharm.D., R.Ph. BCPS
C. Acknowledge Interim Executive Director Brad Avy
D. Motions for Contested Cases & Disciplinary Action – *Efremoff* *Action Necessary*

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 Update - none

5. Consider rules and send to Rulemaking Hearing - none

6. Policy Issues for Discussion / Updates:
   - Div 045 Compounding – draft rules review * **#A – A6**
     - 2018 Intergovernmental Working Meeting on Drug Compounding (FDA), 9/25-16/2018, Silver Spring, MD – *Efremoff/Fox*
     - FDA Memo 12/10/18 – *Efremoff/Karbowicz*
     - Veterinary Compounding Info

   - Technician Informational

B. Public Health and Pharmacy Formulary Advisory Committee **#B-B1**
Karbowicz/MacLean/Efremoff
1. Committee Meeting and Recommendation update –10/26/18, 1/11/19
2. Consider rules & send to Rulemaking Hearing – none

Lunch – estimated time depending on the length of discussions

C. Discussion Items:
1. Waiver Requests:
   a. Samaritan Pharmacy Services request – **#C - CONFIDENTIAL** *Karbowicz*
   Action Necessary
   b. Deschutes County Health Services request – **#C1** *Karbowicz*
   Action Necessary
2. TCVP: none
3. Other:

a. Schedule of LEDS Audits **#C2** Hennigan *Action Necessary*

VIII. ISSUES/ACTIVITIES

A. Board Meeting Dates

- April 3-4, 2019 Portland
- June 5-6, 2019 Portland
- August 7-9, 2019* Portland (**3 day meeting*)
- October 2-3, 2019 Portland
- November 6-7, 2019 Portland (*Strategic Planning – subject to change*)
- December 11-12, 2019 Portland
- February 5-7, 2020* Portland (*3 day meeting)
- April 15-16, 2020 Portland
- June 17-18, 2020 Portland
- August 12-14, 2020* Portland (*3 day meeting)
- October 14-15, 2020 Portland
- November 18-19, 2020 TBA (*Strategic Planning – subject to change*)
- December 16-17, 2020 Portland

B. Rulemaking Hearing Dates

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

- May 22, 2019
- July 23, 2019 (possible)
- November 26, 2019

C. Committees/Meetings

1. OSPA Annual Convention, 10/12-14/2018, Portland – *Efremoff/Beaman*
2. NABP District VI-VIII, Mtg Kansas City, MO 10/14-17/2018 – *Vipperman*
3. OSHP Fall Meeting –11/10/18, Portland – *Karbowicz*
4. OSPA Lane Co. Mid-Winter CE Seminar, Eugene – 2/16-17/2019 – *Karbowicz/Logan/Baldwin*
5. OSHP Spring Meeting – Sunriver - 4/26-28/2019
6. NABP 2019 Annual meeting – Minneapolis, MN - May 16-18, 2019 *Action Necessary*
7. NABP District VI-VIII Mtg. Boise, ID, 10/6-9/2019

D. Board Member/Staff Presentations – *DeBarmore*

- Pharmacy Coalition – 10/16/18, 11/3/18, 1/8/19
- Professional Practice Roundtable – 11/13/18, 1/10/19

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

F. Legislative update – *Karbowicz*

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

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 – May 1, 2018 – August 31, 2018 **# CONSENT – 1 CONFIDENTIAL**
2. MPJE Scores – May 1, 2018 – August 31, 2018 **# CONSENT – 2 CONFIDENTIAL**
3. License/Registration Ratification – December 4, 2018 - January 22, 2019 **# CONSENT – 3**
4. Pharmacy Technician Extensions – none
5. Board Minutes – December 13-14, 2018 **# CONSENT – 4**

2:00 APPEARANCE

Sherry Carter HR Partner (90 minutes to 2 hrs)
RE: Level-set Strategic Planning Expectations

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

Adjourn

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

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

Changes to these rules include: (1) Expectation of full compliance with all USP Chapter standards commensurate with the compounding performed; (2) Registration, including the requirement for compounding pharmacies to be accredited by a Board approved entity every 3 years at a minimum; this does not replace the Board's annual inspections; (3) Personnel responsibilities, including required policies and procedures (P&Ps); (4) Labeling; and (5) Documentation.

Note: There is a distinction between compliance with safety standards and compliance with law/rule. The Oregon Board of Pharmacy is committed to *Compliance Through Education* and one way that is achieved is through clear rules that articulate compliance expectations. Therefore, these rules provide for the broad directive to "Comply with all USP Chapters" as well as provide structure and clarity to licensees who compound drugs by specifying required P&Ps and documentation.

Regarding enforcement, USP intends to make compounding chapters official on December 1, 2019. The Board plans to discuss policy, compliance and enforcement expectations at upcoming meetings, as these rules are promulgated.

Policy Items for Discussion:

Does the Board want to provide guidance similar to California's process for a pharmacy to make a formal request (waiver) for a specific amount of time needed to comply with these rules, due to physical construction or alterations to facility? (see lines 71-79)

Does the Board want to retain Shared Services allowances for provision of certain non-patient specific compounded drugs (also known as "Office Use/Stock"? (see lines 573-586)

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

855-045-0200
Application

(1) These rules ~~(OAR 855-045-0200 to 855-045-0270)~~ apply to any person, including any business entity, located in **or outside** Oregon that engages in the practice of compounding **a**

drug~~s,~~ **for use or distribution in Oregon.** ~~or any person, including any business entity, located in any other state that compounds drugs for the use of patients located in Oregon. Compounding of radiopharmaceuticals is specifically exempted from these rules where these rules are in conflict with the rules or guidelines established by the Nuclear Regulatory Commission, the Radiation Protection Services of the Oregon Department of Human Services or any other applicable agency.~~ Any person located outside Oregon that compounds drugs for the use of patients located in Oregon is ~~expected~~ to 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 **a drug** ~~medications that are prepared for a specific patient and that are prescribed or ordered subject to a valid practitioner – patient relationship~~.

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

~~(4) Any compounding activity that is not pursuant to a valid prescription or an order to prepare for administration and for a specific patient is considered to be manufacturing, and any person engaged in manufacturing must be registered in accordance with OAR 855-060-0001, with the following exceptions:~~

~~(a) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon that is covered by a Shared Pharmacy Services agreement as defined in OAR 855-006-0005;~~

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

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

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

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

<ENTER WAIVER LANGUAGE HERE, IF DESIRED (see lines 24-26)>

California: (f) Where compliance requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver. (https://www.pharmacy.ca.gov/forms/waiver_comm_phy.pdf)

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

855-045-0210
~~**Definitions**~~ **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 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 must register with the Board as a manufacturer drug outlet.

(4) A resident facility distributing non-patient specific drugs outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(a) A preparation prepared according to the manufacturer's labeled instructions and other manipulations when preparing sterile products that expose the original contents to potential contamination, and includes all preparations compounded in IV rooms; or~~

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

~~(c) Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the above two characteristics, and which include, but are not limited to, baths and soaks for live organs and tissues, implants, inhalations, injections, powders for injections, irrigations, metered sprays, and ophthalmic and otic preparations.~~

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

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

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

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

855-045-0220
Personnel and Responsibilities

All drug compounding must adhere to 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 Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 1072, 1116, 1160, 1163, 1211 and 1229.5.

(1) **All** ~~P~~**p**ersonnel who prepare **and supervise the preparation of** compounded pharmaceuticals~~, both sterile and non-sterile, shall~~ **must complete** ~~be provided with~~ appropriate training **and be capable and qualified to perform assigned duties.** ~~before they begin to prepare such products including for CSPs, training in the theoretical principles and practical skills of aseptic manipulations.~~

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

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

(b) Hand hygiene;

(c) Garbing;

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

(e) Cleaning activities, addressing but not limited to sanitizing and disinfecting;

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

(g) Creating Master Formulation Records;

(h) Creating Compounding Records;

(i) Establishing BUDs;

(j) Continuous quality assurance program and quality controls, addressing but limited to release testing, end-product evaluation, quantitative/qualitative testing;

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

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

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

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

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

~~(a) Ensure all pharmacy personnel involved in preparing compounded products are trained and have demonstrated skills commensurate with the complexity of the procedures they are performing;~~

~~(b) Establish a procedure for verification by a pharmacist of the preparation of each completed compounded product. This verification shall be accomplished by a review of each compounded product that includes but is not limited to:~~

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

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

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

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

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

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

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

~~A person licensed to practice pharmacy by the Oregon Board of Pharmacy who is working in a compounding pharmacy, including a pharmacy that only prepares sterile parenteral products, has the duty to exercise that degree of care, skill, diligence and professional judgment that is used by~~

~~ordinarily competent, careful pharmacists in the same or similar circumstances in the community of the pharmacist or a similar community.~~

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

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

~~(b) Dispense a compounded product only subject to a valid prescription except as provided in OAR 855-045-0200(4), and only when, in their professional judgment, it results from a valid prescriber-patient relationship;~~

~~(c) Compound only products that are not commercially available except as allowed in OAR 855-045-0240(2), and, except that with the prior approval of the Board, a commercial product that is temporarily in short supply or otherwise unavailable, may be compounded subject to OAR 855-045-0200(4)(c);~~

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

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

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

~~(a) An organized index;~~

~~(b) Product formula information;~~

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

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

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

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

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

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

~~(I) Product labeling;~~

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

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

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

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

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

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

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

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

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

~~(a) Establishment of BUD;~~

~~(b) End Product Testing;~~

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

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

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

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

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

~~(B) Protocols for establishing BUDs. BUDs may not exceed those in USP 797 guidelines unless a quality assurance program is established that verifies End Product Testing beyond the dating established by USP 797. Records to verify sterility and pyrogenicity must be maintained and available for review for three years.~~

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

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

~~(a) The date obtained;~~

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

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

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

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

(a) **The generic or official name of each active ingredient;** ~~Establish, maintain and enforce written policies and procedures associated with the pharmacy's preparation and dispensing of parenteral products. Policies and procedures shall be available for inspection at the pharmacy. These policies and procedures shall include all requirements of OAR 855-045-0230 as appropriate to the practice setting and:~~

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

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

(d) The dosage form and route of administration;

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

(f) The total quantity of the drug product;

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

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

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

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

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

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

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

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

~~(B) Beyond Use Date;~~

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

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

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

~~(c) Patient Care Services: Counseling shall be available to the patient or patient's agent concerning proper use of parenterals and related supplies furnished by the pharmacy.~~

~~(2) In addition to complying with all the requirements in section (1) of this rule, licensed pharmacy personnel preparing parenteral admixtures as defined in OAR 855-045-0210 may:~~

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

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

~~(c) Reassign a parenteral admixture to another patient if the admixture does not exceed the documented BUD for that admixture, and the parenteral admixture that was prepared and dispensed for a patient specific order, and has been stored at all times under the control of a person trained and knowledgeable in the storage and administration of drugs;~~

~~(d) In the case of a patient specific parenteral admixture, the pharmacist does not need to comply with the worksheet and log requirements in these rules provided that a quality assurance process is in place to address drug recalls, and appropriate safeguards are in place.~~

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

~~855-045-0250~~
~~Definitions of Risk Levels for Sterile Preparations~~

~~The three risk levels of CSPs recognized by USP 797 are based on the probability of contamination by microbial, chemical or physical agents. Low-Risk and Medium-Risk Level CSPs are determined by the potential for microbial contamination during preparation, and High-Risk Level CSPs by the potential for not being properly sterilized before administration to patients. These risk levels are defined, and products must be prepared and managed as follows:~~

~~(1) Low-Risk Conditions:~~

~~(a) CSPs prepared using aseptic manipulation within an air quality environment that is equal to or better than ISO Class 5, using only sterile ingredients, products, components and devices;~~

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

~~(c) Manipulations limited to:~~

~~(A) Aseptically opening ampoules;~~

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

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

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

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

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

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

~~(2) Medium Risk Conditions:~~

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

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

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

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

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

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

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

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

~~(3) High Risk Conditions:~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(4) Immediate-use:~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(3) Effective January 1, 2009, for preparation of medium-risk level CSPs, an ISO 5 certified or better BSC, CAI or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. These areas must have positive airflow unless used to prepare hazardous drugs. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or better environment, or in accordance with the manufacturer's specifications.~~

~~(4) Effective January 1, 2009, for preparation of high-risk level CSPs, an ISO 5 certified or better BSC, CAI, or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. Unless used to prepare hazardous drugs, the buffer room or zone shall have a positive air pressure of 0.02 to 0.05 inch water column and may not contain a sink or drain. Surfaces and essential furniture in buffer rooms and zones and anterooms shall be nonporous, smooth, nonshedding, impermeable, cleanable and resistant to disinfectants. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or better environment, or in accordance with the manufacturer's specifications.~~

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

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

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

~~(a) A cleaning policy that requires the cleaning of all work surfaces in ISO 7 and 8 areas to be performed at least daily. Floors in ISO 7 and 8 areas cleaned at least daily. Surfaces that are used to prepare CSPs must be cleaned either with a high-level disinfectant or with a medium-level disinfectant that is alternated regularly with another medium-level disinfectant. Empty shelving, walls and ceilings in anterooms and buffer rooms will be cleaned at least monthly with appropriate disinfectant solution;~~

~~(b) All ISO classified areas will be checked and certified by a qualified individual no less than every 6 months and whenever the LAF, BSC, or CAI is relocated or the physical structure of the buffer room or anteroom has been altered;~~

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

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

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

855-045-0270
Records

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

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

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

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

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

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

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

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

(e) Engineering and environmental control records,

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

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

(b) Physical description of the final preparation;

(c) Ingredient identities and amounts;

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

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

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

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

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

(i) Quality control procedures and expected results; and

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

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

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

(b) Physical description of the final preparation;

(c) Master formulation record reference for the preparation;

(b) Quantity prepared;

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

(d) Pharmacy unique lot number;

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

(f) Beyond Use Date;

(g) Identity of verifying pharmacist;

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

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

~~(j) Mixing instructions;~~

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

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

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

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

(k) Total quantity compounded;

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

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

(n) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure.

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

~~(d) In the case of a patient specific parenteral admixture, the pharmacist does not need to comply with the worksheet and log requirements in these rules provided that a quality assurance process is in place to address drug recalls, and appropriate safeguards are in place.~~

POLICY DISCUSSION:

~~(3)~~ **(4)** ~~Record of maintenance and certifications for all equipment must be retained for a minimum of three years and be available for inspection by the Board.~~ **Records of 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:**

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

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

855-006-0005
Definitions

As used in OAR chapter 855:

(28) "Shared Pharmacy Service" means a written agreement, that has been approved in writing by the board, that exists for the processing by a pharmacy of a request from another pharmacy or a practitioner licensed to prescribe the drug, to fill or refill a prescription or a drug order, or to perform processing functions including but not limited to:

(a) Dispensing;

(b) Drug utilization review;

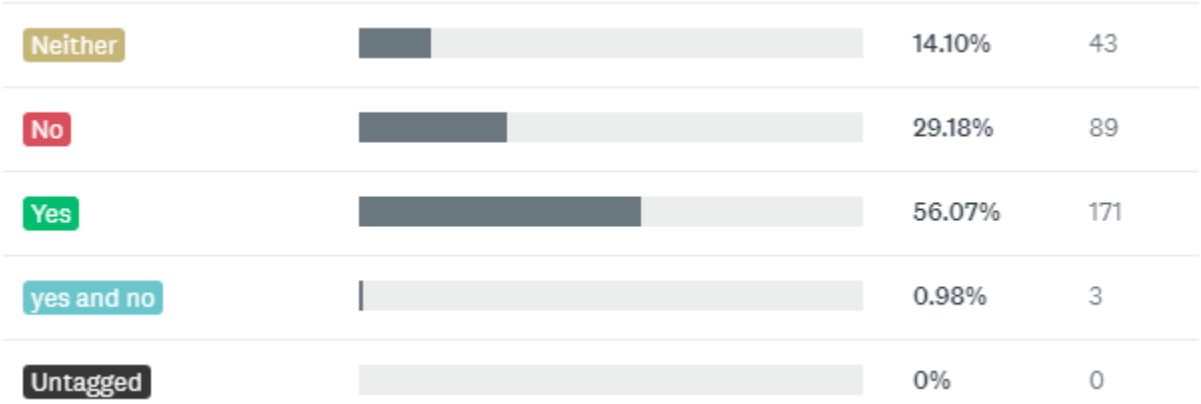
(c) Claims adjudication;

(d) Refill authorizations;

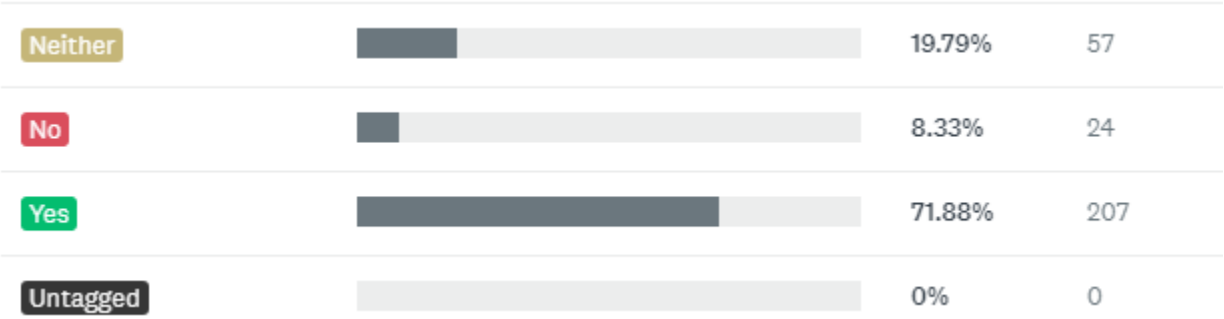
(e) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon for Oregon outlets and practitioners located in Oregon only; and

(f) Therapeutic interventions.

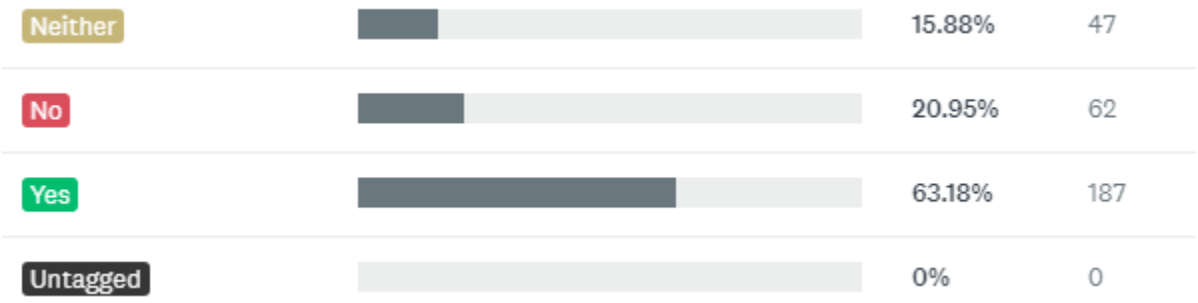
Q1: For the purposes of additional safety assurances, the Oregon Board of Pharmacy is considering requiring an outlet's compounding pharmacy processes to be routinely validated via an "outside" or "3rd party" accreditor, such as NABP-VPP, Joint Commission, ACHC, PCAB, etc. Do you agree with this policy initiative? Why or why not? (*305 Responses)*



Q2: Should Oregon regulations continue to allow "Shared Services" for compounding? Why or why not? (Shared Pharmacy Service means a Board approved written agreement for compounding by a pharmacy located in Oregon for Oregon outlets and practitioners located in Oregon only). (*288 Responses)*



Q3: Should a new rule be added to require notification to the Board of a patient-level recall of a compounded drug distributed or dispensed by an Oregon licensed pharmacy? Why or why not? (*296 Responses)*



Q4 For the purposes of additional safety assurances, the Oregon Board of Pharmacy is considering requiring an outlet's compounding pharmacy processes to be routinely validated via an "outside" or "3rd party" accreditor, such as NABP-VPP, Joint Commission, ACHC, PCAB, etc. Do you agree with this policy initiative? Why or why not?

Answered: 305 Skipped: 11

#	RESPONSES	DATE
1	No. Our Hospital and Home Infusion Pharmacies are already Joint Commission accredited. These locations prepare larger batches of compounded medications and require more stringent inspections. The compounding in our ambulatory sites is primarily more immediate or same day use, which is at lower risk for contamination. Accrediting our ambulatory sites would put a strain on resources reserved to maintain compliance in our compounding suites that is already stretched thin. Requiring Oregon Board of Pharmacy Inspectors to be more knowledgeable in compounding requirements so that during their annual inspections they could identify and help the compounding pharmacies correct any issues or discrepancies would result in more timely resolutions.	9/17/2018 2:37 PM
2	No, this could be a significant added expense without providing value. The OR BOP and Joint Commission already review our compounding policies and practices during site visits. As part of a health-system, we take every precaution to follow USP 797 and address with policies and procedures. We do not feel an outside accreditor would provide additional benefit or assurances.	9/17/2018 2:33 PM
3	yes	9/17/2018 1:20 PM
4	Just put them all out of business. The PBM's are going to be requiring it pretty soon. Pharmacies can't afford.to do it. So, then the boards complete the process by requiring it and then they cannot do any cash compound prescriptions either. Basically, you will only have a handful left in whole state, ran by corporations. Goodbye to the art that originated our profession.	9/17/2018 12:14 PM
5	Yes	9/17/2018 10:00 AM
6	No. The OBP inspection should be more than adequate to assure all safety measures are in place and that all rules and regulations are being followed	9/17/2018 9:24 AM
7	No. Too costly and how do we know the verification company understands Oregon's below par compounding rules.	9/17/2018 8:40 AM
8	No, Expire dates, shipping causes financial loss	9/17/2018 7:44 AM
9	Yes. An extra set of eyes and ears can only help promote patient safety.	9/16/2018 6:18 PM
10	No, If you are a small pharmacy the cost may put you out of business	9/16/2018 1:40 PM
11	no all we do is magic moouthwash	9/16/2018 10:27 AM
12	No	9/16/2018 12:44 AM
13	Yes I agree. I see a great risk of error in pharmacy compounding, which is reduced with clearly defined processes that people are held accountable to follow.	9/15/2018 6:23 PM
14	Not. Visits are too infrequent to maintain true good practices. Surveyors often do not understand compounding rules or know what questions to ask. Feel as if certification is just an excuse to charge money	9/15/2018 1:17 PM
15	agreed	9/14/2018 9:56 PM
16	Not for simple compounding like magic mouthwash or mixing two creams	9/14/2018 9:47 PM
17	Yes, due to the possibility of impurities in compounded medications that could cause health issues or occurrences if best practice guidelines are not being followed or enforced.	9/14/2018 9:12 PM
18	Yes, it holds the pharmacy to higher standards and improves patient safety	9/14/2018 3:57 PM

19	No. The BOP should be able to independently assess compliance with standards set by the BOP. Requiring a pharmacy to incur the cost and labor associated with being "validated" by an outside accreditor seems unreasonable.	9/14/2018 10:01 AM
20	We are accredited with NABP for DMEPOS, we have had Joint Commission accreditation -- exhaustive paper processes, expensive and require a lot of time for the surveys. There are learning opportunities for staff and process improvements. I believe following USP 797 in board rules and in the pharmacy is appropriate. The board can ensure compliance through 797 inspections without requiring accreditation.	9/14/2018 9:10 AM
21	No. Our pharmacy is set up and run by USP standards. Adding another accreditation agency will not improve quality of well run pharmacies, it will simply increase our cost. The issue is improving the practice at poorly run pharmacies.	9/13/2018 3:06 PM
22	Yes. I believe accreditation will help ensure that any pharmacy providing compounding services has been properly trained and equipped to do so and will increase patient safety.	9/13/2018 1:06 PM
23	no, should be done by board of pharmacy	9/13/2018 11:30 AM
24	Yes this should be done	9/13/2018 10:14 AM
25	Not really, unless computing require technical situation. Today ,s compounding for Marilyn is add one item to next, or mixing two cream/ointment which happen just a few times per year	9/12/2018 8:33 PM
26	Yes because there will be no bias	9/12/2018 7:59 PM
27	Yes. I want to be assured that 5he compound practice is done appropriately.	9/12/2018 6:59 PM
28	Why wouldn’t audits be done by the Board of Pharmacy?	9/12/2018 5:52 PM
29	Do not agree. This add much additional cost at a time when reimbursement to hospitals is the worst it's ever been. This can be done in other ways.	9/12/2018 5:31 PM
30	Yes. PATIENT SAFETY!	9/12/2018 5:19 PM
31	I do not agree. Standards should not be handed over to a third party. State Board of Pharmacy should create standards and maintain oversight. Paying an outside entity does not guarantee proper oversight, but it DOES guarantee an additional financial burden on pharmacies.	9/12/2018 5:19 PM
32	Yes. It is an added measure of quality and safety for patients.	9/12/2018 11:26 AM
33	I agree. Hospitals are already required to be accredited by a CMS-approved auditing agency such as TJC or DNV. All outlets that perform sterile compounding should have such requirements to ensure consistent levels of care across settings.	9/12/2018 10:36 AM
34	Yes, it is good to have standards	9/12/2018 10:29 AM
35	No, due to the cost involved and our home state requires 797	9/12/2018 9:48 AM
36	N/A	9/12/2018 9:43 AM
37	I do not agree that a third party accreditor should be mandated to perform compounding services. State regulations should drive guidelines and best practices ensuring quality and safety for the public. A third-party company with financial, political or industry position could create an environment where patient safety and quality is no longer the primary focus.	9/12/2018 9:27 AM
38	Yes	9/12/2018 8:44 AM
39	yes	9/11/2018 10:09 PM
40	yes, I think having a third party come in would be good for standardization of compounding.	9/11/2018 10:01 PM
41	Yes. It would help assure patient safety.	9/11/2018 7:15 PM
42	Supportive if validated means the standard survey. Not supportive if additional costs are required for certification	9/11/2018 5:59 PM
43	Agree. Preparation of CSPs is a highly specialized area of pharmacy. As such, it should be monitored and certified by an agency well versed in the technical and logistical details involved.	9/11/2018 5:28 PM
44	Yes, a different pair of eyes could benefit on what areas to improve.	9/11/2018 4:31 PM
45	Depends on what the validation looks like.	9/11/2018 3:52 PM

46	No. Having been through various "outside" reviews I have come away with the belief that the people doing the evaluation (especially NABP) were not experienced in the practice of pharmacy compounding . If the various state pharmacy boards would train their inspectors properly, it would not be necessary for organizations like NABP to try and expand their kingdoms. Do you realize how much it would cost to pay for them to bring a team of people to your pharmacy for up to one week to "evaluate" your business? Joint commission costs hospitals many thousand dollars and in my experience (50 plus years) I have never seen them make a reasonable suggestion for improvement. My NABP visitor basically walked around for two days. He asked some questions that indicated quite clearly that he really didn't know what was going on. When he left, he gave me a packet full of questions that he said " must be completed in 10 days and mailed to their office". All of use in the pharmacy felt quite certain that his job was to go through the questions during his visit. It is probably obvious that my opinion is clear. State boards of pharmacy should step up and do their job and not bring in third parties and extra expense to your pharmacies.	9/11/2018 3:44 PM
47	Yes. Any kind of additional regulation would be good	9/11/2018 3:27 PM
48	I agree with this policy. I believe PCAB or NABP-VPP would be appropriate.	9/11/2018 3:08 PM
49	I agree. Oregon should come into line with National standards. National standards are USP standards and these group help ensure adherence. Patient safety is incredibly important and we stand out as a state who has not adopted National standards.	9/11/2018 2:47 PM
50	I do agree with this or some kind of similar policy, as some pharmacies do not have adequate support for self-auditing. I DO believe, however, that one must take into account the scope of compounding and that not all compounding pharmacies should be held to same standards--a small rural pharmacy that offers some compounding should not be held to exact same standards as a busy urban pharmacy that does a greater percentage (or is a compounding only pharmacy)	9/11/2018 2:46 PM
51	Sorta of. I feel that it should be based on the amount of compounding that is being done. For rural areas of Oregon it would be hard to pay for the amount that is done. The pharmacy that compounds in rural Oregon provide a benefit for patients in certain situations such as hospice care. The pharmacies do not do enough to be able to cover the costs of an outside 3rd party.	9/11/2018 2:11 PM
52	yes	9/11/2018 12:20 PM
53	I am aware that this is the practice in some states like Michigan. However, it is not the norm. I do se the value if the location does not undergo routine inspections (e.g., Joint Commission). However, if location already undergoes those inspections, I do not see the need for an additional inspection. I would encourage the BOP to think of this along two tiers - for a retail site that does not undergo inspections from anyone other than BOP, this may be appropriate. However for traditional acute care locations this would be overkill, increase cost, and not bring much additional patient safety or value to the patient.	9/11/2018 11:55 AM
54	I agree. This would allow standard review processes and a national validation of high standards. Rules should allow OBOP independent inspection for outlets with complaints, deficiencies in accreditation visits. or for random validation of 3rd party inspection quality.	9/11/2018 10:24 AM
55	Possibly. We only compound magic mouthwash/GI cocktails. I don't think we need a 3rd party accreditor for something simple like that.	9/11/2018 10:08 AM
56	Unclear, I'll need to know more	9/11/2018 9:52 AM
57	I agree with this initiative for outlets which compound CSPs, as well as non-CSPs which are intended for multiple patient use (e.g. bulk bottles). I think this would be too labor intensive and not well received by independent and smaller community pharmacies, and may lead to larger chains which do compound to eliminate that service offering. If this proposal is accepted, then all accreditors need to be considered as equal and the board should not take preference for one over the others.	9/11/2018 7:47 AM
58	Yes. I believe an outside accreditor provides a higher level of accountability and standardization. I embrace the idea of "another set of eyes" on the processes can only improve the quality and safety of final products, and overall outcomes for end users.	9/11/2018 7:30 AM
59	Yes. I have worked in Home Infusion as well as compounding and have always appreciated the input that the process has brought to our facilities.	9/11/2018 7:28 AM
60	I do not agree. We already have USP 797 and USP 800. It seems like a waste of time and money to do it twice.	9/10/2018 8:24 PM

61	Good idea due to quality and safety issues in general. For most pharmacies this should not be too much extra work because the compounding is usually simple and infrequent. As a pharmacist, I can appreciate the value of a standardized process. Our methods and standards should be routinely inspect However, the red tape could ultimately limit access and inflate prices, potentially hurting clients in a different way. Some pharmacies will likely stop offering those services if it becomes too complex.	9/10/2018 8:11 PM
62	Yes. Our facility is routinely accredited by Joint Commission voluntarily already.	9/10/2018 7:23 PM
63	agree.	9/10/2018 4:48 PM
64	What does it mean to be accredited by Joint Commission? If it requires the basic accreditation from them that comes with the hospital then supportive.	9/10/2018 4:02 PM
65	Yes - I am surprised that the outpatient infusion pharmacies are not subject to the same assessments as the inpatient and home infusion pharmacies.	9/10/2018 3:13 PM
66	I like the idea of this but it doesn't seem practical for smaller pharmacies that do a minimal amount of compounding.	9/10/2018 1:44 PM
67	No, I feel that as an Oregon pharmacy, serving Oregon patients, following Oregon rules, under the jurisdiction of the Oregon board of Pharmacy it should be the Oregon board that validates us. The additional costs and inspections take time and only go to say that the board isnt capable of supervising the pharmacies of this state.	9/10/2018 1:01 PM
68	Agree for safety and standards, but I feel feasibility in incorporating practices may be in question and costs - as long as these are reasonable it may be positive.	9/10/2018 12:42 PM
69	No, it does not seem that it would help practices except to increase costs, ultimately costing more to patients without seeing more safety practices	9/10/2018 12:29 PM
70	Yes and no. I would depend on the chosen accreditor and how the validation is performed. Compliance through education should be the theme, regardless.	9/10/2018 12:16 PM
71	NO, just more regulatory government excess.	9/10/2018 11:28 AM
72	3rd party accreditation may be an effective tool to assist the board in their inspection process of compounding pharmacies. My main concern is ensuring that once pharmacies achieve 3rd party accreditation, they continue to meet the standards of the accreditation. Is there follow up inspections after the initial accreditation process? I know of a couple local compounding pharmacies that are no longer in business after being essentially shut down by the FDA, if my memory serves me right, these business were PCAB accredited. So although third party accreditation may be useful in some situations, it is not the end all be all. If the board is going to require 3rd party accreditation it should be with a trusted, well-vetted organization and should only be used as a tool to assist the board with inspection, not something to replace inspection by the board itself. Compounding pharmacies will indeed incur a large cost to become accredited and it may be less feasible for small organizations to comply with the requirement.	9/10/2018 11:24 AM
73	Yes	9/10/2018 11:09 AM
74	Yes, definitely. To ensure sterility, training, accuracy, and the public's trust in the profession of pharmacy.	9/10/2018 11:04 AM
75	No, maybe a commission though. Don't they have enough restrictions? Also funding and time. Why don't doctors and insurances have restrictions like pharmacies?	9/10/2018 10:48 AM
76	Yes, everyone is validated	9/10/2018 10:43 AM
77	Yes, accountability is important	9/10/2018 10:28 AM
78	yes; compounding falls within the pharmacists capabilities and knowledge base. the is an historical precedent for pharmacist compounding	9/10/2018 9:44 AM
79	No, my site only compounds simple non-sterile compounding, and this would significantly affect my ability to do so. Patients would be negatively impacted by only being able to go to sights that have been accredited and small businesses couldn't afford to meet every criteria.	9/10/2018 9:33 AM
80	Yes. Added safety precautions	9/10/2018 9:31 AM
81	For 503a facilities, I think NABP-VPP would be a good idea. For 503b facilities, the FDA inspections are much more appropriate.	9/10/2018 9:21 AM

82	no. this is not providing safety. Board regulations are sufficient and if the Board disagrees they should provide data to support that position.	9/10/2018 8:54 AM
83	Agree. We are being required to accredit with a third party anyway just to have access to order medications. ACHC is who we are working with to obtain accreditation in specialty and home infusion.	9/10/2018 8:29 AM
84	I support this initiative. Not only will it identify egregious offenders who are not compounding sterile products in good faith, but it will also help well-intentioned, legitimate compounding pharmacies ensure they are meeting required state and federal legal obligations. One issue - who would bear the burden of paying for regular inspections?	9/10/2018 8:01 AM
85	Yes standard must be set in phamacuticals	9/10/2018 7:10 AM
86	I do not know enough about this topic to have an educated opinion.	9/10/2018 6:56 AM
87	Should be policed by an outfit like pcca as THEY know what good and safe practices are, as they deal with compounding daily	9/10/2018 6:19 AM
88	Yes (safety)	9/10/2018 5:37 AM
89	Yes. We have had Joint Commission visit our pharmacy before. I think it would be fine.	9/10/2018 5:13 AM
90	Agreed; I feel that it’s very important that all compounding is held accountable to the very high standards necessary to keep the patients safe.	9/10/2018 12:15 AM
91	No. It's another layer of regulation that increases our costs without really doing anything more than the federal/State regulations in place. I feel like these organization aren't there to help pharmacies, they're simply there to "Cash In" on the regulations Omnibus. How does this benefit our patients?	9/9/2018 11:25 PM
92	I agree. Patient safety is our main priority. No shortcuts should be allowed.	9/9/2018 11:12 PM
93	Sure, however I don’t practice this type of pharmacy, so don’t know what the workflow or financial impact to a pharmacy would be from this requirement.	9/9/2018 10:57 PM
94	For sterile compounding, yes, to make sure that standards are met. For non-sterile compounding, this seems unnecessary.	9/9/2018 9:59 PM
95	Yes, there is already validating on some equipment like the sterile hood. License or no license is a better way to make areas safe, and national standards may be the best approach.	9/9/2018 9:40 PM
96	Agree. Requiring an NABP-VPP, (or home-state inspection to the VPP blueprint) or PCAB/ACHC inspection certainly dives more deeply into major considerations of compounding standards and exceeding those "basic expectations". I do not see the value in Joint Commission outside of a hospital setting. Many state inspections and inspectors are not fully prepared to examine the finer details of what makes a compounding pharmacy truly compliant. The inspections listed previously are specifically designed to assess compliance with compounding regulations in addition to pharmacy standards. I would find that annual inspections of this degree may be excessive and unnecessary for pharmacies that have PCAB accreditation or a successful NABP-VPP inspection, but 3 is too long of a time between; 2 years would match more closely with renewals and registrations.	9/9/2018 9:37 PM
97	Yes, there is so much fraud associated with compounding. There needs to be a more intensive governing process.	9/9/2018 9:18 PM
98	No. An outside agency would not necessarily find anything that the Oregon Board of Pharmacy could not. This has more potential to hinder the pharmacy’s ability to provide compounds that patients are reliant on if the pharmacy has to meet regulations from two agentcies.	9/9/2018 9:06 PM
99	Would agree only for pharmacies where primary business is compounding. Otherwise, it seems unnecessarily burdensome and not too helpful (depending on the accreditor).	9/9/2018 8:58 PM
100	No. The tangible and intangible costs associated with maintaining compliance with an additional safety body may outweigh the potentially marginal improvement to safety.	9/9/2018 7:50 PM
101	no, We only compounded lotions and oral suspensions and simple things on an ad hoc basis. A visit by an outside investigator would complicate matters unnecessarily.	9/9/2018 5:16 PM
102	No- decreased patient access to compounded medications	9/9/2018 5:11 PM
103	Yes	9/9/2018 4:23 PM

104	I believe that for hospitals, the requirement should be a part of their regular accreditation process such as Joint Comission. I don't believ they should be required to do a separate accreditation. For retail sites, I believe the state inspectors should be sufficiently trained to accreditate them. I don't believe an outside source is required to accredit them unless compounding is all that they do.	9/9/2018 3:22 PM
105	Disagree, cost vs value, corporate/chain compliance efforts should be adequate to ensure standards are met.	9/9/2018 2:07 PM
106	we are already validated by Joint Commission. I think it is a good idea as improper compounding can be life threatening	9/9/2018 1:52 PM
107	unsure, what would this "validation" entail? For example, The Joint Commission accreditation survey already includes a surveyor tool/checklist that assesses compliance with USP 797. I support this level of scrutiny, I question what value an additional survey would offer and I would not be in support of an additional survey especially if it would require hospitals/health-systems to incur additional costs to complete.	9/9/2018 12:32 PM
108	No, just another layer of bureaucracy that serves no purpose but to increase our taxes, of fees.	9/9/2018 11:57 AM
109	No I am not sure and clear about the question that is being asked. Need more details	9/9/2018 11:32 AM
110	No, the current USP 797 guidelines are already too stringent for pharmacies. The risks to patients do not begin and end with pharmacy preparations. Where are is safeguards in other professions, especially nursing. Place more emphasis on training and competency if the feeling is the public is not already protected enough.	9/9/2018 10:32 AM
111	Agree.	9/9/2018 9:53 AM
112	Yes, as long as the 3rd party is validating via the same critiera.	9/9/2018 9:44 AM
113	Yes but please make sure there is more than one accreditor to choose from. I think 3rd party validation or accreditation will help bring to light issues that the pharmacy or the BOP have missed. It's also helps with balance of power for lack of a better phrase. We don't necessarily want someone that works at a pharmacy having significant control of it's own oversight.	9/9/2018 9:26 AM
114	Agree, it’s important to make sure the recipes being compounded are correct and accurate	9/9/2018 8:49 AM
115	Yes, as long as it allows for reasonable exceptions. Mixing a kit (Benzaclin gel) or reconstituting (antibiotic suspensions) should not require accreditation. There may also be other exceptions (mixing creams, mouthwash).	9/9/2018 7:42 AM
116	Yes-quality control is important	9/9/2018 6:50 AM
117	Yes. Universal and unambiguous standards of practice assessed by indisputable authority is essential to protect patients.	9/9/2018 5:14 AM
118	Yes I do because at my pharmacy we do the little things like magic mouthwash and some creams but anything that more than that we already have a third party.	9/9/2018 12:30 AM
119	Yes. This seems expensive, but it seems like it would be a good way to ensure policies are being adhered to. I don't really know since I don't compound at my location...	9/8/2018 9:33 PM
120	I would be concerned about the rural areas.	9/8/2018 9:31 PM
121	Yes. Every pharmacy to compound any medication for public use should be monitored through unbiased testing and compliance.	9/8/2018 8:39 PM
122	It only seems fair if you do this then you need to monitor hospital IV's too.	9/8/2018 7:53 PM
123	I like the idea on paper but I think as long as a pharmacy is using studies and formulas from accredidated companies (pcca) that should be regulation enough.	9/8/2018 6:32 PM
124	Yes, I think any additional safety is important for compounding	9/8/2018 5:35 PM
125	No. Compliance with regulations via USP 797 and 800 should be monitored within the state board of pharmacy or FDA and another level of oversite is unnecessary. Out of state pharmacies should be inspected by their state board if regulations are similar or a 3rd party accreditor if the Oregon Board of Pharmacy determines the states regulations are not consistant with the standard of care as defined in the Oregon Regulations. If additional regulations are required, the pharmacy should be be allowed to charge for the additional cost of the inspection via a fee that must be able to be charged to the patient or the patient’s insurance.	9/8/2018 3:54 PM

126	This would be ok, only if the outside accreditor strictly followed the requirements of the board of pharmacy and applied them to all they would validate. Consistency of standards is the key, rather than interpretation of standards by an outside entity.	9/8/2018 3:40 PM
127	Cost prohibitive.	9/8/2018 3:10 PM
128	Yes I agree with this initiative because it would ensure the safety and accuracy of the compounded medications. It would cost pharmacies initially to get this accreditation, but without the accreditation there's no real oversight and it can lead to customers have unwanted side effects due to improper procedures. Active pharmaceutical ingredients aren't like a spice or flavoring, so if something isn't mixed thoroughly or encapsulated evenly, a patient could die. Also, I don't think the average person knows that compounded medications aren't required to be sent off for testing or even necessarily required to be tested in-house such as with QC testing for batches of capsules (mean weight, mix/max, and standard deviation). They're trusting the pharmacy, but pharmacies have multiple conflicting motives, such as with quality assurance and maintain high profit margins. I don't think pharmacies knowingly turn a blind eye to patient safety, but different compounding pharmacies can have different procedures/practices and levels of expertise. I had a family member take troches for a long time, but started feeling side effects like feeling really warm or like the medication may not be working. She went and got her hormones tested and the doctor said that there were none in her system. For that reason, they decided to switch her to a mass produced tablet of Estriol and Estradiol. I asked her why the doctor didn't just switch compounding pharmacies, but he said that you never really know what you're getting with them. I feel like this is why an outside accreditor is critical for the future of compounding.	9/8/2018 1:47 PM
129	Would depend on the amount of compounding yo do. I'd you had an outside lab check your product it could cost in the $500-$700 range. Most of our compounds are 1-2 a month. Would not be cost effective. We can mix Benadryl , Maalox, and lidocaine and it is called simple compounding. However if I mix testosterone powder with propolyne glycol and alcohol it isn't classified as simple compounding. Both are non sterile compounds, the testosterone is a topical.	9/8/2018 1:32 PM
130	No The less the beaurocracy the better	9/8/2018 1:08 PM
131	Yes, if it is set up to improve patient safety.	9/8/2018 12:40 PM
132	I agree with this initiative because I believe it has patient and employee best interest in mind. Non sterile compounding should be validated by 3rd parties.	9/8/2018 12:36 PM
133	Yes, in fact i find that management and supervisors will only get involved and survey their tecnicians when word comes around that a joint commision survey is near by. Only then will they double down and look for errors or flaws in their system, often finding some (not all) and joint commision doing the same.	9/8/2018 12:28 PM
134	No. OR state inspectors should handle these inspections.	9/8/2018 12:23 PM
135	Yes. In hopes that all compounding pharmacies would adhere to compounding practices.	9/8/2018 11:49 AM
136	Yes. Promotes standardization and insures a minimum quality level	9/8/2018 11:29 AM
137	NO, Compounding medications is strictly a pharmacist's specialty and agencies that validate it needs to be strictly a pharmacy agency to understand the strict adherence to compounding pharmaceutical products.	9/8/2018 11:10 AM
138	No. Suspect a third party auditor would be expensive to hire. Cost likely would be passed on to pharmacies, staff via increased licensing fees. Inspectors I would think would be qualified to validate process.	9/8/2018 11:00 AM
139	yes, I think every product needs to be tested.	9/8/2018 10:12 AM
140	Yes, it's too easy to take shortcuts	9/8/2018 9:52 AM
141	Yes, because not all non-sterile compounding policies are being followed; specifically for hazardous drugs.	9/8/2018 9:27 AM
142	Yes. It reassures the public and prevents profit from overcoming professionalism	9/8/2018 9:15 AM
143	No, we can regulate our selfs and these organizations add a tremendous cost to providing this service.	9/8/2018 9:11 AM
144	Yes. It should be a part of their survey. Everything done in the pharmacy should be reviewed.	9/8/2018 8:42 AM
145	yes, we need to insure patient safety and validate pharmacies sterile practices.	9/8/2018 8:36 AM
146	No.	9/8/2018 7:24 AM

147	I can see this being fine with most larger hospitals who are already checked by TJC, but I can see it being an issue with smaller critical access hospitals in rural areas.	9/8/2018 1:42 AM
148	Yes, additional safety in the world of compounding is always going to be an additional way to assure technician is properly following compounding procedures.	9/8/2018 1:15 AM
149	Yes, an objective third party that may not have an established relationship with those being inspected would further ensure full compliance.	9/8/2018 12:14 AM
150	Yes. The 3rd party would help keep pharmacies up to the requirements to operate a safe environment to produce a quality product.	9/8/2018 12:05 AM
151	yes for public safety	9/8/2018 12:00 AM
152	Yes	9/7/2018 11:27 PM
153	Yes	9/7/2018 11:07 PM
154	Hospitals, home care and health management organizations all have this policy because they understand the importance of outside accreditation. Compounding pharmacies dispense medications that can be life altering. We have seen how poor compounding techniques and standards have affected patients in recent news and unfortunately some pharmacies cut corners to make profit. These preventable instances are reason enough to adopt stricter policies.	9/7/2018 10:55 PM
155	Not necessarily...all reactive to a pharmacy on East Coast's sterile compounding practices. Where was was that state pharmacy board's due diligence and accountability for monitoring it's in state pharmacies?	9/7/2018 10:46 PM
156	Yes, I think sterilization validation by a third party will help assure that correct and regular measures are met.	9/7/2018 10:44 PM
157	Yes, I agree. It helps keep safety in check	9/7/2018 10:30 PM
158	Disagree. It is not necessary as we already have certification of our clean rooms and hoods that is surveyed by the OBOP. We don't need additional administrative costs.	9/7/2018 10:24 PM
159	No	9/7/2018 10:03 PM
160	A third neutral party is an additional safety net to ensure proper procedures and techniques are being implemented in an aseptic environment.	9/7/2018 9:46 PM
161	No, many retail pharmacies do not know they are allowed to perform non-sterile compounding such as Magic Mouthwash which is commonly prescribed. If an additional license is required it would be avoided even more. Considering sterile compounding, Yes it should be required (if it isn’t already I don’t know).	9/7/2018 9:30 PM
162	No, I think the inspector team should be able to tell if they are following usp 797 guidelines. Just ask for the logs.	9/7/2018 9:17 PM
163	Yes, I agree, but only if the routine validation is multiple times per year and inspections are not announced.	9/7/2018 9:17 PM
164	Yes. Consumer safety	9/7/2018 9:09 PM
165	Not sure. This added validation may discourage retail from even compounding small items such as magic mouthwash.	9/7/2018 9:03 PM
166	No, already difficult to keep up with current policies and guidelines for compiunding	9/7/2018 9:00 PM
167	No. Board inspection should be sufficient. 3rd party outlets provide no additional benefit. Increase the cost of doing business and continue to decrease access patients have to care by increasing the price of compounds.	9/7/2018 8:56 PM
168	No. It is a waste of resources. The BOP conducts the same inspection on a yearly basis. The third party is just a piece of paper that costs a business thousands of dollars.	9/7/2018 8:04 PM
169	Yes, oversight from a governing body with set standards is a good idea.	9/7/2018 7:53 PM
170	Depends on type of compounding I would think. We only compound some basic diaper rash creams/ointments, or suspensions for children unable to swallow tablets or for g-tube use. For sterile compounding pharmacies if the board inspectors were not up to performing such inspections thoroughly, then I would support outside accreditors. But at whose expense and the costs?	9/7/2018 7:41 PM

171	yes	9/7/2018 7:34 PM
172	No. This is extremely costly for the pharmacies and the margins in healthcare are pushing us to cut costs dramatically. More cost will cause use to close smaller hospitals and not provide needed services through our outpatient pharmacies for our community.	9/7/2018 7:32 PM
173	Yes, for safety. Please make it affordable.	9/7/2018 7:26 PM
174	No, they get paid to keep you as a customer.	9/7/2018 7:19 PM
175	I do think validating processes is a good idea... especially for big compounding pharmacy. It would be great if we as a chain retail pharmacy we could compound simple compounds with out over kill on a sterile area.... sometimes mixing a compound of antacid, antihistamine and lidocaine for a customer would be a huge advantage for there health	9/7/2018 7:08 PM
176	yes	9/7/2018 6:47 PM
177	Yes, will only serve to increase quality	9/7/2018 6:37 PM
178	Yes. It ensures the quality and the standards are being followed and if not, what can be set in to be a new practice to ensure the safety and quality for our patients who receive care from iv technicians.	9/7/2018 6:24 PM
179	Yes	9/7/2018 6:18 PM
180	Oversight often adds additional cost...and insurances routinely deny payment on compounding claims which then forces the patient to pay 100% of the medication cost. So, if the additional oversight adds financial burden / barrier to patient treatment, then I disagree with this initiative. However, if costs to patient remain unchanged, then I might be in favor.	9/7/2018 6:17 PM
181	Yes, but both USP <797> and <800> are enforceable and can shut down a pharmacy operation.	9/7/2018 6:13 PM
182	I would have to know more about what the validated process is all about	9/7/2018 6:10 PM
183	Absolutely agree. We need more regulation in this very needed area of pharmacy practice. As an intern, I had a rotation at a compounding pharmacy that would have benefited greatly from a third-party accreditor. I would add that I think the pharmacy itself should pay for that reoccurring certification to maintain licensure; versus taxpayers.	9/7/2018 6:05 PM
184	Yes, because this validates that the medication is safe and effective	9/7/2018 5:55 PM
185	Yes, monitored by joint Commission	9/7/2018 5:42 PM
186	Yes, because there will be extra quality and safety workflow/protocols to put in place	9/7/2018 5:23 PM
187	No	9/7/2018 5:10 PM
188	I agree. Just for the sake of making sure everything is up to standard.	9/7/2018 5:10 PM
189	Yes	9/7/2018 5:09 PM
190	I do agree. Right now this is an optional certification but this means that not all pharmacies are being held to equal standards of safety and quality.	9/7/2018 5:09 PM
191	yes	9/7/2018 5:03 PM
192	Sure. Of course most pharmacies will then stop- which should occur. Is this day and age compounding is too antiquated. ONLT SPECIALIZED pharmacies should do it ever	9/7/2018 5:02 PM
193	No, because it is just one more fee for rules that are already in place	9/7/2018 5:01 PM
194	I think it would be helpful to set standards but I don't think it is necessary.	9/7/2018 4:54 PM
195	Yes more people checking the better	9/7/2018 4:52 PM
196	We are under enough scrutiny	9/7/2018 4:46 PM
197	yes. for the public safety in response to NECC scandal.	9/7/2018 4:42 PM
198	No. There is no extra pay for this, and the techs that regularly mix don’t need to prove they are good at it.	9/7/2018 4:32 PM
199	Yes, as long as everyone is required. This may be difficult for hospital pharmacies.	9/7/2018 4:32 PM
200	No, we already have annual testing and a certification process	9/7/2018 4:31 PM
201	yes	9/7/2018 4:26 PM

202	Yes I agree. Having an outside agency will help see things that the pharmacy may overlook	9/7/2018 4:22 PM
203	Hopitals are already joint commission certified every three years but outpatient compounders aren't. If this joint commision accreditation would count then I would support this.	9/7/2018 4:19 PM
204	I would only agree with this policy if it applied to compounding pharmacies. For retail pharmacies that do minimal compounding, that seems unnecessarily burdensome.	9/7/2018 4:19 PM
205	Yes, agree. outside audit could be more strict without bios.	9/7/2018 4:17 PM
206	Yes could be a good thing, but is it practical?	9/7/2018 4:17 PM
207	No, for non sterile compounding. Yes, for sterile compounding. You should limit the role of this parasite industry.	9/7/2018 4:14 PM
208	No, too much time and expense for independent pharmacies.	9/7/2018 4:13 PM
209	No, this will prevent many good pharmacies from being able to participate in compounding due to the expense involved with ACHC/PCAB accreditation. I ran a pharmacy that got PCAB and the expense was close to $10k for the initial approval. We got approval back when insurance was paying for compounds so that expense was manageable. Now that all compounding is done for cash, the expense would be considerable. If a pharmacy is selling a compound for $60, they might be making a profit of $30 on each. In that case they would need to fill 333 rxs just to cover the expense. It would make more sense to me to have the inspectors better trained or give them a checklist of items to check for when visiting pharmacies that compound	9/7/2018 4:13 PM
210	Yes. Patient safety and appropriate skill set	9/7/2018 4:04 PM
211	The hospital has policies and procedures.	9/7/2018 4:04 PM
212	What's the risk with non-sterile compounding? If the pharmacy declines the accreditation requirement, what will happen to the care of the hundreds of magic mouthwash patients this winter???	9/7/2018 4:04 PM
213	no, Most pharmacists are good people. We have had a knee jerk reaction to a few rotten apples. I feel the board of pharmacy in Massachusettes is partly to blame because they cited the pharmacy but didn't follow up quickly. Routinely validating a compounding pharmacy would add extra cost to an already cost burdened public.	9/7/2018 4:03 PM
214	No. It seems unnecessary and purely bureaucratic, simply for the sake of making business more convoluted, overly complicated and wholly more time consuming. Compounding Pharmacies are already subject to surprise inspections from the Board of Pharmacy. That is sufficiant enough.	9/7/2018 3:59 PM
215	Yes, I do agree	9/7/2018 3:55 PM
216	No. It will drive up there costs for compounding and licensees and thus the finished product.	9/7/2018 3:49 PM
217	No	9/7/2018 3:44 PM
218	No, another ridiculous hurdle to jump through to serve our patients.	9/7/2018 3:37 PM
219	yes	9/7/2018 3:32 PM
220	Yes. For the reason of patient safety, and it will reflect a professional face for OBOP and the compounding pharmacies it oversees.	9/7/2018 3:31 PM
221	no- unless there is a yearly inspection such as the Board of Pharmacy does- once validated, does not mean there is a continued standard of practice going forward.	9/7/2018 3:28 PM
222	Yes. Compliance verification is vital in the health & safety of our patients and employees.	9/7/2018 3:21 PM
223	Yes and No. Will be an extra cost to the outlet but could make it safer.	9/7/2018 3:18 PM
224	I see positive and negative sides to this decision. Accreditation does not guarantee compliance. I believe resources (money, time, man hours, etc) would be better spent doing random audits of general and compounding practices in pharmacies. Our accreditation board visited us within the past two weeks. They spent very little time observing/ questioning technicians about our every day practices, and more time running elbows with our pharmacy director who arrived early and ensured everything was put away, in order, done special for the visit. I'll tell you now, they didn't see the normal practices of our pharmacy. All compounding was done after they left by coincidence.	9/7/2018 3:15 PM
225	Yes- for patient protection	9/7/2018 3:03 PM

226	Routinely is very vague. Yearly or bi yearly seems more cost effective when dealing with 3rd parties. Also this may put strain on Independent pharmacy's that may have to pick up the cost for a 3rd party inspector. In addition who would dictate the 3rd party standard? Will they all equally judge? What guidelines are being set for these 3rd party judges?	9/7/2018 3:01 PM
227	Yes, it seems as though I read about more and more problems regarding this so an extra safety measure seems prudent.	9/7/2018 3:01 PM
228	No. It wastes my time that could be spent with patients or compounding. Non-routine inspections, not monthly, yearly, bi-yearly inspections.	9/7/2018 3:00 PM
229	I disagree that more regulations are needed. As a society, we are being regulated to death. So much for the land of the free. These measures to have extra licenses create more unnecessary hoops to jump through, and greater expenses, causing more unemployment and economic hardship.	9/7/2018 2:59 PM
230	Yes. NABP VPP is a robust review and compounding is inherently more dangerous than traditionally FDA approved drugs.	9/7/2018 2:59 PM
231	Yes - It will help guarantee a consistent level of competency.	9/7/2018 2:57 PM
232	yes-it will prevent some of the serious contamination problems seen in the past	9/7/2018 2:57 PM
233	Yes. Routine auditing of processes that directly affect patient care should be implemented for all practice settings.	9/7/2018 2:57 PM
234	Yes there has to be standards	9/7/2018 2:54 PM
235	ABSOLUTELY DISAGREE. THIS WOULD JUST CREATE MORE UNNECESSARY REGULATIONS THAT WOULD BE AN ABSOLUTE DESTRUCTION OF COMPOUNDING PHARMACIES IN THE STATE OF OREGON.	9/7/2018 2:53 PM
236	We currently have Joint Commission as our accreditor. I think all compounding centers (e.g. physician clinics) should be validated by a 3rd party as well.	9/7/2018 2:52 PM
237	The OBoP already comes and does inspections annually all sites. I feel like this would be an unnecessary extra expense.	9/7/2018 2:52 PM
238	We are under supervision of a pharmacist. Perhaps the pharmacist should be accredited in this field.	9/7/2018 2:47 PM
239	Yes so compounds are done accurately!	9/7/2018 2:46 PM
240	Yes. There is no good reason why they shouldn't pass a routine validation by accreditation companies unless they are not following standards and good practice technique. So why not!	9/7/2018 2:46 PM
241	No - requiring this additional 3rd party accreditor will increase administrative fees to outlets operational expenses, while not necessarily guaranteeing additional safety assurances. Some of our smaller outlets may not be able to comply and result in reduction of available "compounding" pharmacies in the state. With that said, the board should be evaluating some of these standards during your annual audits of each pharmacy as baseline.	9/7/2018 2:45 PM
242	I agree with this, currently other states/insurance entities require this. My company is currently inspected by multiple 3rd party entities every year including state boards of pharmacy, joint commission, etc. I think this would be helpful in reducing the number of incompetent/not up to current healthcare standards companies that are able to produce sterile products in Oregon or ship into Oregon.	9/7/2018 2:36 PM
243	Yes, for critical areas like sterile parenterals.	9/7/2018 2:32 PM
244	Yes validation should be done to keep processing safe for staff and patients	9/7/2018 2:32 PM
245	Unknown	9/7/2018 2:31 PM
246	don't need the red tape for simple common compounded products. too expensive for businesses, especially the few small places that are left and have working relationships with doctors. If the pharmacy does primarily compounding, then perhaps they need more oversight, but not everybody else..... If RPh doesn't feel comfortable making compounded product they shouldn't be making it. Not as many compounded prescriptions are written as they were in the past....	9/7/2018 2:28 PM

247	Agree for out of state pharmacies but the Oregon board should be qualified to validate with a compounding specific inspection process. If you do not want to create a compounding task force within the boards ranks then using a 3rd party accreditor would suffice. Would recommend that multiple options (accreditors) be available for selection. The cost of these inspections are escalating and driving some pharmacies away from compounding. You may see a shift from pharmacy compounding to bedside compounding due to excessive costs and regulations.	9/7/2018 2:27 PM
248	Unsure. What does it mean to be accredited by Joint Commission? If it requires the basic accreditation from them that comes with the hospital then supportive. If it requires specialty certification (https://www.jointcommission.org/certification/mdcbop.aspx) then not supportive as it adds more cost into the health care system.	9/7/2018 2:25 PM
249	yes, more safety	9/7/2018 2:24 PM
250	Yes, to help with safety and QA	9/7/2018 2:21 PM
251	Yes. I feel like holding compounding facilities accountable by multiple outside entities is a completely acceptable request. When facilities only get limited feedback certain process can lack. All entities should have extensive training as to what they are looking at. Things look great on paper but unless you look at the process you may be missing opportunities to improve product quality.	9/7/2018 2:21 PM
252	I do not agree. I feel like it will delay patient care by spending further time testing and the patient will continue to wait for medication	9/7/2018 2:20 PM
253	not sure	9/7/2018 2:17 PM
254	yes, it is an additional safety check	9/7/2018 2:17 PM
255	No. I believe the annual self inspection report, inspector reviews and periodic QA testing on a cross section of products is sufficient.	9/7/2018 2:16 PM
256	I'm not sure what type of compounding you are asking about - is it IV preparation, mixing of ointments?? We do a small amount here and it seems like getting an accreditor would be a lot of extra work and time involved. We do need to follow some standards so if that is all it is fine.	9/7/2018 2:10 PM
257	Good for the reason of safety	9/7/2018 2:08 PM
258	Yes. I agree ! Earlier in my career I worked for a compounding pharmacy that serviced nursing homes and intensive care units. The pharmacy was a member of an organization for regulating and evaluating pharmacies that prepared IV, IM and medicines. This organization provided education, compliance and standardization of all pharmacies that were members.	9/7/2018 2:07 PM
259	No. Only those who actually go to pharmacy or medical school should have an influence or opinion.	9/7/2018 2:04 PM
260	No. These organizations serve a redundant purpose, since resident state boards of pharmacy already go over compounding compliance during their inspections.	9/7/2018 2:04 PM
261	for sterile compounding yes. There is a huge risk involved	9/7/2018 2:04 PM
262	Yes	9/7/2018 2:03 PM
263	Only if most of the business a pharmacy conducts is compounding. The vast majority of all pharmacies don't do compounding at all.	9/7/2018 2:03 PM
264	No, that will limit access to simple compounding services in rural areas. For sterile compounding this services should.be required.	9/7/2018 1:55 PM
265	Agree. To improve quality and for consistency in applying regulations	9/7/2018 1:52 PM
266	Yes. Having more experts look at these pharmacies would ensure greater accountability. More scrutiny is needed to ensure patient safety.	9/7/2018 1:52 PM
267	No. I feel like we are already held to a strict standard under USP 797 and 800, and are currently regulated by the Joint Commission, and the Board of Pharmacy. We do not need to be held accountable to an additional 3rd party. If it were just expanding the oversight of a 3rd party that we already deal with in the hospital, then it would probably be fine.	9/7/2018 1:51 PM
268	I agree with the policy. The Pharmacy I practice in is accredited with ACHC/PCAB and I believe the accreditation gives us an advantage in accountability, increases our quality, and keeps us improving.	9/7/2018 1:48 PM

269	For sterile compounding I agree with it, but for non sterile compounding, unless it is big batch compounding, I think it is overkill. The small independent pharmacies compounding the single patient specific compounds can't afford to pay for outside validation, routinely, and they will be forced to not compound, reducing the availability of non sterile, simple compounds to the public. It will also raise the price to the consumer, as all costs are passed on to them.	9/7/2018 1:46 PM
270	yes, insurance companies would like to know the products dispensed are of the appropriate standard	9/7/2018 1:46 PM
271	yes	9/7/2018 1:37 PM
272	Would rather see the Board dedicate resources to routinely evaluate compounding practices. The Joint Commission does not currently accredit compounding practices in pharmacies, but relies on State Boards of Pharmacy.	9/7/2018 1:34 PM
273	Yes so long as compounding pharmacies are given the proper tools to adapt to 3rd party accreditor requirements.	9/7/2018 1:27 PM
274	no, unnecessary process, probably would cost alot and most pharmacies do very little compounding.	9/7/2018 1:19 PM
275	No. It's time consuming and expensive	9/7/2018 1:17 PM
276	Only if a compounding pharmacy only. Small amounts of compounding should still be a part of everyday practice (limited/non-sterile)	9/7/2018 1:17 PM
277	As a member of the USP Expert Panel authoring <825> I urge that teh OR BOP consider the current revision of <797> and the new chapter <800> on HD drugs as well as <825> on radiopharmaceuticals. In our practices as define by <825> we are NOT compounding. TJC, ACHC, PCAB as well as NABP-VPP know nothing about radiopharmacy practice. I urge the OR BOP to wait until the chapters <797>, <800> and <825> are all official and enforceable Dec 1 2019.	9/7/2018 1:16 PM
278	No, the pharmacy board needs to be responsible for this.	9/7/2018 1:15 PM
279	Yes. Cantrell is closed and Pharmedium has been cited numerous times for their compounding and storage practices. They need more oversight because when they have recalls, it also creates pseudo shortages	9/7/2018 1:14 PM
280	No. I do not consider the Joint Commission expert in this field and would not want a separate expert industry created with a profit motive.	9/7/2018 1:13 PM
281	No. Not all facilities can afford the cost of these accreditations.	9/7/2018 1:10 PM
282	Yes I do.	9/7/2018 1:07 PM
283	Yes, for quality assurance	9/7/2018 12:54 PM
284	No, I feel it’s another barrier to limit access and the pharmacist has already been through training	9/7/2018 12:49 PM
285	Compounding is an important function of the pharmacist. I do thing it’s important for oversight of this function especially sterile products.	9/7/2018 12:44 PM
286	Yes. Better regulation and compliance may occur.	9/7/2018 12:43 PM
287	Yes, hopefully gets some consistency between compounding pharmacies	9/7/2018 12:38 PM
288	Yes, it’ll make sure all pharmacies are on the same standard	9/7/2018 12:38 PM
289	No. NABP is a racket. Why can’t this be delegated to the Board?	9/7/2018 12:32 PM
290	Yes. Already required/recommended for some insurance contracting so not an additional burden to retail outlets that bill insurance and institutions that are held to higher standards. Additionally, it would be better to have an outside third party from a cost/training standpoint to the board.	9/7/2018 12:29 PM
291	This is ok if the the 3rd party does not set it's own standards. Those are being set by USP and multiple standards would be difficult to meet.	9/7/2018 12:29 PM
292	No, if applied to all compounding. I would support accreditation of sterile compounding pharmacies.	9/7/2018 12:28 PM
293	I agree, based on the issues arising from compounding pharmacies over the years I think it is a good oversight mechanism. Providing for better patient safety	9/7/2018 12:28 PM

294	Agreed, so there is a set (constant) standard for the assessment, and the information would be available to any interested parties to review	9/7/2018 12:27 PM
295	It does sound good in practice for QA issues but for smaller pharmacies that is unbearable burden. There should be some inbetween or help for smaller pharmacies.	9/7/2018 12:27 PM
296	Agree	9/7/2018 12:26 PM
297	No. I am not accredited because I don't want to bill insurance for compounds.	9/7/2018 12:26 PM
298	No. Very expensive and many pharmacies have limited resources.	9/7/2018 12:22 PM
299	yes - there needs to be some oversight of 3rd party compounding pharmacy to ensure quality and patient safety	9/7/2018 12:20 PM
300	Yes- gives a "2nd opinion" on compounding processes instead of relying on BOP	9/7/2018 12:20 PM
301	No-BOP can do that.	9/7/2018 12:19 PM
302	Yes. NECC.	9/7/2018 12:18 PM
303	Yes. Pharmacists/technicians are not trained properly to use sterile technique. There should be a 3rd party accreditor.	9/7/2018 12:18 PM
304	yes-we are already validated with NABP	9/7/2018 12:18 PM
305	Agree	9/7/2018 12:17 PM

Q5 Should Oregon regulations continue to allow "Shared Services" for compounding? Why or why not? (Shared Pharmacy Service means a Board approved written agreement for compounding by a pharmacy located in Oregon for Oregon outlets and practitioners located in Oregon only).

Answered: 288 Skipped: 28

#	RESPONSES	DATE
1	Yes. We centralized our compounding services to improve patient safety by providing a well-trained staff and location that is/are dedicated to compounding exclusively. This model provides increased monitoring of compounding practices and facilities. This allows for better management of drug resources and shortages, allowing us to provide safer compounded medication to our patients.	9/17/2018 2:37 PM
2	We have a Shared Service agreement with a compounding pharmacy in Oregon for a few products and this has been very helpful in freeing up resources to perform other important tasks that need to be done. We also have an agreement with a sister hospital to compound nitroglycerin products for them. It is used appropriately and safely and is very beneficial to us.	9/17/2018 2:33 PM
3	yes, would save time for technicians and be cleaner especially for smaller locations	9/17/2018 1:20 PM
4	Oh my gosh, yes. Over the past couple of years I have heard from my personal providers of how horrible it is getting for them to have the simplest things made they use in office. Things that they cannot purchase otherwise. Isn't that the point of compounding?	9/17/2018 12:14 PM
5	not sure	9/17/2018 10:00 AM
6	Yes. It is a written agreement between health care professionals to allow the providing of a type, strength or form of medication that may not be available on the market. What purpose would this serve to remove this regulation?	9/17/2018 9:24 AM
7	Yes. The are good for the people.	9/17/2018 8:40 AM
8	yes, as stated above	9/17/2018 7:44 AM
9	No. It is hard to assure the safety and stability of a drug coming from another source.	9/16/2018 6:18 PM
10	yes, we should all work together due to all the drug shortages	9/16/2018 1:40 PM
11	yes	9/16/2018 10:27 AM
12	No	9/16/2018 12:44 AM
13	Yes for convenience.	9/15/2018 6:23 PM
14	See. Helps limit size and scope of services. Also minimize transport times and potential storage issues	9/15/2018 1:17 PM
15	Share services	9/14/2018 9:56 PM
16	Sure.	9/14/2018 9:47 PM
17	Yes, because not all pharmacies can compound on site	9/14/2018 9:12 PM
18	Yes, some pharmacies don't have the space, time, resources, workforce to do their own compounding	9/14/2018 3:57 PM
19	Yes	9/14/2018 10:01 AM
20	Yes. We have shared services for the needs of compounding where the safety of compounding in a USP 797 environment for an entity that needs sterile compounding but it's not financially able to build a compounding clean room for the limited products needed. I believe it has been working and the agreement can be tracked by BOP for inspections.	9/14/2018 9:10 AM

21	I don't have an opinion on this, as I've not been involved in a shared services compounding scenario, so don't know the pro's and con's.	9/13/2018 3:06 PM
22	Yes. Medical and Dental providers rely on the knowledge of compounding pharmacist to provide safe and effective specialty medication that is not commercially available to help them with medical/dental procedures they may provide. I do not believe it is safe practice for a compounding pharmacy to provide compounded medications to a provider for resale to a patient. To ensure the safety of the patient compounding medications for personal use should be provided directly from a compounding pharmacy.	9/13/2018 1:06 PM
23	yes	9/13/2018 11:30 AM
24	Yes this makes it easier to get products.	9/13/2018 10:14 AM
25	It appears to be a good idea. It would be less work for Board Ispecter and retail chain pharmacy	9/12/2018 8:33 PM
26	Yes	9/12/2018 7:59 PM
27	Yes.	9/12/2018 6:59 PM
28	Yes; I believe that would be a good way to hold compounders accountable for their products.	9/12/2018 5:52 PM
29	Yes. Shortages and sole source manufacturers means we need all options for obtaining some of these must needed medications.	9/12/2018 5:31 PM
30	Yes.	9/12/2018 5:19 PM
31	Yes. This allows smaller pharmacies access to compounded medications without having to pay for expensive facilities and equipment, while enjoying access to high quality, compounded, pharmaceutical products.	9/12/2018 5:19 PM
32	I'm not sure. I have not researched this.	9/12/2018 11:26 AM
33	Yes. We would hope that the process for acquiring a SSA would be streamlined. The needs of different facilities or organizations can vary and if an organization can demonstrate that a unique practice can provide similar or better quality at a lower burden than the standard, that should be encouraged by the board.	9/12/2018 10:36 AM
34	Yes, lots of chains these days.	9/12/2018 10:29 AM
35	yes	9/12/2018 9:48 AM
36	N/A	9/12/2018 9:43 AM
37	I am aligned with the allowance of "shared services".	9/12/2018 9:27 AM
38	Yes	9/12/2018 8:44 AM
39	yes	9/11/2018 10:09 PM
40	Yes, pharmacies should hold a special license to compound for patient safety.	9/11/2018 10:01 PM
41	Yes. In long term care we fill IV RX's for nursing homes.	9/11/2018 7:15 PM
42	Yes, centralizing services is a good thing	9/11/2018 5:59 PM
43	I do not understand the question.	9/11/2018 5:28 PM
44	Yes.	9/11/2018 4:31 PM
45	yes	9/11/2018 3:52 PM
46	Of course these arrangements should be allowed to continue. If they don;t work as intended, the parties involved will most likely dissolve them. Where does it say that Boards of anything should be involved in peoples right to practice "freely" as long as it is legal and not harmful to the public?	9/11/2018 3:44 PM
47	N/A	9/11/2018 3:27 PM
48	It seems as though the FDA feels differently about this regulation. If we are to engage in shared services will there be potential for the FDA to deem this agreement inappropriate?	9/11/2018 3:08 PM
49	Pros/Cons are incredibly varied.	9/11/2018 2:47 PM

50	I do think this should be allowed as it is a needed service and can streamline pharmacy safety and efficiency,but I think the burden of proving that the compounding pharmacy is not really a "manufacturer" supplying large quantities of compounded preparations to another pharmacy or practitioner for profited resale should fall on the pharmacy, not on the Board or any other auditing party	9/11/2018 2:46 PM
51	Yes, it allows to keep the service local for the pharmacy. Once it is not allowed they will look for it outside of the town and then think they need to go out of town for other things as well.	9/11/2018 2:11 PM
52	yes	9/11/2018 12:20 PM
53	Yes, this is an appropriate method of oversight that helps to reduce cost for the patient.	9/11/2018 11:55 AM
54	Yes. I see no reason why these processes and agreements schould change, or that they have resulted in significant patient safety concerns.	9/11/2018 10:24 AM
55	No opinion	9/11/2018 10:08 AM
56	Yes, particularly for veterinary patients. The FDA currently has only ~75 registered 503B entities, few of which engage in veterinary compounding and all of which are out of state. The House appropriations committee (US Congress) as well as a bipartisan group of 63 representatives have signaled to the FDA that DQSA did not intend to completely remove the practice of 503A compounding for office use on a limited basis. Without shared service agreement, veterinarians are unable to provide essential and life-saving care in this state	9/11/2018 9:52 AM
57	Yes - I think this is a valuable service which provides for the provision of better patient care overall. I think that pharmacies which utilize these SSAs should be identified as such on a list or on the license lookup page, so that consumers and other interested parties can identify where their products are coming from.	9/11/2018 7:47 AM
58	Yes. This would be a more efficient use of resources and the expertise in providing this specialty service.	9/11/2018 7:30 AM
59	Yes. I believe that this agreement holds both parties accountable for the products that are dispensed and received.	9/11/2018 7:28 AM
60	Yes. I'm sure it's more cost effective to have others compound for smaller facilities, it is also better for patients in those areas to receive these medications.	9/10/2018 8:24 PM
61	Sure. Those same processes then need to be vetted through this outside agency.	9/10/2018 8:11 PM
62	agree. This allows pharmacies that cannot afford to update to revised 797 standards the ability to acquire meds with extended dating	9/10/2018 4:48 PM
63	Yes. It is extremely expensive to build compliant clean rooms. We need to remove cost from the health care system. If sites can centralize operations while maintaining quality, then it should be allowed.	9/10/2018 4:02 PM
64	Yes, we do not have the means to compound certain medications that our patients need. Since we treat patients ranging from a few grams to several hundred kilos, we need to be able to use a wide variety of medications that may not be commercially available or practical for use to compound in our own setting. The shared services agreement allows us to reach out to compounding pharmacies with more resources, equipment, compounding knowledge, and staff.	9/10/2018 1:44 PM
65	Yes, Shared Services should be continued and if possible expanded back to include controlled substances. This services fill a hole that is often left by commercial products and eliminating them would only serve to hurt patients and limit options to providers.	9/10/2018 1:01 PM
66	Yes - I continually rely on Shared Services for items I cannot compound for inpatients - please continue this!	9/10/2018 12:42 PM
67	Yes, it works	9/10/2018 12:29 PM
68	Yes but hold businesses accountable for having in-date shared service agreements.	9/10/2018 12:16 PM
69	yes, should be able to send compounded Rx internationally	9/10/2018 11:28 AM

70	Shared Service agreements are a absolute necessity for many medical practices in Oregon. The most relevant field of medicine is Veterinary medicine. It is known that there are very limited medications available commercially for cats and dogs. Compliance is a huge issue as most cats and many dogs will not take solid dosage forms. Veterinarians rely on having compounded liquid and solid dosage form medications (that are not available commercially) to use for patients that urgently need to get started on medications. If the vet is able to give the first couple doses while the patient is in the clinic, they can improve treatment outcomes and can also improve compliance by showing the owner how to use the medication. The most relevant example is when a pet owner brings in an injured pet that needs pain medication immediately. The vet must have compounded oral buprenorphine, the drug of choice for pain relief, on hand, so that they may treat the patient immediately. Imagine if the vet had to send the owner to the pharmacy to pick up a patient specific prescription for buprenorphine while their animal waits on the table in excruciating pain. In my opinion, the use of shared service agreements should be extended for human use in dental offices, urology clinics, urgent care facilities and other practices where access to office use compounded medications is not currently allowed. I believe that not allowing shared service agreements for compounded office use items is a barrier to treatment and creates unnecessary hurdles for patients to receive care. We have to deny dental offices all the time when they ask for topical lidocaine gel preparations, as currently that product would only be available under a patient specific prescription. Many pharmacies out there provide this compound to the clinic anyways, usually under the doctor's name and the clinic diverts use to all of their patients. At least by allowing shared service agreements the board would be involved in the process and would know which pharmacies are providing these products directly to clinics. If shared service agreements were taken away, it is very likely that pharmacies will continue to provide products to clinics under a doctor's name or under a "clinic pet" and the clinic will choose to divert the product to their patients in-clinic. It would be better for the board to continue to allow shared services and be involved in the process to some extent.	9/10/2018 11:24 AM
71	No	9/10/2018 11:09 AM
72	Still not sure what this is... sorry	9/10/2018 11:04 AM
73	Yes, since we need them	9/10/2018 10:48 AM
74	Dont know what shared services is	9/10/2018 10:43 AM
75	Yes, more access to services can only benefit patients, pharmacies and providers.	9/10/2018 10:28 AM
76	yes; this is a good system	9/10/2018 9:44 AM
77	Yes. Manufacturer supplied product is often not available in the strengths, volumes, or dosages needed by practitioners or clinics. Pharmacists have the skill, knowledge and training to provide preparations to meet this need.	9/10/2018 9:37 AM
78	Yes	9/10/2018 9:31 AM
79	I do not practice in Oregon, so I have no experience or perspective for this question.	9/10/2018 9:21 AM
80	yes	9/10/2018 8:54 AM
81	Yes. Can the process for acquiring a SSA be streamlined. Certain sites have safety equipment and greater staffing to prepare medications and this should be encouraged not discouraged.	9/10/2018 8:29 AM
82	Yes. Not every facility has the physical plant or the technical means to compound their own medications, and having these services available (especially with external validations) is a positive for providing the highest quality and most economically effective patient care.	9/10/2018 8:01 AM
83	No not good for business	9/10/2018 7:10 AM
84	Yes, better control for sterility and quality.	9/10/2018 6:56 AM
85	No I think it should be open to any state	9/10/2018 5:37 AM
86	Yes. All compounding should be board approved.	9/10/2018 5:13 AM
87	Yes; not sure what the alternative would be. Seems reasonable that compounding pharmacies would continue to supply compounded admixtures to outlets and practioners that may not be equipped to provide their own	9/10/2018 12:15 AM
88	yes. This helps both Doctors and pharmacies to treat patients.	9/9/2018 11:25 PM
89	Yes, if a facility is set up to comply with all BP rules.	9/9/2018 11:12 PM
90	Sure	9/9/2018 10:57 PM

91	Yes, if the agreement standards are high enough.	9/9/2018 9:59 PM
92	Not sure.	9/9/2018 9:40 PM
93	Yes. This can allow the state to more easily track and regulate specific compounding pharmacies, while preventing less qualified from taking the place of these pharmacies. Eliminating this would certainly open up the potential for less qualified outlets and practitioners to undertaking much more compounding they may not have the facilities to perform.	9/9/2018 9:37 PM
94	Not sure	9/9/2018 9:18 PM
95	Yes. There are some medications routinely used by Oregon practitioners that are not commercially available. If shared services were to be removed there should be an alternative program in place to dispense compounds to practitioners.	9/9/2018 9:06 PM
96	Yes, this helps keep access to medications for our patients where we don't have the volume to justify providing these medications ourselves.	9/9/2018 8:58 PM
97	Yes. This is necessary to ensure patient's have access to needed drugs that are not commercially available.	9/9/2018 7:50 PM
98	yes. a licensed, regulated entity preparing exactly what they are licensed and regulated to produce should be allowed. If not what is the point??	9/9/2018 5:16 PM
99	Don't know	9/9/2018 5:11 PM
100	Yes	9/9/2018 4:23 PM
101	As long as the pharmacy doing the compounding is following all regulations required of a compounding pharmacy, I see no harm in allowing a pharmacy to utilize such services.	9/9/2018 3:22 PM
102	Yes	9/9/2018 2:07 PM
103	yes as long as the facilities are being inspected/validated	9/9/2018 1:52 PM
104	Yes, there needs to be flexibility for sites to have this as an option; practice sites must have a process to evaluate quality/compliance of any site they are considering utilizing, but need to retain the option to utilize these agreements.	9/9/2018 12:32 PM
105	Yes, to serve public needs.	9/9/2018 11:57 AM
106	Sure	9/9/2018 11:32 AM
107	Yes, not everyone has the resources needed for compounding sterile products.	9/9/2018 10:32 AM
108	Yes. Sharing services outside the state opens the door for fraud. Shared services within the state allows providers to access compounded meds that might not be available locally. This is a win-win decision.	9/9/2018 9:53 AM
109	Yes, having experienced the drug shortes with employer having an additional pharamcy to obtain medications is critically important to meet patient needs	9/9/2018 9:44 AM
110	I don't understand this issue well enough to comment.	9/9/2018 9:26 AM
111	Yes	9/9/2018 8:49 AM
112	I think so. Compounding requires extra time and knowledge. It makes sense to "centralize" these services.	9/9/2018 7:42 AM
113	Yes-1 pharmacy can carry the workload properly/safely while many locations/patients can benefit	9/9/2018 6:50 AM
114	Yes. This would allow specialization of staff and economy of scale.	9/9/2018 5:14 AM
115	Yes	9/9/2018 12:30 AM
116	I'm not sure about this. I have no idea who this impacts or what it entails.	9/8/2018 9:33 PM
117	This would seem like the logical option for companies or small pharmacy's that are not in a metro area. Especially if its something that a child needs and they are 2-3 hours from the nearest facility.	9/8/2018 9:31 PM
118	Yes. Receiving compounds held to the same standards as your own builds confidence and reliability to serve the public.	9/8/2018 8:39 PM
119	Yes	9/8/2018 7:53 PM

120	Yes. By limiting shared services you are decreasing the usage and awareness of the availability of compounds. The future of medication is in specialized medications for specific patients. If you stop shared services practitioners will be less likely to look into compounding for their clients.	9/8/2018 6:32 PM
121	Yes	9/8/2018 5:35 PM
122	yes	9/8/2018 3:54 PM
123	I think this should have the option of using pharmacies outside the state as long as they would honor oregons written standards.	9/8/2018 3:40 PM
124	yes, provides a valuable service.	9/8/2018 3:10 PM
125	I may be misunderstanding the question, but I think a compounding pharmacy should be able to compound for practitioners and outlets outside of the state as well. I actually didn't know they couldn't. Does the question only include 503a pharmacies or 503b ones as well?	9/8/2018 1:47 PM
126	We live on the border and many of our patients drive over to Crescent City, which is less than 30 miles. Otherwise would be ok, except a number of our patients live just over the border. Would cause a great inconvience for them	9/8/2018 1:32 PM
127	Yes	9/8/2018 1:08 PM
128	I dont have a valid opinion on this question because I do not fully understand Shared Services. I dont understand the implications of keeping it in place, not removing it.	9/8/2018 12:36 PM
129	Unsure	9/8/2018 12:28 PM
130	Yes.	9/8/2018 11:49 AM
131	Undecided. Many patients, especially home care patients, have special circumstances, for example vacations out of state or traveling out of state for medical care	9/8/2018 11:29 AM
132	Yes. Any compounding done for Oregonians should be limited within the state of Oregon. This is to benefit the pharmacists in Oregon as well as for easy tracking and inspection.	9/8/2018 11:10 AM
133	Would think so. Do not see how patient safety is enhanced by changing current definitions, requirements.	9/8/2018 11:00 AM
134	yes, it should be allowed.	9/8/2018 10:12 AM
135	No opinion	9/8/2018 9:52 AM
136	Yes. This allows more patient access to compounded drugs.	9/8/2018 9:27 AM
137	Yes. It is more within the control of our Board’s regulatory power when the entire production and vending chain is in our state.	9/8/2018 9:15 AM
138	This service needs to be provided, but not sure that a shared agreement is required as it is imposed when requested by the prescriber. Especially with all the manufacture shortages.	9/8/2018 9:11 AM
139	Yes. Patient care	9/8/2018 8:42 AM
140	Yes, only if its with the same organization.	9/8/2018 8:36 AM
141	Yes.	9/8/2018 7:24 AM
142	Does this mean hospitals under the same company (Legacy, Providence, Kaiser, St. Charles, etc.) can compound batched products for each other? Because I think that's a completely necessary service. Especially considering remodels, lack of staffing or proper hoods for longer dating for smaller hospitals in the group, etc.	9/8/2018 1:42 AM
143	Yes,compounding is quite scientific, and if not trained properly can be dangerous for both patient and technician.	9/8/2018 1:15 AM
144	No opinion.	9/8/2018 12:14 AM
145	No. To make sure each individual pharmacy operates within the regulations, each should be held accountable along with any corporate entities.	9/8/2018 12:05 AM
146	yes for public safety	9/8/2018 12:00 AM
147	Yes saves money in compounding sterile equipment	9/7/2018 11:27 PM
148	Yes	9/7/2018 11:07 PM

149	Although I am not thoroughly knowledgeable in all aspects of this topic, I believe for emergency use and other special cases this should be continued. However, if there are problems with offices or pharmacies abusing this system, better documentation process could be in order.	9/7/2018 10:55 PM
150	Not sure	9/7/2018 10:46 PM
151	Yes	9/7/2018 10:44 PM
152	Yes provides unique service that may otherwise not be available	9/7/2018 10:30 PM
153	Continue... We don't need to be punished for the poor practices of a few mass compounding outlets. Within the same hospital system there is no reason we can't safely have shared compounding services. Some hospitals in a system that are smaller take advantage of the larger hospital's compounding abilities (example: using a TPN compounding machine) which is actually much safer than the hand mixing that would take place otherwise.	9/7/2018 10:24 PM
154	No idea	9/7/2018 10:03 PM
155	I can't answer this question for the lack of knowledge in this area.	9/7/2018 9:46 PM
156	Yes, it seems this will allow non compounding pharmacies to serve patients with compounded Rxs.	9/7/2018 9:30 PM
157	yes	9/7/2018 9:17 PM
158	Yes, as long as they are inspected often.	9/7/2018 9:17 PM
159	Not sure	9/7/2018 9:09 PM
160	Yes, to reduce the number of outlets compounding to keep quality higher	9/7/2018 9:00 PM
161	I have no opinion on this	9/7/2018 8:56 PM
162	Yes. It is mutually beneficial for both parties and allowed better access for patients who may otherwise be unable to receive their medications.	9/7/2018 8:04 PM
163	Yes, if such facilities are accredited and would be accepted by BOP.	9/7/2018 7:41 PM
164	No. Compounding for patients in Oregon shouldn’t be limited to in Oregon pharmacies only.	9/7/2018 7:34 PM
165	Yes. We need to be able to compound in a single site for other facilities in our health system. We cannot afford to purchase duplicate equipment in multiple sites that ensures safe compounding practices for our patients.	9/7/2018 7:32 PM
166	Yes if it is working productively	9/7/2018 7:26 PM
167	Unsure	9/7/2018 7:19 PM
168	I’m not sure about this, I just want to ba able to do simple compounds for people	9/7/2018 7:08 PM
169	yes	9/7/2018 6:47 PM
170	yes	9/7/2018 6:18 PM
171	No opinion. I do not have knowledge of Shared Services regulations.	9/7/2018 6:17 PM
172	Yes	9/7/2018 6:13 PM
173	I did not know this was something that was done. I guess it depends on what kind of compounded prescriptions. I would not think sterile products should be in this written agreement?	9/7/2018 6:10 PM
174	If it is serving rural patients, than yes, continue it.	9/7/2018 6:05 PM
175	I'll say yes but I'm still not sure what this means so there's that	9/7/2018 5:55 PM
176	Yes-if sterile and quality controls in place, alternate compounding sites help with drug shortages and longer expiration dates on limited quantity products (compounding facilities can check/test product routinely).	9/7/2018 5:42 PM
177	Yes, this allows access to rural and small practices the products	9/7/2018 5:23 PM
178	Absolutely!	9/7/2018 5:10 PM
179	Yes	9/7/2018 5:10 PM
180	Yes	9/7/2018 5:09 PM

181	Yes shared services should still be allowed. This allows clinics and hospitals to receive the compounded products that they need without writing everything patient specific.	9/7/2018 5:09 PM
182	yes	9/7/2018 5:03 PM
183	If you compound then yes	9/7/2018 5:02 PM
184	yes	9/7/2018 5:01 PM
185	Yes, because those compounding pharmacies are monitored for good sterile compounding practices.	9/7/2018 4:54 PM
186	Yes	9/7/2018 4:52 PM
187	Yes	9/7/2018 4:46 PM
188	NA to me	9/7/2018 4:32 PM
189	Yes, how else would hospitals get the drugs they need in a timely manner.	9/7/2018 4:32 PM
190	No	9/7/2018 4:31 PM
191	maybe, in limited circumstances of non commercially available drugs	9/7/2018 4:26 PM
192	Yes.	9/7/2018 4:22 PM
193	Yes, any way to maintain quality and increase flexability and decrease cost is supported	9/7/2018 4:19 PM
194	I do not see any reason to disallow this practice. I think it provides a mutually beneficial way for pharmacies to engage in a small, reasonable amount of compounding and for other outlets/practitioners to be able to provide their patients with medications.	9/7/2018 4:19 PM
195	Should allow shared service, so the compounding practice handled in specific pharmacy who is accredited.	9/7/2018 4:17 PM
196	Yes because that can give patients more alternatives to acquiring often times life saving medications	9/7/2018 4:17 PM
197	No, too much conflict with federal law.	9/7/2018 4:14 PM
198	No, it is easier for outlets and practitioners to bypass regulations and rules to save money.	9/7/2018 4:13 PM
199	Yes, this seems like a helpful service	9/7/2018 4:13 PM
200	No opinion	9/7/2018 4:04 PM
201	Yes.	9/7/2018 4:04 PM
202	Yes.	9/7/2018 4:04 PM
203	yes	9/7/2018 4:03 PM
204	No. Quit trying to add more rules and regulations to an industry already inundated with them. Governments and regulatory bodies are quick to pass legislation and more regulation without really ever considering the financial impact it has on its workers or patients.	9/7/2018 3:59 PM
205	Yes, especially in rural communities/settings. In Eastern Oregon some Oregonians only get mail delivery 3 days per week. Getting a compound via mail is not providing good patient care. To continue Shared Pharmacy Services would allow rural providers and community retail compounding pharmacies to continue to provide needed compounded medication same day in some instances and no more than 24-hour turn around.	9/7/2018 3:59 PM
206	I have no idea how it has to be ruled, but I think it works great so far, because we can provide services to our customers on time.	9/7/2018 3:55 PM
207	No opinion	9/7/2018 3:49 PM
208	No	9/7/2018 3:44 PM
209	n/a	9/7/2018 3:32 PM
210	No. It’s a waste of time and they are always approved anyways.	9/7/2018 3:31 PM
211	Yes- a huge service to allow vets order for their clinics-especially for the variety of species and sizes	9/7/2018 3:28 PM

212	Very tricky question. Not all pharmacies have budgets in place to upgrade their compounding facilities, so having Share Service compounding facilities is the best option. But, I also think large health systems with census' >125 shound complete compounding in-house. Facilities should be held accountable for the drugs being administered within their facilities.	9/7/2018 3:21 PM
213	No comment.	9/7/2018 3:15 PM
214	no	9/7/2018 3:03 PM
215	Yes, doctors offices can't always get the medication for procedures. Especially with compounding were it can be more specific in the needs of the office.	9/7/2018 3:01 PM
216	?	9/7/2018 3:01 PM
217	Yes, it makes sense for patients to receive their compounded RX3 in a timely fashion.	9/7/2018 3:00 PM
218	Pharmacy tech licenses should be valid across the entire country. Drugs don't change from one state to another. Only allowing techs to work in one state on their license reduces opportunities for economic betterment.	9/7/2018 2:59 PM
219	No, Oregon should push these business models to become 503B outsourcing facilities in order to encourage the FDA to assist in active review of these types of facilities.	9/7/2018 2:59 PM
220	Not sure - Only for office use?	9/7/2018 2:57 PM
221	yes-same reason as above	9/7/2018 2:57 PM
222	Yes	9/7/2018 2:54 PM
223	YES, BECAUSE THE BUSINESS IS GOING TO OUT OF STATE PHARMACIES RIGHT NOW AND BY NOT ALLOWING COMPOUNDING TO BE DONE IN STATE YOU ARE HAMPERING COMMERCE AND NOT ALLOWING THE PATIENTS AND PHYSICIANS TO ACCESS CARE IN STATE	9/7/2018 2:53 PM
224	yes	9/7/2018 2:52 PM
225	I don't see why we would need to change this. However this does not affect our site either way.	9/7/2018 2:52 PM
226	Yes	9/7/2018 2:47 PM
227	No they shouldn't. Because compounding needs to be done accurately.	9/7/2018 2:46 PM
228	Yes. Mainly due to the fact that most hospitals and care facilities may need compounding products for inpatient purposes and shared service agreements make that possible so the hospital doesn't have to do the compounding themselves on certain things.	9/7/2018 2:46 PM
229	Yes, "Shared Services" are necessary in order to facilitate relationships between hospital pharmacies and local compounding pharmacies that may be able to supply unmet compounding needs. Maintaining a "Shard Services" agreement provides baseline QA between the two entities. However, I would recommend the board remove requirements for Hospital and health systems to have shared services when they are producing compounded products within their own systems/networks - with the understanding that there are organizational policies and procedures in place that would meet the spirit of "Shared Service" agreements.	9/7/2018 2:45 PM
230	Not applicable to me or my practice	9/7/2018 2:36 PM
231	Yes	9/7/2018 2:32 PM
232	Yes there has been no problem for us.	9/7/2018 2:32 PM
233	Yes, one facility may be better equipped to compound than another	9/7/2018 2:31 PM
234	Yes but should be highly regulated to ensure that the compounder has not crossed over into "manufacturing". 503A vs 503B compounding.	9/7/2018 2:27 PM
235	Yes. It is extremely expensive to build compliant clean rooms. We need to remove cost from the health care system. If sites can centralize operations while maintaining quality, then it should be allowed.	9/7/2018 2:25 PM
236	Yes	9/7/2018 2:21 PM
237	As long as they comply with the FDA 503b regulations it should not be a problem.	9/7/2018 2:21 PM
238	I do agree with that. I do not agree with shipping compounded medications out of state.	9/7/2018 2:20 PM

239	yes	9/7/2018 2:17 PM
240	yes, its logical	9/7/2018 2:17 PM
241	No opinion	9/7/2018 2:16 PM
242	don't know	9/7/2018 2:10 PM
243	Yes	9/7/2018 2:08 PM
244	I am not informed enough to give an opinion either way.	9/7/2018 2:07 PM
245	No. I think each practice has different clientele and should have more of a choice on what they feel is right.	9/7/2018 2:04 PM
246	yes to have the best training and quality assured practices	9/7/2018 2:04 PM
247	Yes	9/7/2018 2:03 PM
248	Yes, it's part of basic pharmacy practice.	9/7/2018 2:03 PM
249	Yes,	9/7/2018 1:55 PM
250	Yes. Need to support out of state business.	9/7/2018 1:52 PM
251	No. Pharmacies and doctors should be held at a higher standard.	9/7/2018 1:52 PM
252	Yes. It's not always cost effective to make everything at each facility, especially for specialty items.	9/7/2018 1:51 PM
253	No. I've been the lead compounding Pharmacist in a large Pharmacy for much of the past 12 years. I'm opposed to office-use compounding. It completely bypasses the patient-pharmacist-physician relationship that compounding is based on. The NECC disaster was partially a result of office-use compounding (quite literally) "on steroids." Compounding based on a legitimate prescription for a legitimate patient is the safest and most legally clean in my very informed opinion.	9/7/2018 1:48 PM
254	Yes, it is safer this way.... for STERILE compounds	9/7/2018 1:46 PM
255	I would prefer the 3rd party accreditor	9/7/2018 1:46 PM
256	Yes, as long as the compounding pharmacy meets USP 797 requirements.	9/7/2018 1:37 PM
257	Yes, with robust assessment of compounding practices during inspections.	9/7/2018 1:34 PM
258	Yes to ensure that clear relationships are documented between pharmacies and practitioners.	9/7/2018 1:27 PM
259	yes. makes more sense for one pharmacy in a large organization to have the resources to make the compound rather than each individual location to have all the ingredients especially when many of the compounds are not made very often. Much less waste of ingredients expiring. Plus if central outlet makes the compound its more efficient since they would be most familiar with how to make it.	9/7/2018 1:19 PM
260	Yes.	9/7/2018 1:17 PM
261	Yes on "shared services" but contracted compounding pharmacy should be accredited.	9/7/2018 1:17 PM
262	Compounding is a process that requires 3 participants. The prescriber, the patient and the pharmacist. Adding a 4th participant looks to be like manufacturing.	9/7/2018 1:16 PM
263	Yes, it's no practical for every pharmacy to compound.	9/7/2018 1:15 PM
264	No because there is no evidence of quality control, testing lot numbers etc from these outlets. Some of them are charlatans in their compounding practices. It is only about the money and not true patient care.	9/7/2018 1:14 PM
265	It would be helpful to be allowed in extreme shortage situations.	9/7/2018 1:13 PM
266	Yes. If this is not allowed, it impedes patient care	9/7/2018 1:10 PM
267	Yes. This accommodation allows Pharmacies to have access to formulas, equipment and other amenities for patients benefit.	9/7/2018 1:07 PM
268	Yes, so there is better oversight	9/7/2018 12:54 PM
269	Yes,	9/7/2018 12:49 PM
270	Yes Each state should be responsible for its own licensed practitioners	9/7/2018 12:44 PM

271	Yes	9/7/2018 12:43 PM
272	no opinion	9/7/2018 12:38 PM
273	Yes, it'll help utilize staff efficiently	9/7/2018 12:38 PM
274	Not sure. Wouldn't this cross over into manufacturing?	9/7/2018 12:32 PM
275	Personally, no. It places the compounder in the middle between state and federal law interpretations.	9/7/2018 12:29 PM
276	Yes. This would continue to allow compounding to be performed by pharmacies with the best facilities and abilities to do so.	9/7/2018 12:28 PM
277	Yes. This may limit the number of compounding sites and possibly maintain a higher quality process than having many less qualified/experienced centers.	9/7/2018 12:28 PM
278	Yes, as long as the outlet is fully accredited	9/7/2018 12:27 PM
279	no.	9/7/2018 12:27 PM
280	Yes	9/7/2018 12:26 PM
281	Yes	9/7/2018 12:26 PM
282	Yes, allows experts to continue to provide the service.	9/7/2018 12:22 PM
283	no	9/7/2018 12:20 PM
284	Yes- pharmacies should be able to offer their services to other outlets/practitioners as long as they meet all of the licensing guidelines	9/7/2018 12:20 PM
285	Yes--need for service	9/7/2018 12:19 PM
286	Define Shared Services.	9/7/2018 12:18 PM
287	yes	9/7/2018 12:18 PM
288	yes because of drug shortages	9/7/2018 12:18 PM

Q6 Should a new rule be added to require notification to the Board of a patient-level recall of a compounded drug distributed or dispensed by an Oregon licensed pharmacy? Why or why not?

Answered: 296 Skipped: 20

#	RESPONSES	DATE
1	It would depend on the reason for the patient level recall. For example, if it is for reasons of correcting labeling, but the compounding product is sound, then it does not rise to the level of Board notification. Recalls at the patient level requiring Board notification should only be required if the integrity of the drug product is compromised at the point of compounding or storage prior to being received by the user.	9/17/2018 2:37 PM
2	no	9/17/2018 1:20 PM
3	No. Because you don't require it for all others? We are required to respond and keep recall notices. Just have them in a separate file with compound paperwork.	9/17/2018 12:14 PM
4	Isn't there a rule already in place that requires patients be notified of a patient-level recall.	9/17/2018 9:24 AM
5	Yes. It would give regulators a "heads up".	9/17/2018 8:40 AM
6	Unsure	9/17/2018 7:44 AM
7	Not sure	9/16/2018 6:18 PM
8	yes, then the board could follow up that any appropriate follow up with pt has been done	9/16/2018 1:40 PM
9	if its from a compounding pharmacy which may be making batches of a product yes definitely. retail chain- separate commercially available ingredients have their own recalls alread	9/16/2018 10:27 AM
10	Yes	9/16/2018 12:44 AM
11	Yes for patient safety it sounds wise. The Board would hopefully use this information to track the cause and frequency of certain types of recalls.	9/15/2018 6:23 PM
12	Only if recall is significant health risk. Should not recall for purely admin reasons	9/15/2018 1:17 PM
13	recall	9/14/2018 9:56 PM
14	Yes	9/14/2018 9:47 PM
15	Yes, since this type of occurrence, if repeated, could serve as a red flag and highlight an issue that may have gone undetected or otherwise remain unknown to the board.	9/14/2018 9:12 PM
16	Yes, it will help improve patient safety	9/14/2018 3:57 PM
17	Absolutely not	9/14/2018 10:01 AM
18	Yes, the Board should know if a pharmacy has recalled a compounded drug, volume recalled, number of patients affected and what steps were taken.	9/14/2018 9:10 AM
19	That seems reasonable, as it may alert the Board of a pharmacy to watch.	9/13/2018 3:06 PM
20	Yes. Any compounding pharmacy should have a system in place to recall any medication that has been provided to a patient. This includes medications that are utilized by medical/dental providers per a shared service contract.	9/13/2018 1:06 PM
21	yes, patient safety of course	9/13/2018 11:30 AM
22	Yes the safety of the patients are our top priority	9/13/2018 10:14 AM
23	Any recall notification is/are good idea both for patient (providing patient can not bring back a finish item) and pharmacy which alert pharmacist to look up shelf inventory	9/12/2018 8:33 PM
24	Yes because all drugs are used for its efficacy	9/12/2018 7:59 PM
25	Sure	9/12/2018 6:59 PM

26	not necessarily; i think that should be at the discression of the pharmacy manager.	9/12/2018 5:52 PM
27	No, iff we haven't needed it up to now, we don't.	9/12/2018 5:31 PM
28	Yes. Patient safety.	9/12/2018 5:19 PM
29	Unless State Board of Pharmacy is going to maintain a database of such events, and track recalls on a per pharmacy basis, AND take action against pharmacies with a higher than (insert standard here) of compounded products recalled due to substandard compounding practices, the rule would be pointless.	9/12/2018 5:19 PM
30	I think the Board should be aware of all recalls.	9/12/2018 11:26 AM
31	Hospitals work hard to minimize errors but it does happen that errors occasionally leave the pharmacy but are caught by nursing and/or barcode administration before reaching the patient. Would these be considered "dispensed" and then "recalled" and therefore reportable? I could encourage the board to proceed with caution in how such an rule is worded if the intent is to focus on contamination or mass-produced errors a la NECC. The board should consider how much resources they have to review reports and actually act on them rather than just allow them to accumulate. Also, hospitals especially have highly effective internal auditing mechanisms for quality that are already surveyed by the CMS-approved agencies like TJC and DNV. Such accredited organizations should be given credit for the quality of their internal QA process and excluded from a board process intended to provide CMS-like review to facilities that are not accredited.	9/12/2018 10:36 AM
32	NO, as they are really time consuming and happen a lot.	9/12/2018 10:29 AM
33	yes, board needs to know	9/12/2018 9:48 AM
34	N/A	9/12/2018 9:43 AM
35	I would support this as long as the process was streamlined and intuitive.	9/12/2018 9:27 AM
36	Yes - effects public health	9/12/2018 8:44 AM
37	yes	9/11/2018 10:09 PM
38	Yes, any material found to possibly be hazardous to a patients health the pharmacy should be required to notify patients	9/11/2018 10:01 PM
39	If the recall involves an error by the pharmacy technician and/or pharmacist in compounding, then yes.	9/11/2018 7:15 PM
40	It would depend on the intent of the reporting. Not in support if this is an effort to enforce disciplinary action. In support if this is an effort to reinforce a just culture	9/11/2018 5:59 PM
41	I see no reason why the rule would be different for compounded medications vs. traditional medications. Each has a high capacity to harm the patient is dispensed incorrectly.	9/11/2018 5:28 PM
42	Yes, because it shouldn't have been dispensed and we need to know how to fix this going forward.	9/11/2018 4:31 PM
43	no. institution just needs to document the action taken and be able to show that.	9/11/2018 3:52 PM
44	No. What would you do about it, create a new department? The problem, in this case, has been found and measures are being taken to resolve it.	9/11/2018 3:44 PM
45	Yes	9/11/2018 3:27 PM
46	I think this is not necessary if the pharmacy has policies and procedures in place for this event.	9/11/2018 3:08 PM
47	I am not sure of the purpose? All patient-level recalls are directly communicated to the patient. Is the board directly notified of every patient-level recall of a non-compounded drug.	9/11/2018 2:47 PM
48	Hmm...that is a tough one...in general, I think that is a good idea, as it would allow the Board to help track small problems that could indicate larger systemic problems with a pharmacy's internal auditing systems or quality control. On the other hand, in my experience with having to recall patient-level compounded rxs, they are rare and usually because of a minor formulation error or inactive ingredient allergy issue rather than something more worrisome like the wrong active was used or contaminated, and that could create a burden of paperwork for the pharmacy (and the board) that could possibly incentivize suppression of information. I would definitely support this if it were possible to define the terms of what would constitute a "recall", certainly if the chemical supplier issued a recall of the active ingredient used that should be reported!	9/11/2018 2:46 PM
49	I do not have an opinion on this one way or the other.	9/11/2018 2:11 PM

50	no	9/11/2018 12:20 PM
51	No. This process is already heavily overseen by internal quality management processes. Adding BOP reporting to this would create additional layers of complexity with little value to the patient.	9/11/2018 11:55 AM
52	I think this information should be retained on site for inspection by the Board during its annual inspection. Reporting each incident concurrently seems to be a burden on the outlets and the Board.	9/11/2018 10:24 AM
53	Yes. For patient safety.	9/11/2018 10:08 AM
54	This depends on the ease of notification. If via electronic portal open to all practitioners and pharmacists and responsibility of reporting parties is clear, it may be "do-able". If reporting responsibility is unclear or burdensome, then it may thwart the intent.	9/11/2018 9:52 AM
55	Notification should be made to the board by the pharmacy who prepared the product - if that is a shared service agreement pharmacy, then that pharmacy needs to notify the receiver and OBOP. The receiving/distributing pharmacy should be responsible for the notification to patients in conjunction with the SSA pharmacy.	9/11/2018 7:47 AM
56	Yes, if it there is a safety or treatment outcome concern (lack of potency).	9/11/2018 7:30 AM
57	No. I believe that these are well handled by the facility itself through other mechanisms. This would only complicate matters. Most, except small pharmacies, have their own internal system that addresses this.	9/11/2018 7:28 AM
58	No. The Board can stay out of it. Let the pharmacy handle it the way it's always been.	9/10/2018 8:24 PM
59	I believe that would be best for bulk products. However, if the compound is a one-off type, that would be the same as requiring mandatory error reporting to the BOP. Do we also eventually mandatory report the near-misses? Where does it stop?	9/10/2018 8:11 PM
60	agree. patient level should be reported to all	9/10/2018 4:48 PM
61	No. The Board of pharmacy has a culture of disciplining licensees and outlets. We are trying to create a safety culture in our organization. Requiring this notification will impact our ability to continue down this pathway.	9/10/2018 4:02 PM
62	Yes - in case there is an issue that applies to other pharmacies so they can be aware or the recall expanded to them	9/10/2018 3:13 PM
63	If something occurs that warrants a patient level recall I feel it would be appropriate to notify the board any ways of the potential issues. So I would be ok with a rule to that effect.	9/10/2018 1:01 PM
64	Not sure - if it is a severe safety concern only?	9/10/2018 12:42 PM
65	Yes, it increases safety for others	9/10/2018 12:29 PM
66	Yes as you would be aware of what is coming down the pike. Board staff should be aware of what is about to "hit the fan" beforehand.	9/10/2018 12:16 PM
67	yes, should be same as FDA approved medications	9/10/2018 11:28 AM
68	I cant think of a disadvantage to requiring reporting to the board in this situation.	9/10/2018 11:24 AM
69	Yes. If a patient level recall is warranted	9/10/2018 11:09 AM
70	I assumed the Board knew about these already. Seems like they should since they license these compounding pharmacies.	9/10/2018 11:04 AM
71	Probably, but sometimes the recalls are really not even an issue. They would cause concern when it is not really an important issue.	9/10/2018 10:48 AM
72	Yes, all recalls should be publised	9/10/2018 10:43 AM
73	Yes, more information is always beneficial.	9/10/2018 10:28 AM
74	yes; the Board is concerned with patient safety as well as pharmacist oversight and communication between pharmacists and the Board is critical	9/10/2018 9:44 AM
75	Only if these rules will be universally applied/expected for hospital, retail, and community compounded products.	9/10/2018 9:37 AM
76	No. There's already a process in place	9/10/2018 9:31 AM

77	I do not practice in Oregon, but our policies and procedures do require notifying our Board of Pharmacy. It is important for the Board to understand what is happening in its licensed facilities. I also believe an inspection of that facility is likely warranted to make sure the public is protected.	9/10/2018 9:21 AM
78	yes, if you are talking about widespread distribution of the drug. if it is an individual prescription, then no.	9/10/2018 8:54 AM
79	No. We are already required to have internal auditing and QA processes in place to be compliant with accreditation companies. It seems like it would be duplicate work for the pharmacy and place additional burden on the board to review.	9/10/2018 8:29 AM
80	It depends. What would the board do with this information? Is there any current notification process in place? I think that mandatory reporting of such a recall is a good idea, but I want to know what actions (if any) would be taken based on this notification.	9/10/2018 8:01 AM
81	Yes compounding may have good practice but they too get their chemicals from other companies. Should be recall when needed.	9/10/2018 7:10 AM
82	Yes, more transparency. No hiding poor compounding or dispensing practices.	9/10/2018 6:56 AM
83	Yes safety	9/10/2018 5:37 AM
84	Yes. If there is a recall of drugs we use for compounding a patients medication, the board should be notified of the drug recall and we would have records of pulling that drug from being used . Also if a drug was compounded and distributed to the patient already, the patient should be notified of the recall and any steps to take for their safety.	9/10/2018 5:13 AM
85	Yes; seems like that should already be a rule	9/10/2018 12:15 AM
86	No. As a reputable compounding pharmacy the patients well being is of highest priority so of course we would take care of any patient-level recall. How does notifying the Oregon Board of pharmacy aid the patient? If the Board can show how this benefits the patients then i may reconsider my answer.	9/9/2018 11:25 PM
87	No. Hospital pharmacies have good incident reporting processes.	9/9/2018 11:12 PM
88	I don’t know if the board is notified when a patient level recall is issued by other pharmaceutical manufacturers. This requirement should be consistent.	9/9/2018 10:57 PM
89	I see no reason why this would be necessary. If a patient is notified properly and you are working with a drug manufacturer, that is enough.	9/9/2018 9:59 PM
90	If this means to follow a recall on a specific powder or liquid used in compounding, then that would be appropriate. I don't assume you mean how compounders products would be recalled based on their manufacturing practices. Most compounds are patient specific and compounders deal with product issues with the customer on a one on one basis. Not seeing where a rule on individual compound would need that level of recall. Ingredient recalls to level of consumer, yes.	9/9/2018 9:40 PM
91	Yes. Many other states already require this and I find that it creates a higher level of accountability for the licensed pharmacy. That being said, I do not feel the board should implement this rule for punitive intent. Having the capabilities of a pharmacy to effectively track and trace compounded medications plus communicate to those impacted speaks volumes to the current quality systems in place. If the board were to review and provide feedback on these systems in an instance of a notification of recall, that would certainly promulgate higher quality standards.	9/9/2018 9:37 PM
92	Yes, patient safety.	9/9/2018 9:18 PM
93	No. Patient level recalls for chemicals used in compounding should be handled the same way other drug recalls are. The extra step of notifying the board only creates more work for the pharmacy and the board during an already stressful situation.	9/9/2018 9:06 PM
94	No, overly burdensome to both the pharmacy and the board if done broadly (for certain circumstances I could see this as being good for patient safety)	9/9/2018 8:58 PM
95	No, but a requirement for having a policy for what to do in such a situation and record-keeping should be in place.	9/9/2018 7:50 PM

96	No. This will lead to requiring a notification on ALL patient-level prescriptions or God forbid a recall is issued by the manufacturer for whatever reason, because what is the difference? A prescription is a prescription. Whoever made it, whether it's a pill or a pharmacist compounded Amoxil 250/5ml or triamcinolone 50mg in 200ml cetaphil lotion. If we're going to start notifying you every time ANY prescription is called back where is the professionalism involved in that? What's the point of pharmacy school? Why should we have all that training and testing and preparation to become pharmacists? No, my answer is No.	9/9/2018 5:16 PM
97	Yes for patient safety	9/9/2018 5:11 PM
98	Yes	9/9/2018 4:23 PM
99	Yes, by the compounder, not by the distributor. I think it's imperative that the Board be aware of such a recall and determine what additional actions , if any beyond recall are warranted.	9/9/2018 3:22 PM
100	Indifferent. Value to public health vs burden to Board staff?	9/9/2018 2:07 PM
101	yes it would make it easier to spot a potential issue with the compounding facility	9/9/2018 1:52 PM
102	No, this should follow internal processes and federal Drug Supply Chain and Security Act (DSCSA) regulations. concern that any board rule on this would appear punitive and could negatively impact the just culture and pro-activeness of reporting errors that hospitals/health-systems are trying to embrace. There is no need an additional board rules surrounding this.	9/9/2018 12:32 PM
103	No, see the first answer.	9/9/2018 11:57 AM
104	Sure for additional safety	9/9/2018 11:32 AM
105	Yes, as long as it is not too onerous.	9/9/2018 10:32 AM
106	Yes. Recalled drugs are potentially lethal. The Board should be notified.	9/9/2018 9:53 AM
107	No, With the safety of the patient in mind the pharmacy in guestion is responsible for notifing any patients affected by the recall.	9/9/2018 9:44 AM
108	Yes. Recalls like that need to be tracked. I understand that recalls happen and they're not necessarily a big deal, but they can be, for example; if there is one compounding pharmacy that has recall after recall after recall that needs to looked into and the OR BOP needs to track it.	9/9/2018 9:26 AM
109	Yes, it’s important for the board to know	9/9/2018 8:49 AM
110	Yes. This should increase patient safety by allowing the board to follow up if necessary. However, the board would need to have appropriate policies/procedures in place for reviewing these reports and following up.	9/9/2018 7:42 AM
111	Probably	9/9/2018 6:50 AM
112	Yes. Even best practices may result in some low level of contamination. The Board should be able to detect outliers.	9/9/2018 5:14 AM
113	Yes because w should have it recorded for the board safety and if someone calls and ask they have this information	9/9/2018 12:30 AM
114	Again, I don't know.	9/8/2018 9:33 PM
115	Do they do that for all other drugs? If not then no. If they do then absolutely.	9/8/2018 9:31 PM
116	Yes. The Board should be notified. What if 6 different pharmacies each had 1 patient-level recall of the same beginning powdered ingredient? Safety first.	9/8/2018 8:39 PM
117	Well it makes sense to me that a recall should be reported since The Board is for the protection of the public	9/8/2018 7:53 PM
118	I'm not quite sure if the question. If youre asking if the board should be notified if a patient complains or returns a compound Id say it would depend on the reasons. If it's because a cream isn't completely smooth or something similar I would say no that would be a waste of time.	9/8/2018 6:32 PM
119	no	9/8/2018 5:35 PM
120	yes. Quality control reported recalls should be reported to the board of pharmacy. Drug dispensing errors should go through a quality control process, but not necessarily go to the board of pharmacy except where currently required.	9/8/2018 3:54 PM
121	would suggest both patient and pharmacy supplying compounded medication be notified, that way patients would have the opportunity to contact the pharmacy with any questions.	9/8/2018 3:40 PM

122	only if the same is required for commercially produced prouducts	9/8/2018 3:10 PM
123	Yes because the Board is the oversight for all pharmacies and should know of when something was made incorrectly. The only downside is that pharmacies would likely be fearful to notify the Board thinking it could make them look bad, that it would have negative consequences, or lead to more Board random audits. So I guess the other side of the coin is that if the pharmacy caught their error and figured out what caused it to make sure it doesn't happen again, why sully the relationship with the Board by bringing them in? However, not all pharmacies do that and may even get defensive to where they don't find the root cause or think they were the problem. For this reason, I think the Board is needed as a fair and objective outside opinion and to make sure what's wrong has been fixed going forward.	9/8/2018 1:47 PM
124	No opinion	9/8/2018 1:32 PM
125	No Trust the practioners	9/8/2018 1:08 PM
126	Yes. I did not know that the Board is not currently notified in the event of patient level recalls of compounded drug distributed or dispensed by an Oregon licensed pharmacy.	9/8/2018 12:36 PM
127	Yes, there should probably be a state record of pharmacy recalls for legal reasons, and to help track who may have been harmed.	9/8/2018 12:28 PM
128	Yes. This is a good policy	9/8/2018 12:23 PM
129	No.	9/8/2018 11:49 AM
130	Yes. A step in higher quality products	9/8/2018 11:29 AM
131	Yes, any recall affecting Oregonians should be reported to the Board immediately so that the board is aware of the problem and communicated to the pharmacists to protect Oregon's patients.	9/8/2018 11:10 AM
132	Couldn't answer one way or the other. What does notification involve? Would the Board require patient information? What would be the benefit for Board notification?	9/8/2018 11:00 AM
133	yes, We get dinged for being 2 days late on our C2 inventory I think the board should know if a patient may have been hurt by a bad compound.	9/8/2018 10:12 AM
134	Yes. OBP needs to know if a recall effects Oregonians.	9/8/2018 9:52 AM
135	Yes. I do not see any harm in this policy.	9/8/2018 9:27 AM
136	Yes! We are both morally and legally charged with protecting our patients. The recall should be public especially if the cause of a defect is uncertain.	9/8/2018 9:15 AM
137	If drug manufactures are required to report all recall to the OBP then yes, but if not no. What would be the value of notifying the OBP? Would the OBP aid in the process or hender it?	9/8/2018 9:11 AM
138	Not sure what this means. Any adverse reaction needs notification	9/8/2018 8:42 AM
139	yes, we need to insure patient safety and why the product is being recalled. ex: raw ingredient recall, product compromised because of staff etc..	9/8/2018 8:36 AM
140	yes, patients should always be notified when there is a drug recall for the protection of their haealth	9/8/2018 8:03 AM
141	No.	9/8/2018 7:24 AM
142	Hmm, not sure on this one.	9/8/2018 1:42 AM
143	Absolutely. If any medication has an error effecting patients in an adverse way,i think it should absolutely be reported.	9/8/2018 1:15 AM
144	Yes it should, accountability is too low in some pharmacies and issues are too often swept under the rug and away from the Board.	9/8/2018 12:14 AM
145	Yes. So the board can make an assessment on the pharmacy making too many mistakes and take an appropriate action.	9/8/2018 12:05 AM
146	yes for patient safety	9/8/2018 12:00 AM
147	Yes. Logical for patients safety	9/7/2018 11:27 PM
148	Yes	9/7/2018 11:07 PM

149	The rule would encourage better preparation monitoring to track lot numbers and help raise red flags for repeat offenders. Certain drugs such as sterile or scheduled substances have a stronger argument for this rule as they have more devastating affects on patients.	9/7/2018 10:55 PM
150	Not sure	9/7/2018 10:46 PM
151	Yes	9/7/2018 10:44 PM
152	No, it is the pharmacy's responsibility to ensure patients are notified and records kept.	9/7/2018 10:30 PM
153	No, What would the Board do with that information? The Board can subscribe to the same recall services that the outlets can.	9/7/2018 10:24 PM
154	No idea	9/7/2018 10:03 PM
155	I believe that the board should be notified of a scale of this magnitude.	9/7/2018 9:46 PM
156	No, the current recall rules seem effective.	9/7/2018 9:30 PM
157	yes	9/7/2018 9:17 PM
158	Yes, because our priority should be the safety of the patients for any compounded medication. An ingredient could cause an adverse affect or event, and any other compounded medications with that ingredient should be recalled. The ingredients are listed on every compound, and with a digitized recording system it would make it easy to search for the ingredient and allow for a quick recall. Safety for all patients should be the first priority, even if there has been no other known adverse effects or events.	9/7/2018 9:17 PM
159	Yes . Consumer safety	9/7/2018 9:09 PM
160	Yes	9/7/2018 9:03 PM
161	Yes, patient deserves the right to know about the safety of their medications if it will truly effect their safety	9/7/2018 9:00 PM
162	I have no opinion	9/7/2018 8:56 PM
163	Yes. The board should be notified if there is a patient-level recall based on compounding errors. Material errors should be the responsibility of the manufacturer and should not be blamed on the pharmacy.	9/7/2018 8:04 PM
164	Yes!!! We need to be diligent in protecting our patients safety. Transparency is very important in improving our practices.	9/7/2018 7:53 PM
165	Yes, I would think the BOP would like to be aware of any recalls, especially if sterile compounded products.	9/7/2018 7:41 PM
166	Yes	9/7/2018 7:34 PM
167	I am fine with this. It is more admistrative cost for our health system but if it allows us to care for our patients without outside accreditation cost we can at least control this type if cost	9/7/2018 7:32 PM
168	No , let the Pharmacies take care of it	9/7/2018 7:26 PM
169	No, it will discourage some recalls from occurring.	9/7/2018 7:19 PM
170	N/A	9/7/2018 7:08 PM
171	yes	9/7/2018 6:47 PM
172	Depends on what the recall is for, if something that could have caused them harm and needs to be addressed, then yes. If it will just serve to incite panic for no real purpose being served, I don't see the point.	9/7/2018 6:37 PM
173	Yes. Treat is as a recall of any drug. It should be notified. It is important and is a safety issue	9/7/2018 6:24 PM
174	yes	9/7/2018 6:18 PM
175	My opinion would be that yes, if a patient-level recall occurs the board should be aware, especially if the recall was based on pharmacy error.	9/7/2018 6:17 PM
176	Yes. It would seem prudent.	9/7/2018 6:13 PM
177	I think so since the consequences to the patient could be severe, especially if recall involved parenteral products	9/7/2018 6:10 PM

178	Yes, for patient safety and possible audits for compounding practices	9/7/2018 5:55 PM
179	Not sure I understand the question? If any product (lot or batch) is suspected of adulteration/contamination, I would expect a compounding company to recall the product. If it was a seven day batch for one patient, and harm is reported by the patient, I thought that is already required to be reported. If no harm, report should be part of facility's self monitoring program, which is audited.	9/7/2018 5:42 PM
180	I don't think there needs to be additional notification on top of what is already in place	9/7/2018 5:23 PM
181	No- board shouldn't be involved in patient level recall.	9/7/2018 5:10 PM
182	I guess yes, as the error should've been caught before then.	9/7/2018 5:10 PM
183	Yes, possible ingredient contamination just the same as tablet or capsule recall.	9/7/2018 5:09 PM
184	Yes, I think the board should be made aware of any recall that affects the patient. That way they can monitor the quantity and severity of recalls that happen.	9/7/2018 5:09 PM
185	no I think each pharmacy should be required to keep up with this on their own	9/7/2018 5:03 PM
186	Oh heck yes!!! Mandatory	9/7/2018 5:02 PM
187	Yes because then the pharmacy board would be aware if a sterile compounding pharmacy is not up to standards.	9/7/2018 4:54 PM
188	Sure	9/7/2018 4:52 PM
189	Not, most the time it would be too late.	9/7/2018 4:46 PM
190	yes. accountability is important.	9/7/2018 4:42 PM
191	I think so, yes. We had a call back of bupiv epidurals that we had compounded	9/7/2018 4:32 PM
192	Not necessarily. If the pharmacy is PCAB accredited (as it looks like this is will be required in the near future), recalls are a big part of the SOP's, and will he handled in an organized, thorough manner.	9/7/2018 4:32 PM
193	Yes	9/7/2018 4:31 PM
194	yes	9/7/2018 4:26 PM
195	Yes	9/7/2018 4:22 PM
196	no, that seems imposible to enforce and just encumbers the system	9/7/2018 4:19 PM
197	Yes, since the Board is responsible for ensuring the health and safety of patients, they should have a way of monitoring a serious issue such as a patient-level recall. It doesn't seem right for a pharmacy to be able to engage in a recall and "sweep it under the rug" without the Board knowing.	9/7/2018 4:19 PM
198	Yes	9/7/2018 4:17 PM
199	Yes, board should be aware of all patient level recalls.	9/7/2018 4:17 PM
200	No. Besides creating more bureaucratic red tape, no benefit is stated. What would be the purpose, of such an activity?	9/7/2018 4:14 PM
201	Yes, patients would be interested in knowing this information for their own safety and knowledge.	9/7/2018 4:13 PM
202	Yes.	9/7/2018 4:13 PM
203	Yes. Patient safety	9/7/2018 4:04 PM
204	No. There are enough procedures for recalls.	9/7/2018 4:04 PM
205	It's a drug recall, isn't it?	9/7/2018 4:04 PM
206	yes, if incidents are not monitored then we cant fix what might be wrong	9/7/2018 4:03 PM
207	No. Why should it be? What relevance does that have if the board is required to be notified in such a case? How is implementing this rule important? What does that do for anyone?	9/7/2018 3:59 PM
208	Recalls should be handled the same.	9/7/2018 3:59 PM
209	No, not necessary, usually compounded products expired in 30 day there is no long period use, recalls are not necessery, before compound has been made Technician will verify product of use.	9/7/2018 3:55 PM

210	Yes. Very valid to the board's work.	9/7/2018 3:49 PM
211	Yes	9/7/2018 3:44 PM
212	No, see above	9/7/2018 3:37 PM
213	yes, but only in extreme circumstances where patient harm may ensue. Not for potency recalls of API's	9/7/2018 3:32 PM
214	Yes, again, for patient safety reasons and reasonable documentation purposes.	9/7/2018 3:31 PM
215	yes- same standards as retail outlets	9/7/2018 3:28 PM
216	If the question is, 'Did the compounded agent have an adverse affect requiring immediate action?' then yes, but if the 'patient-level' recall is do to no immediate reaction, then no.	9/7/2018 3:21 PM
217	Yes.	9/7/2018 3:18 PM
218	No comment.	9/7/2018 3:15 PM
219	yes	9/7/2018 3:03 PM
220	No, this makes more paperwork and gets more people involved where things can get missed and creates a stressful situation for all involved.	9/7/2018 3:01 PM
221	?	9/7/2018 3:01 PM
222	Yes, to protect other patients who obtained from a pharmacy which was not the original preparer.	9/7/2018 3:00 PM
223	Rules, rules, rules! Everyone wonders why our healthcare system is an expensive mess, and this is why. Every added bureaucratic measure creates more unnecessary paperwork, costs patients and license holders more money, and does little or nothing to improve safety. If anything, the added regulations force companies to be nit picky about paperwork rather than focusing on safe, effective, and patient-centered medical care. The answer is fewer regulations, not more.	9/7/2018 2:59 PM
224	Yes, patient level recalls are required to be reported to the FDA depending on the regulation of the pharmacy. It would be nice to know that a regulator has a view into all compounders and not merely the 503B outsourcers.	9/7/2018 2:59 PM
225	Yes. Patient level recalls of compounded drugs present an opportunity for patient harm without any oversight as to the cause for the recall	9/7/2018 2:57 PM
226	yes-the Board can get to the root problem and help to insure it doesn't happen again	9/7/2018 2:57 PM
227	Yes but most meds are already used and gone before recalls	9/7/2018 2:54 PM
228	YES, IF THE COMPOUNDING PHARMACY HAS MADE A SERIOUS MISTAKE THEN THIS TYPE OF RECALL IS ONLY LOGICAL	9/7/2018 2:53 PM
229	No. Not sure why the board would need to be involved in a patient-level recall of a compounded drug...	9/7/2018 2:52 PM
230	Yes, I think the board should be aware of any recalls at any level concerning compounded drugs by Oregon licensed Pharmacies.	9/7/2018 2:52 PM
231	Unsure	9/7/2018 2:47 PM
232	Yes	9/7/2018 2:46 PM
233	Yes. This way the board is aware and can monitor habitual issues from repeat compounders and identify poor practices that may affect patient safety.	9/7/2018 2:46 PM
234	No - patient level recalls are operational in nature and should be a focus of the specific pharmacy and not necessarily a responsibility that board needs to provide further oversight on.	9/7/2018 2:45 PM
235	No because we could notify the patient directly without board involvement. Only thing the board should get involved in/notified of is if any state compounding regulations were broken that resulted directly in a patient level recall or if a pharmacist who is licensed in Oregon directly caused patient level recall due to negligence.	9/7/2018 2:36 PM
236	Yes. If it is bad enough to recall from the patient, the BoP should know	9/7/2018 2:32 PM
237	Yes it's the safe thing to do.	9/7/2018 2:32 PM
238	No	9/7/2018 2:31 PM

239	Yes, if problems are arising, better to stop it sooner than later.	9/7/2018 2:28 PM
240	Yes, some states already require this. Include any patient harm caused by a compounded product. The state should investigate root cause to ensure that additional harm is not caused to patients and that the pharmacy has appropriately quarantined suspect product and taken corrective action to remove additional risk.	9/7/2018 2:27 PM
241	No. The Board of pharmacy has a culture of disciplining licensees and outlets. We are trying to create a safety culture in our organization. Requiring this notification will impact our ability to continue down this pathway.	9/7/2018 2:25 PM
242	Yes	9/7/2018 2:21 PM
243	Unless this recall effects multiple sites I don't see the point in a state wide notification. It may just end up being extra work for someone that is rarely used.	9/7/2018 2:21 PM
244	Yes the board should be notified of all recalls regardless of the level.	9/7/2018 2:20 PM
245	yes	9/7/2018 2:17 PM
246	yes, to see if it happens to many times	9/7/2018 2:17 PM
247	Yes for QA trending	9/7/2018 2:16 PM
248	yes	9/7/2018 2:10 PM
249	Yes safety	9/7/2018 2:08 PM
250	Yes. The Board and the Pharmacy profession should always maintain the highest level of care for our patients.	9/7/2018 2:07 PM
251	Yes! There are so many moving parts in recalls and the pharmacies are sometimes the last to know.	9/7/2018 2:04 PM
252	No. Unless the Oregon Board of Pharmacy will be involved in patient outreach during recalls, then this notification serves no purpose.	9/7/2018 2:04 PM
253	yes. A patient should be aware in case of a recall	9/7/2018 2:04 PM
254	Yes	9/7/2018 2:03 PM
255	Yes, for safety reasons if the source of the ingredients have been compromised.	9/7/2018 2:03 PM
256	Yes, it is required for noncompunded drugs.	9/7/2018 1:55 PM
257	Yes. For patient safety concerns.	9/7/2018 1:52 PM
258	No. Pharmacies should be expected to do the right thing. If they do not, then the Board should be notified.	9/7/2018 1:52 PM
259	Yes	9/7/2018 1:51 PM
260	Yes. Patient-level recalls are by definition serious and the board should be aware of them.	9/7/2018 1:48 PM
261	for STERILE compounds, yes. For BATCH compounds, yes, but I don't think is needed for single patient specific nonsterile compounds, as recalls are very rare for these.	9/7/2018 1:46 PM
262	yes, potential adverse effects to patient	9/7/2018 1:46 PM
263	Only if it is a result of the sterile preparation. I would not require if one of the ingredients has been recalled	9/7/2018 1:37 PM
264	Would rather see a confidential, voluntary, and non-punitive system of healthcare incident reporting in Oregon similar to the Aviation Safety Reporting System. Since that is not likely to happen any time soon, yes. The question is how will that improve quality & safety and what will the Board do with the information? Regulatory agencies are generally not the best vehicles for quality improvement and information sharing.	9/7/2018 1:34 PM
265	Yes, so a regulatory body can investigate the reasoning behind the recall to make sure that all compounding guidelines are being followed to ensure patient safety and care.	9/7/2018 1:27 PM
266	yes, if the board is then responsible for notifying the patients of the issue, No if the board is not going to do anything.	9/7/2018 1:19 PM
267	No.	9/7/2018 1:17 PM

268	Yes. Patient safety issue.	9/7/2018 1:17 PM
269	This would be good, but remember the differing definitions of "compounding".	9/7/2018 1:16 PM
270	No, distributed yes, dispensed no.	9/7/2018 1:15 PM
271	Yes. That should be done anyway as it is a loose federal requirement. We should know at all times what patients got in regard to manufacturers, lot #s and expiration dates of products dispensed/administered. If we can't prope track, how we we know which patients have been affected and or harmed?	9/7/2018 1:14 PM
272	No. What is the value of this? The burden of record keeping would be very high compared to the incidence and use of the stored data.	9/7/2018 1:13 PM
273	No. A patient level recall often occurs due to the FDA registered API manufacturer and trickles through by the vendor. This should only be required if retail pharmacies have to alert the board for manufactured drug recalls (i.e. valsartan)	9/7/2018 1:10 PM
274	Yes. This is the ethical think to do.	9/7/2018 1:07 PM
275	Yes, again for quality assurance	9/7/2018 12:54 PM
276	No, it's not required for manufactured produced products, so don't feel the extra burden is required	9/7/2018 12:49 PM
277	Yes The board oversees all pharmacies in Oregon and if there is any recall needs to be aware	9/7/2018 12:44 PM
278	Yes. The board can keep track of pharmacies that have repeated issues and provide guidance or penalty if required.	9/7/2018 12:43 PM
279	yes, because of the possible severity of recall	9/7/2018 12:38 PM
280	Yes, patient safety	9/7/2018 12:38 PM
281	Yes, if out of the purview of the FDA	9/7/2018 12:32 PM
282	Yes. Aligns with the mission of the board for patient safety. How can the board protect patients when they are unaware of not just perceived, but actual issues?	9/7/2018 12:29 PM
283	Not necessary, the new USP 795/797 standards will require the pharmacy to maintain these records.	9/7/2018 12:29 PM
284	Yes. This could help the Board identify compounding pharmacies that have concerning practices.	9/7/2018 12:28 PM
285	Yes, we need transparency for quality control and patient safety	9/7/2018 12:28 PM
286	Yes, so that the patients and others in Oregon are aware of the recall	9/7/2018 12:27 PM
287	yes because if patients aren't aware of it, they aren't be safe.	9/7/2018 12:27 PM
288	Yes	9/7/2018 12:26 PM
289	Yes - I would imagine any recall should be required to be notified to the board	9/7/2018 12:26 PM
290	Not sure, but believe no. I am unclear what purpose this would serve.	9/7/2018 12:22 PM
291	yes; it comes back to patient safety being the priority and quality assurance	9/7/2018 12:20 PM
292	Yes- BOP should be aware if a compounding pharmacy must recall its' compounded products from pt's	9/7/2018 12:20 PM
293	Yes--makes sense	9/7/2018 12:19 PM
294	Yes. Oversite.	9/7/2018 12:18 PM
295	yes	9/7/2018 12:18 PM
296	no	9/7/2018 12:18 PM

From:	MACLEAN Karen S * BOP
To:	MACLEAN Karen S * BOP
Subject:	FW: FDA Making New Efforts to Assure the Quality of Compounded Drugs
Date:	Friday, December 21, 2018 10:12:50 AM
Attachments:	image001.png

From: Elwood, Will <William.Elwood@fda.hhs.gov>
Sent: Monday, December 10, 2018 4:10 PM

Subject: FDA Making New Efforts to Assure the Quality of Compounded Drugs

Good evening/afternoon,

Because of your interest in this issue, I want to let you know that today, FDA Commissioner Scott Gottlieb, M.D., and Deputy Commissioner Anna Abram issued the following statement on new efforts the Agency is making to assure the quality of compounded drug products. Should you have any questions or require additional information, please contact me directly.

Many thanks,
Will

Will Elwood
Intergovernmental Affairs Specialist

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U.S. FOOD & DRUG ADMINISTRATION

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Statement from FDA Commissioner Scott Gottlieb, M.D., and Deputy Commissioner Anna Abram on New Efforts to Assure the Quality of Compounded Drugs

As FDA continues to implement our 2018 Compounding Priorities Plan, our mission is to preserve patient access to compounded drugs to meet patients' individual medical needs while also protecting patients from the risks of contaminated or otherwise harmful products. We're especially focused on the importance of ensuring compounded product quality. Through enforcement actions, we've been addressing insanitary conditions and manufacturing quality issues at compounders' facilities across the country. More activities are planned, and we've stepped up our collaborative work with the Department of Justice. But preventing problems before they put patient safety at risk is our key objective to protect consumers.

Although compounded drugs can serve an important role for certain patients whose medical needs cannot be met by an FDA-approved drug product, it's important to understand that compounded drug products haven't undergone FDA premarket review for safety and effectiveness. Compounders who are uniquely permitted under law to compound and distribute certain compounded drugs without receiving patient-specific prescriptions are referred to as outsourcing facilities. There has been a lot of discussion around the issue of "office stock" – the drugs that doctors may keep on hand for certain procedures. If certain conditions are met, the law allows outsourcing facilities to provide hospitals, physicians' offices, and other health care facilities with supplies of compounded drugs to keep on hand as "office stock" for their patients, who may need quick or emergency medication upon diagnosis.

While this practice is permitted, outsourcing facilities must comply with certain requirements, including current good manufacturing practice (CGMP) requirements, and FDA routinely inspects outsourcing facilities to determine whether their products are manufactured appropriately. Today we're updating some of our proposed policies related to these outsourcing facilities. Among our goals is to make it more feasible for compounding pharmacies to become outsourcing facilities.

Our principal focus remains patient safety.

Compliance with CGMP is particularly important in outsourcing facilities, as they often operate on a larger scale than other compounders and their compounded drug products may reach many patients across the country. As such, ensuring that their products are not contaminated, contain the right amount of each component, and maintain quality while stored on the shelf for a period of time are critical for office stock production. By adhering to CGMP requirements, such product quality problems and potential patient harm are more likely to be avoided. But, unfortunately, we continue to find concerning conditions and practices that can lead to contaminated, super or sub-potent, or mislabeled products. This is especially true when the compounder does not adhere to CGMP requirements, which we often observe in compounding pharmacies not registered as outsourcing facilities that are subject to CGMP and other requirements because they continue to engage in activities such as providing office stock.

Our aim is to protect patients and see more of the activity that creates the greatest potential for risk be done by compounders that meet CGMP requirements rather than by those that do not.

Some of these higher risk activities include compounding done on a large scale, for drugs that must be sterile, and made using many manual manipulations.

That is why today we're releasing a revised draft guidance with recommendations for protecting patients from the risk of contaminated or otherwise substandard products produced by outsourcing facilities. The aim is to outline practices for drugs produced under CGMP requirements by outsourcing facilities.

Maintaining the necessary standards to protect patients from contaminated or otherwise substandard products is of utmost importance. Quality is best assured by implementing appropriate controls throughout the manufacturing process, with end-product testing providing additional assurance. Through our efforts to develop guidelines that are applicable to and reflect outsourcing facility compounding operations, our aim for this guidance is to recognize the differences in drug production between outsourcing facilities and conventional drug manufacturers. The guidance is intended to provide clarity on quality assurance, maintaining suitable facilities, sterility, stability testing and beyond-use or expiration dates for products that don't go through the FDA drug approval process.

We've heard the feedback from stakeholders to our proposed 2014 draft guidance that certain CGMP policies would have made it difficult for outsourcing facilities to fill smaller orders and that some compounded drug products that practitioners requested for office stock were not available from outsourcing facilities due to those policies. We want to advance policies that make it more feasible for outsourcing facilities to fulfill requests for office stock while maintaining product quality. This revised draft guidance includes changes intended to help achieve this goal, particularly through revisions related to release testing, stability testing and beyond-use dating, as well as policies that differentiate between production of sterile and non-sterile drug products.

In addition to the revised draft guidance that we're releasing today, we'll also be holding a public meeting in May to solicit comments on the potential impact of the policies, if finalized as described in the updated draft guidance, on outsourcing facilities supplying compounded drugs for office stock. Health care professionals, outsourcing facilities, entities considering becoming outsourcing facilities, and other interested parties will have the opportunity to present to FDA their perspectives concerning how the draft guidance revisions may impact them. We hope to gain additional clarity from stakeholders on outsourcing facility production of office stock products, the fulfillment of smaller orders of these office stock products, and the production of products with beyond-use-dating desired by providers, among other topics.

Effectively providing patients and clinicians with access to compounded products made under appropriate production standards is key to helping mitigate risk and assure quality for patients. In implementing the new law, we're seeking to strike a balance that helps ensure compounded products are accessible to patients that need them and that they meet appropriate quality standards. The FDA is still concerned that we see far too much unsafe activity in the compounding sector, including at facilities that have not registered with FDA as outsourcing facilities but continue to distribute office stock products. And we're concerned that patients still face too many risks. We're seeking to focus on supervision of this sector and appropriate enforcement activities. And we'll advance other new efforts to promote our oversight in this sector, to make it more feasible for compounding pharmacies to become outsourcing facilities, and for outsourcing facilities to meet provider requests. We'll also continue to conduct risk-based inspection and enforcement efforts with respect to compounders not registered as outsourcing facilities, especially if they appear to be distributing compounded sterile drugs nationwide without valid patient-specific prescriptions. Our goal is to ensure industry compliance. And the FDA will take action against facilities with deficient practices to try and stop issues before they lead to patient harm.

Soon we'll also be taking action to further define what substances can be used in compounded products by traditional compounders. We'll be issuing a final rule that identifies the criteria we are using to evaluate bulk drug substances for the list of bulk drug substances that may be used in compounding under section 503A (503A bulks list). This final rule will also identify bulk substances the agency has evaluated and will or will not place on the 503A bulks list. It's key to balancing access to appropriately compounded drugs and protecting patients from compounded products that could cause harm. We'll continue our rulemaking effort and plan to seek public comment on additional bulk drug substances for the 503A bulks list.

As part of this effort, today we're also adding two new entries to the "withdrawn or removed" list of drug products that cannot be compounded because they've been found to be unsafe or ineffective.

Compounded drug products play an important role for many patients, and we have made meaningful progress throughout 2018 on our compounding policy priorities and the implementation of the Drug Quality Security Act. We remain committed to this critical public health effort and look forward to continuing this important work next year, including laying out new compounding priorities in 2019.

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.

OREGON VETERINARY
medical association

Compounding Summary
(Oregon Veterinary Medical Association)

Veterinary needs: compounded medications for office stock

As health care providers, veterinarians rely on compounded medications to treat multiple species of animals that come in different shapes and sizes and with their own unique anatomy and physiology. And Oregon practitioners are capably served by Oregon compounding pharmacies for many reasons:

- When a manufacturer has discontinued a veterinary drug or equivalent FDA-labelled human formulation.
- When a medication is in shortage and no product is available or no allocations are given to veterinarians.
- When a particular dosage is not readily available for the patient.
- When a patient requires a formulation that is easier to administer.
- When there is a need to administer multiple medications to a patient.
- In rare cases, when no veterinary product exists and the retail price of the needed FDA-labelled human product precludes its use in non-human patients (e.g. apomorphine and fomepizole which are critical for both emergency and general small animal practice). This is uncommon but may arise from monopoly pricing, orphan drug status, or other market distortions.

Like physicians, veterinarians have a need to maintain sufficient quantities of certain compounded preparations in their hospital/facility (office stock) for administration or dispensing in order to treat patients with urgent and emergent needs. A large majority (88%) of practitioners in our recent survey of both OVMA and PVMA members feel that they would be unable to provide adequate care to their patients without access to compounded office-stock.

Current challenges with obtaining compounded office-stock for veterinarians

The FDA attempted to harmonize veterinary office-stock compounding with DQSA regulations (draft guidance #230 released in 2015); this guidance sought to require the use of 503B outsourcing facilities for non-patient specific compounding (office-stock) of veterinary drugs. However, to register as an FDA-recognized 503B entity, a compounder *must compound products for human medicine, must engage in some sterile compounding* (entities which compound only non-sterile products cannot register) *and must adhere to CGMP*. (The restrictive eligibility for 503B registration was driven by DQSA applicability to human compounding only.) Most veterinary compounders are not eligible for 503B registration; this fact, in addition to stakeholder comments, resulted in the withdrawal of draft guidance #230 in the autumn of 2017. In his testimony before a congressional committee in January 2018, FDA Commissioner Scott Gottlieb said "we pulled it for a variety of reasons, but largely because we don't think we got it right". Currently there is no available FDA guidance for veterinary compounding and no federal statutory law which addresses this area.

The FDA anticipated that a large number of compounding pharmacies would register as 503B Outsourcing Facilities. However, this has not happened. Of current 503B registrants (~75 total), only four facilities compound veterinary medications (see list below), with only one currently engaged in sterile compounding. It should also be noted that, despite FDA guidance requiring 503B registration for

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office-stock human compounding, the House Appropriations Committee has directed the FDA to continue to allow limited office-stock compounding by 503A pharmacies in multiple yearly budget signing statements.

Oregon veterinarians rely on the use of Shared Pharmacy Services Agreements under current OBOP rule. Until an FDA framework for veterinary office-stock compounding is available, and in the absence of compounding capacity for veterinarians under DQSA regulations, veterinarians will need to rely on state regulation to ensure access to office-stock for the care of their patients. The variety of size, species, and conditions seen by veterinarians makes it extremely unlikely that an FDA-approved drug will ever be available for each of our patients and their conditions (much as we would like that to be the case). While we encourage all efforts to ensure safe and efficacious medications for all patients, we respectfully suggest that OBOP maintain shared services for veterinarians with rules similar to those adopted by the Ohio Board of Pharmacy) until such time as federal regulatory framework and capacity are available for veterinary office-stock compounding.

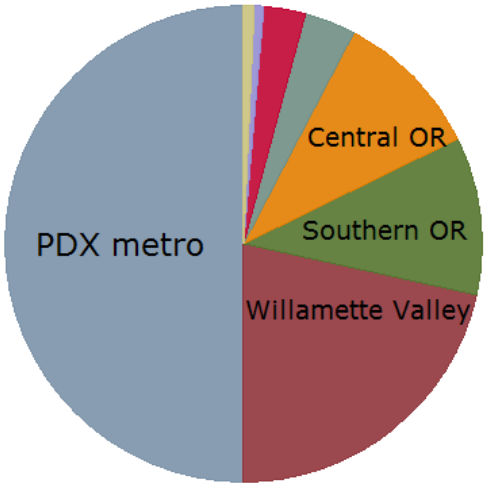
List of 503B Outsourcing Facilities that serve the veterinary profession

Stokes Pharmacy Mount Laurel, NJ	https://www.stokespharmacy.com	Sterile and non-sterile, apomorphine not available but forthcoming, ophthalmics available
KRS Global Biotechnology Boca Raton, FL	http://krsbio.com/	Non-sterile only, primarily oncology drugs
US Compounding Conway, AR	https://www.uscompounding.com/	Non-sterile only (fairly limited formulary)
Atlas Pharmaceuticals	http://www.atlasdrugs.com/veterinary/	Non-sterile only; not yet shipping to Oregon

Oregon Veterinary Medical Association 2018 Office-stock Compounding Use Survey Results

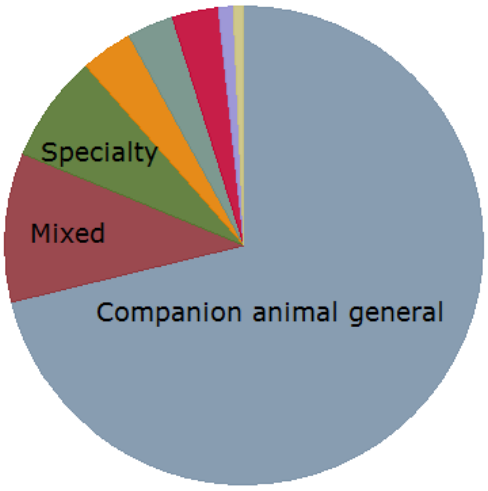
1. Respondents' practice region

Practice region	*Number*	*Percent*
Portland Metro Area	144	50
Willamette Valley	62	21.53
Southern Oregon	31	10.76
Central Oregon	29	10.07
Oregon Coast	10	3.47
Eastern Oregon	8	2.78
Other	2	0.69
Retired	2	0.69
Total	288	100



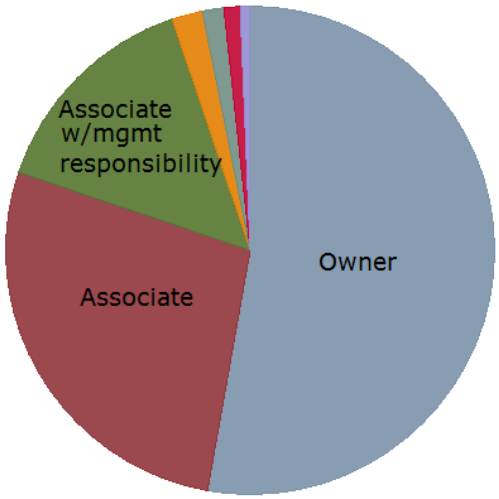
2. Respondents' practice type

Practice type	*Number*	*Percent*
Companion animal general	205	71.18
Mixed animal	29	10.07
Specialty	21	7.29
Emergency — Companion animal	10	3.47
Equine	9	3.13
Shelter	9	3.13
Other	3	1.04
Exotics and/or avian	2	0.69
Total	288	100



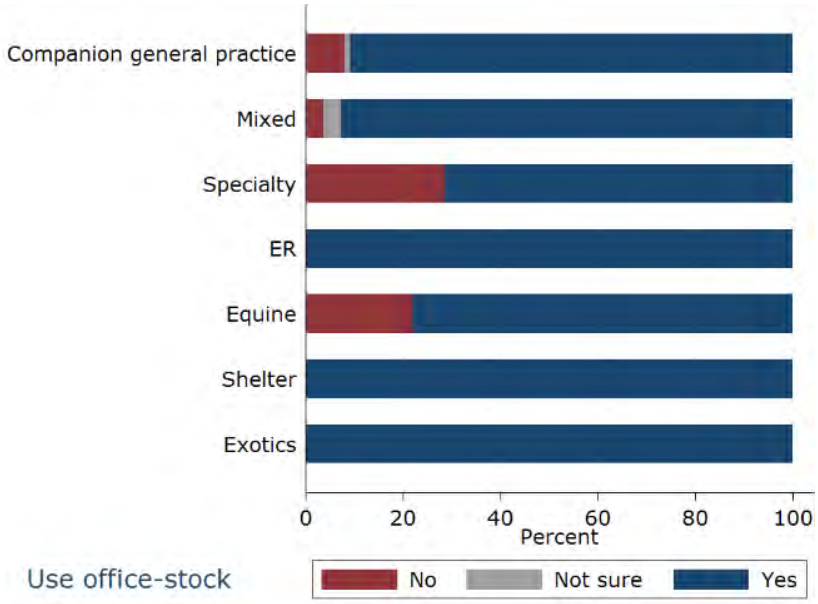
3. Employment position

Position	*Number*	*Percent*
Owner	152	52.78
Associate	79	27.43
Associate w/mgmt responsibility	42	14.58
Relief	6	2.08
Retired	4	1.39
Other	3	1.04
Practice manager	2	0.69
Total	288	100



4. The majority of respondents reported using office-stock compounded medications. Eighty-nine (89) percent of all respondents who answered the question reported using office-stock for in-hospital or dispensing purposes

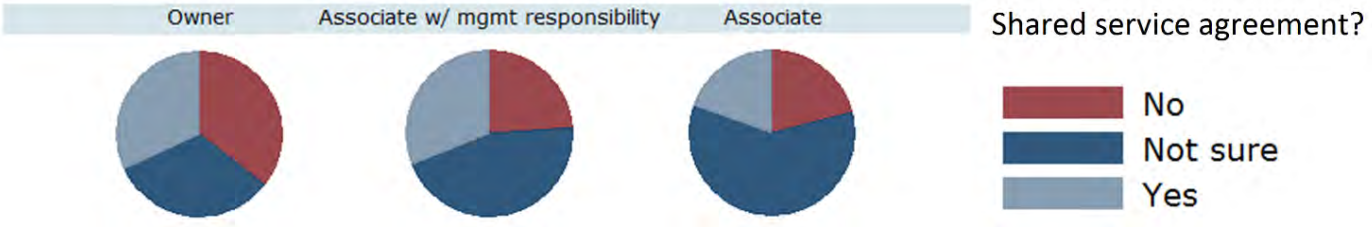
Office-use stock	*Number*	*Percent*
Yes	247	85.76
No	27	9.38
Not sure	3	1.04
Not answered	11	3.82
Total	288	100



5. A minority (26.4%) of respondents reported having a shared service agreement with compounder(s) for office-stock. The majority of respondents reported having no agreement or were unclear as to whether they had an agreement, or what a shared services agreement entailed.

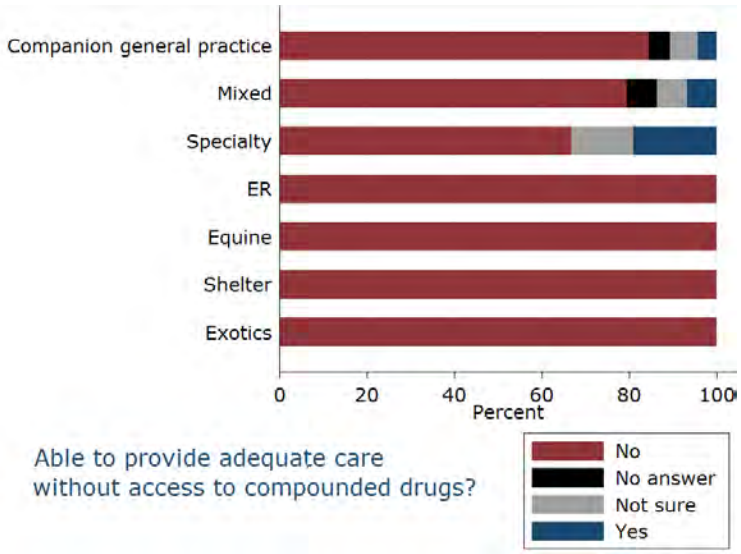
Do you have a shared-service agreement?	*Number.*	*Percent*
Yes	76	26.39
No	84	29.17
Not sure	115	39.93
No answer	13	4.51
Total	288	100

Owners and associates with management responsibilities were marginally more likely to report have a shared service agreement than were associates who did not report participating in management. The two practice managers who responded to the survey reported having shared service agreements.



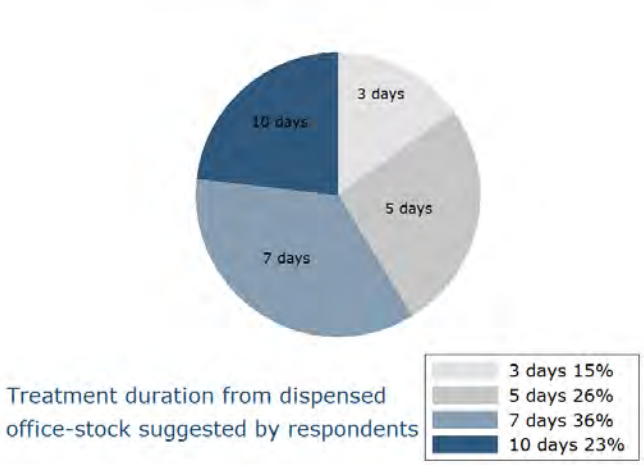
6. A large majority of respondents did not feel that they could provide adequate care to their patients without the use of office-stock compounded medications.

Can you provide adequate care without access to office-stock compounded drugs?	*Number*	*Percent*
No	241	83.68
Not sure	18	6.25
Yes	16	5.56
No answer	13	4.51
Total	288	100



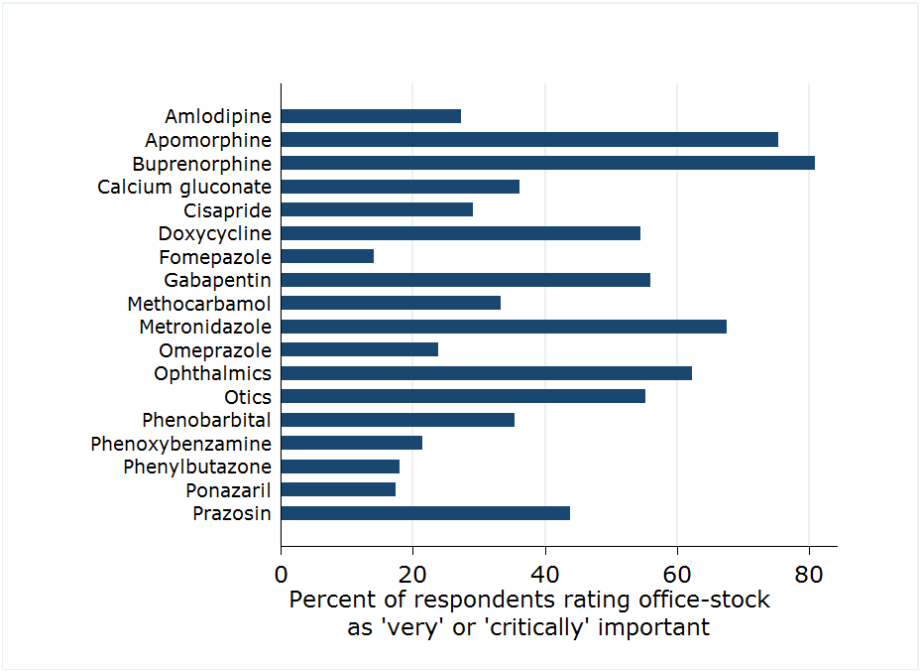
7. Quantity of office-stock available for dispensing purposes.

Respondents were asked to specify the duration of treatment should be available for dispensing of office-stock compounded medications. The median suggested duration of the 225 respondents who answered this question was 7 days. There were no statistically significant differences in duration of time suggested by geographic region of practice.



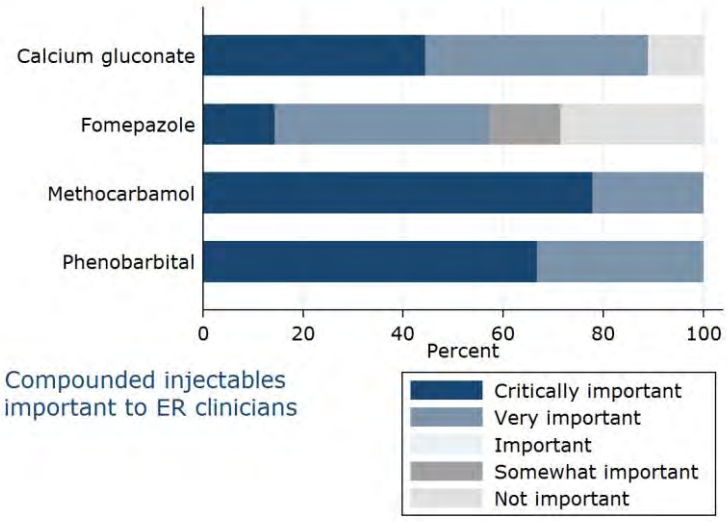
8. Importance of access to specific compounded medications.
Respondents were asked to rate the importance of availability of specific compounded products on a Likert scale: 'not important', 'somewhat important', 'important', 'very important', or 'critically important'.

The percentage of respondents who ranked specific items as 'very' or 'critically' important are shown in the figure at right.

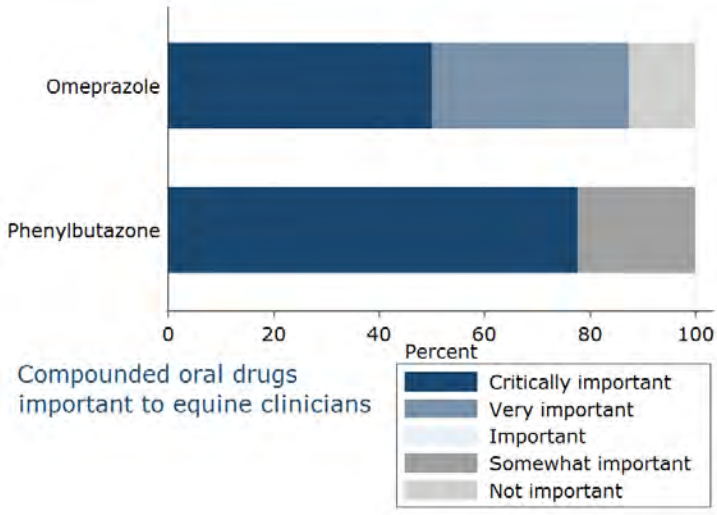


Even compounded products not ranked as critically or very important by the majority of respondents were of greater importance in certain areas of practice:

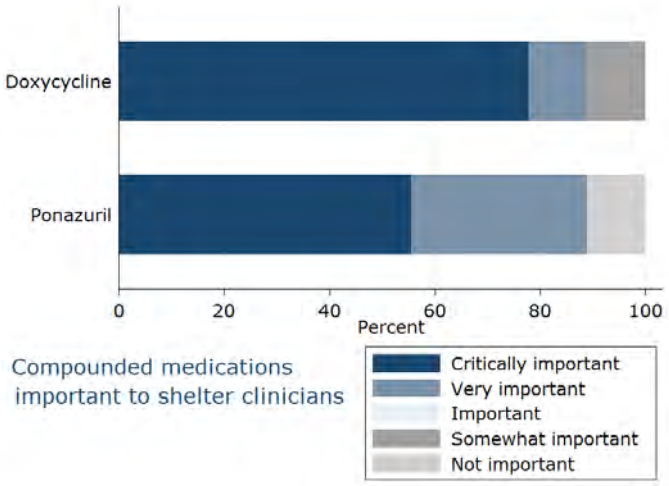
1. Emergency clinicians had greater need of specific compounded injectables than the majority of respondents.



2. More than 75% of equine clinicians ranked two compounded oral medications as critically or very important to the care of their patients.



3. More than 85% of shelter clinicians ranked two compounded medications as critically or very important to the care of their patients.



Other compounded office-stock drugs apart from our specific listing were described by respondents for specific practice areas; these are listed in the table on the following page.

Additional drugs suggested to be important for office-stock

Practice area	*drug*	*Practice area*	*drug*
Emergency	hydromorphone	*Oncology*	L-asparinase lomustine actinomycin-D prednisilone mustargen chlorambucil cyclophosphamide ondansetron ursodiol
Equine	dexamethasone powder methocarbamol oral ranitidine oral enrofloxacin oral rifampin oral	*Anesthesiology*	amandine aminocaproic acid
Exotics/avian	diazoxide enrofloxacin oral azathioprine metoclopramide prednisilone	*Ophthalmology*	depending on shortage
Mixed	DES ACTH gel Xylazine tetracycline ketoconazole vasopressin flunixin meglumine sulfasalazine	*Dermatology*	oral anti-fungals
Companion general	diazepam DES Enrofloxacin Pimobendan Mirtazapine Methimazole azithromycin hydromorphone	*Shelter*	No additional suggestions

4729-16-12 Drugs compounded by a pharmacy for use by a veterinarian.

(A) This rule only applies to compounded drugs intended for animal use by a licensed veterinarian.

(B) For all non-sterile compounded products, the pharmacy shall comply with the United States pharmacopeia chapter <795>, USP 38 - NF 33, or any official supplement thereto (9/10/2015).

(C) For all sterile compounded products, the pharmacy shall comply with the United States pharmacopeia chapter <797>, USP 38 - NF 33, or any official supplement thereto (9/10/2015).

(D) In accordance with applicable federal laws and regulations, a pharmacist working at an pharmacy licensed as a terminal distributor of dangerous drugs may compound and provide without a prescription a non-patient specific drug pursuant to a request made by a veterinarian, or by an agent of the veterinarian, for a drug to be used by the veterinarian for the purpose of the direct administration to patients in the course of the veterinarian's practice pursuant to division (C)(5) of section 4729.01 of the Revised Code and the following:

(1) The pharmacy shall only provide compounded drug products that are not commercially available, as defined division (C)(5) of section 4729.01 of the Revised Code, to a veterinarian which are needed:

(a) To treat an emergency situation;

(b) For an unanticipated procedure or treatment for which a time delay would negatively affect a patient outcome;

(c) For diagnostic purposes.

(2) A limited quantity of the drug is compounded and provided to the veterinarian. "Limited quantity" means a quantity of a compounded drug that meets the following:

(a) Is sufficient for that veterinarian's office use consistent with the beyond use date of the product;

(b) Is reasonable considering the intended use of the compounded medication and nature of the veterinarian's practice; and

(c) The pharmacist who provides the veterinarian with a compounded drug exercises their professional judgment as to whether the quantity of the drug is appropriate.

(E) A veterinarian may personally furnish up to a seven day supply of a compounded drug to a patient when, in their professional judgment, failure to provide the drug would result in potential harm to the patient.

(F) The pharmacy shall not sell a compounded drug to another pharmacy or wholesaler.

(G) Veterinarians shall not:

(1) Sell a compounded drug to another prescriber;

(2) Sell a compounded drug to a pharmacy; or

(3) Return a compounded drug to the supplying pharmacy, unless there is a documented error or recall.

(H) The labeling of a compounded drug product must contain the following:

(1) Proper storage conditions;

(2) Beyond use dates;

(3) The name(s) of the active and inactive ingredients;

(4) The amount or percentage of active drug ingredients;

(5) The quantity of compounded drug provided;

(6) The route of administration;

(7) The pharmacy name, address, and telephone number;

(8) The pharmacy control number assigned to the compounded drug product.

(9) The statement "Compounded Drug Product" or other similar statement.

(I) Compounded drug product containers that are too small to bear a complete label pursuant to paragraph (H) of this rule must bear a label that contains at least the following information:

(1) The storage conditions if other than room temperature;

(2) The beyond use date;

(3) The drug name(s), including all active ingredients;

(4) The drug strength(s);

(5) The route of administration;

(6) The pharmacy control number;

(7) The pharmacy name.

(J) In all cases, a complete label meeting the requirements of paragraph (H) of this rule must be applied to the outside container in which such compounded drug is supplied.

(K) The sale of a compounded drug product to a prescriber is considered a wholesale sale as defined in section 4729.01 of the Revised Code. A pharmacy is required to follow the record keeping requirements for wholesale sales listed in paragraph (H) of rule 4729-9-16 of the Administrative Code.

(L) A pharmacy shall follow the compounding requirements pursuant to rules 4729-16-03 and 4729-16-06 of the Administrative Code, current professional compounding standards, and all applicable federal and state laws, rules, and regulations.

(M) No pharmacy shall sell any amount of non-patient specific veterinarian administered compounds in excess of five per cent of the total amount of drug products sold and/or dispensed from their pharmacy. The five per cent limitation shall be calculated on an annual basis and shall reference the number of dosage units. For non-resident pharmacies, the total amount sold and/or dispensed shall reference the pharmacy's total business within this state.

Effective: 2/22/2016
Five Year Review (FYR) Dates: 02/22/2021
Promulgated Under: 119.03
Statutory Authority: 3719.28, 4729.26
Rule Amplifies: 4729.55, 4729.01, 4729.54, 4729.541

Minutes	**Public Health and Pharmacy Formulary Advisory Committee Meeting** **October 26, 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 - phone
- ❑ Sean Jones, MD
- ❑ Amy Valdez, RPh
- ❑ Amy Burns, RPh
- ❑ Mark Helm, MD
- ❑ Helen Turner, DNP - absent

OBOP Staff to Committee

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

Agenda Item	Desired Outcome
Welcome	Roll call Agenda review and approval o A member inquired about the manner by which the Committee may seek that a certain concept be submitted. It was determined that the Committee members may collectively put forth a request and will hope that a person take the initiative to submit a concept for review. At this time, the Committee is specifically seeking an HIV post-exposure prophylaxis concept. o The Committee stated that, moving forward, they will review items that have been submitted, at a minimum, greater than 4 weeks prior to the next scheduled meeting. This will be added to the Concept Form instructions. **Motion to approve the agenda was made and unanimously carried (Motion by Helm, second by Burns.** 8.24.18 Minutes review and approval (phone call meeting) **Motion to approve the 8.24.18 Committee Minutes was made and unanimously carried (Motion by Burns, second by Jones).**
Committee Business	❖ Committee Update: o Fiona provided the Committee with a rules development update. ▪ In August, the Board voted to adopt foundational rules for prescribing and the Committee's recommended items into Division 020. Edits related to scope were added into Division 019 (Pharmacist) and pharmacy responsibilities were added to Division 041 (Drug Outlets) ▪ The rules were effective upon filing (10/18/2018). o The Committee discussed policy items related to recommendations and rules. ▪ During the Board's discussions and final adoption of these rules, they asked the Committee to discuss the mandated face to face assessment requirement and how this might impact each of the prior 2018 recommendations, as well as how a pharmacist might help address a patient concern when interacting solely with the patient's agent/family member.

- A patient assessment may only be performed when a patient is present, therefore a pharmacist should not prescribe solely on behalf of information provided by a patient's agent.
- The Committee acknowledged that the mandated assessment requirement seemed to have been a focus of a number of the rulemaking hearing comments.
- It was noted that the Board adopted the language pursuant to the Committee's and Board's collaborative work on the foundational elements.
- While there may be circumstances for a pharmacist to provide quality care via a "telepharmacy" method, there are still many unanswered questions related to the provision of telehealth services in Oregon.
- It is understood that one reason it may be desired to remove the face-to-face element is for payment.
- A member suggested that this can be ongoing discussion by the Board, who can begin to create a standard for telepharmacy, and have those in place before removing the face-to-face requirement, particularly because these authorities are still so new, it is good to get pharmacists comfortable with the framework first.
- A member stated this is not an issue we need to solve today and because it is an emerging topic with many facets beyond the scope of the Committee, it is prudent to "keep an eye" on it.
- The Committee discussed a technicality point brought forth that an item on the post-diagnostic drug category may only be prescribed pursuant to a medical diagnosis. In order to allow for when a pharmacist issues a prescription for an albuterol MDI for cough symptoms, to also be able to prescribe and dispense a spacer, the Committee made the following motion: **Motion to recommend a minor edit to OAR 855-020-0300(2)(a)(C) to add "with or without a spacer" for the Oregon Board of Pharmacy adopt by rule was made and unanimously carried (Motion by Helm, second by Anukam).**

❖ High priority items to review at this meeting:

- none

❖ Concept requests submitted via form:

- <u>Continuous Glucose Monitoring</u> (cGM) – (submitted 8/7/2018)
  - Current rules allow a pharmacist to prescribe, under the Formulary: "Devices: Diabetic blood sugar testing supplies". The Committee chose to discuss this as a separate item from what is currently allowed by rule, because the February 2018 conversation that resulted in recommending blood sugar testing supplies did not contemplate cGM.
  - Due to the volume and complexity of data provided by the readings, a pharmacist may not have the time or experience to manage the patient appropriately, as cGM is traditionally reserved for complex patients.
  - The Committee reminds that a pharmacist may issue a prescription for a patient if a continuation of therapy is warranted.

Motion to not recommend Continuous Glucose Monitoring to the Formulary list for the Oregon Board of Pharmacy adopt by rule, noting that a pharmacist may facilitate a patient need for cGM supplies via Continuation of Therapy Protocol, was made and unanimously carried (Motion by Helm, second by Burns).

- Full Prescribing:
  - The Committee discussed the concept request to allow for a pharmacist to prescribe, procure or authorize use of legend drugs, controlled substances, therapeutic devices and over-the-counter medications based upon facility granted scope of practice. (submitted 9/5/2018). This concept contemplates the addition of all legend drug, controlled substances, therapeutic devices and OTCs based on "facility-granted scope of practice". The authority would be granted via additional licensure with the Board of Pharmacy as a Pharmacist Prescriber.
  - The Committee appreciated the time to build this very well-written concept, however determined that this request is outside the scope of the law for the Committee's efforts. The ability to authorize a legal change of scope, and create another licensing category is also outside the scope of the committee, as only the legislature may do so.

Motion to not recommend adding all legend drugs, controlled substances, therapeutic devices and OTC medications, pursuant to facility-granted scope of practice, to the Protocol list for the Oregon Board of Pharmacy adopt by rule was made and unanimously carried (Motion by Burns, second by Jones).

- Smoking Cessation – (submitted 10/13/2018)
  - The Committee determined this is a concept they'd like to consider, and stated it was a great submission with helpful background related to research and excellent information about other state's various methods of addressing this item.
  - The Committee talked at length about various comfort levels with regard to adding all items in the concept, which include: nicotine patches, gum, lozenges, inhaler, nasal spray; bupropion and varenicline.
    - A member shared that smoking cessation is taught as a standard in the pharmacy school curriculum
    - Members discussed the critical importance of the success of combining these smoking cessation aids to behavioral health counseling
    - A member stated that smoking cessation products are universally covered by the ACA
    - The Committee ultimately determined that they were comfortable with Nicotine Replacement Therapy NRT (both OTC and Rx)
    - The Committee ultimately determined that additional work and conversations need to occur regarding bupropion and varenicline.
- **Motion to recommend individual or multiple Nicotine Replacement Therapy (NRT) OTC and Rx for smoking cessation to the Protocol list for the Oregon**

	Board of Pharmacy adopt by rule was made and unanimously carried (Motion by Jones, second by Chinn). ▪ The Committee discussed the possible need to develop and recommend a standardized patient assessment process and treatment care plan for prescribing bupropion and varenicline, as well as whether there is a need to specify an additional mandated education requirement, and plans to discuss at their next meeting (1/11/2019). ▪ Chair Valdez to reach out to author of the smoking cessation concept to discuss additional information related to the addition of bupropion and varenicline. ❖ Additional items to explore: None at this time
Good of the Order	❖ The Committee discussed their upcoming schedule and the need for members to not miss meetings due to the statutory requirements for attendance. ❖ Next meetings • November 16, 2018 *(brief conference call to approve Oct. minutes*) ➢ January 11, 2019 – room 1D ❖ 2019 tentative meeting schedule ➢ January 11, 2019 – room 1D • February 1, 2018 – (*brief conference call to approve minutes*) ➢ May 3, 2019 – room 1E • May 24, 2019 – (*brief conference call to approve minutes*) ➢ July 12, 2019 – room TBD • August 2, 2019 – (*brief conference call to approve minutes*) ➢ October 25, 2019 – room TBD • November 15, 2019 - (*brief conference call to approve minutes*)

Chair Valdez adjourned the meeting at 12:03PM.

MINUTES	**Public Health and Pharmacy Formulary Advisory Committee Meeting** **January 11, 2019, 8:30am** **Portland State Office Building, 800 NE Oregon St. Portland, OR 97232** **OBOP Conference Room 1D**

Committee Members

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

OBOP Staff to Committee

- ❑ Karen MacLean, Administrative Director
- ❑ Brianne Efremoff, Compliance Director

Agenda Item	Desired Outcome
Welcome	Roll call Agenda review and approval **Motion to approve the agenda was made an unanimously cared (Motion by Helm, second by Burns)** 11.30.18 Minutes review and approval **Motion to approve the 11.30.18 Committee Minutes was made and unanimously carried (Motion by Turner, second by Chinn)**
Committee Business	o Compliance Director, Brianne Efremoff provided a brief informational update related to rules development and implementation. ➢ RPH prescribing Update: Success of these processes is defined by actual implementation in order to increase patient access to care. ➢ The challenge today is to inspire implementation to ensure that patients have increased access to care. ➢ The reality is that this service is ultimately a business decision and a business must seek to offer patient assessment and prescribing services. The business then must ensure that pharmacists are appropriately educated, trained and empowered to provide this service. To inspire implementation of adding this service there must be billing processes created. ➢ The profession of pharmacy is being asked to address a number of public health initiatives yet, the infrastructure is not yet built to facilitate this. ➢ In order to be successful, pharmacist must be empowered with the knowledge of the laws and rules and policy and procedure for offering these services. The pharmacist education, training and credentials must be accounted for in the pharmacy's procedure for payment. ➢ Efremoff briefly reviewed the foundational elements that a pharmacist is required to complete prior to prescribing any drug or device. ➢ Patient assessment is the key to the provision of pharmacist prescriptive services, as it informs the evaluation, development of the treatment care plan, and follow-up.

- Concept requests submitted via form:
  - *Smoking Cessation (continued)*
    - Pharmacist Kiyomi Lehman, presented information related to the creation of a standardized patient assessment process and treatment care plan for smoking cessation/prescribing of varenicline and bupropion.
    - The Committee discussed what programs are available to help patients identify follow up care, and that in the absence of an electronic health record, mental health questions must be asked, and the pharmacist must be prepared to make appropriate referrals based on information provided by a patient.
    - The Committee acknowledged adding this service will require RPH time for patient assessment and outlet workflows need to be established for successful prescribing services.
    - The Committee discussed what the appropriate follow up time frame should be to ensure assessment of patients' response to treatment and to evaluate any side effects.
    - A standardized questionnaire was discussed, there was discussion of working with community experts to finalize the questions.
    - Additional follow-up is needed once staff has the opportunity to obtain legal counsel regarding whether specific drugs must be identified for each motion, per statutory authority.

Motion to recommend addition of non-NRT medications for smoking cessation to the Formulary list for the Oregon Board of Pharmacy adopt by rule, with the following:

- **Additional Requirements:**
  - **Educational Requirement: 1 time course minimum 2 hours of CPE**
  - **Standardized Questionnaire to meet the elements as presented and**
    - **PHQ2 required**
    - **Suicide question from the PHQ9**
  - **Mandated Exclusion:**
    - **positive screen on PHQ2**
    - **yes on questions regarding suicide**
    - **using questionnaire content presented to include additional elements for exclusion**
    - **< 18 years old**
  - **Active Referral to the Quit Line or similar program**
  - **Mental Health Assessment and Referral Process including:**
    - **Mental health assessment tool and**
    - **The Oregon suicide hotline or similar program**
  - **Prescribing**
    - **1st prescription may be written for up to 30 days**
    - **Maximum duration: 12 weeks**
    - **Max Frequency: 2 times in rolling 12 months**

- **Mandated Follow up within 7 to 21 days pharmacist must follow up with patients (phone consult permitted)**

- **Pharmacist prescribing requirements: Follow established elements, which include: patient assessment, notification of providers upon prescribing, and documentation, among others.**

was made and unanimously carried (Motion by Chinn, second by Jones).

- *Non-AB Therapeutic Interchange*

  - The Committee discussed the difficulty in tackling this concept.

    - Valdez discussed the possible confusion between current statutes that permits non AB- Therapeutic substitution and the current concept proposed.

    - Efremoff highlighted existing statute ORS 689.515 components that permit a pharmacist to use a certain degree of professional judgment when substituting drug products in the dispensing process. A pharmacist may substitute therapeutically equivalent drugs of the same strength, quantity, dose and dosage form that do not utilize a unique delivery system technology, and when the prescriber is not reasonably available for consultation.

    - The Committee is tasked with making recommendations to the Board to include items to the Compendia for a pharmacist to prescribe; this situation addresses alterations to therapy, which is part of the dispensing function.

    - The Committee stated that this request is outside of their scope but acknowledges that this is an important topic that the Board might want to address in a policy discussion.

Motion to not recommend non-AB therapeutic interchange to the Formulary list for the Oregon Board of Pharmacy adopt by rule was made and unanimously carried (Motion by Chinn, second by Helm).

- *Supplemental Fluoride*

  - The Committee may want to consider this concept but not at this time, to be brought back for a later meeting.

  - Additional work needed to show risk assessment, treatment options, and public health benefit. May request additional information from a subject matter expert at a future meeting.

Motion to deny recommending supplemental fluoride to the Protocol list for the Oregon Board of Pharmacy adopt by rule was made (Motion by Helm, second by Anukam), Turner, Jones, Burns and Chinn abstained. Motion to deny failed. No further action taken.

- *Pre-Travel Consult Medication*

  - Link to the CDC's *Health Information for International Travel*, aka the Yellow Book, was provided for background.

  - The Committee discussed that a substantial amount of education would be needed for a pharmacist to prescribe in these circumstances and that ongoing education would be necessary.

- Burns commented that this would be a valuable service in rural areas where travel services are not generally available.
- The Committee stated that assessment regarding vaccination should be conducted at this time also.
- There was some concern about motion sickness and potential side effects or complications specific to children.
- The Committee discussed a desire to provide recommendations to the Board in a format that would permit a pharmacist to utilize current guidelines and not to specify specific drug classes, drugs or devices. Staff stated that the law states that the Committee is to provide recommendations to the Board via drug or device but that there is a specific carve out to allow for protocol recommendations for travel medications and smoking cessation. Staff stated that they would confer with counsel on this and inform the Committee on how to proceed.

Motion to recommend addition of the four categories of Preventative Travel Medications including: Malaria Prophylaxis (chloroquine, atovaquone/proguanil, mefloquine, doxycycline), Traveler's Diarrhea Prevention and Treatment (ciprofloxacin, azithromycin), Acute Mountain Sickness Prophylaxis (acetazolamide) and Motion Sickness (Scopolamine patches, promethazine tablets/suppositories, meclizine) to the Protocol list for the Oregon Board of Pharmacy adopt by rule:

- **Additional Requirements:**
- **Education minimum: complete APhA immunization training or equivalent plus 4 hour travel vaccination class or equivalent**
- **Continuing Education: every 2 years must complete 1 hour travel medications related CE**
- **Assessment of Routine Vaccination status and appropriate treatment and referral**

- **Pharmacist prescribing requirements: Follow established elements, which include: patient assessment, notification of providers upon prescribing, and documentation, among others.**

was made and unanimously carried (Motion by Burns, second by Turner).

- *Non-occupational post-exposure prophylaxis (nPEP)*
  - This concept is in process; legal counsel review is required.
  - Discussion to be continued at next meeting.

Motion to recommend addition of non-occupations post-exposure (nPEP) (medications: tenofovir disoproxil fumurate/emtricitabine, raltegravir, and dolutegravir) to Protocol list for the Oregon Board of Pharmacy adopt by rule:

- **Additional Requirements:**
  - Mandatory reporting of abuse of minors
  - Want to say follow per nPEP clinical guideline and chose appropriate drug and durations, if they cannot then they would like to recommend by drug class.
- **Pharmacist prescribing requirements: Follow established elements, which include: patient assessment, notification of providers upon prescribing, and documentation, among others.**

was made and carried (Motion by Burns, second by Turner), Anukum abstained.

	o Committee Update: ➢ Rules development update – none ➢ Housekeeping: Administrative Director Karen MacLean briefly discussed Governor mandated annual training for Committee members, mileage reimbursement update and desire to stagger Committee Member terms moving forward at the end of this year and into year two of the Committee's processes. Karen will advise on timing for recruitment and reappointment of members as this is clarified with the Governor's office. We await the on-boarding of our new Executive Director, Joe Schnabel, who starts in February 2019. ➢ The Committee discussed selecting 2019 officers and concluded the following: **Motion to select Amy Valdez as Chair and Mark Helm as Vice Chair was made and unanimously carried. (Motion by Burns, second by Turner).**
Upcoming Meeting Schedule	❖ Next meeting • February 1, 2019 – (*brief conference call to approve minutes*) ❖ 2019 tentative meeting schedule ➢ May 3, 2019 (room 1E) • May 24, 2019 – (*brief conference call to approve minutes*) ➢ July 12, 2019 – room 1E • August 2, 2019 – (*brief conference call to approve minutes*) ➢ October 25, 2019 – room 1D • November 15, 2019 - (*brief conference call to approve minutes*)
	❖

Chair Valdez adjourned the meeting at 2:50PM.

**If special accommodations are needed for you to attend or participate in this meeting, please contact: Administrative Director, Karen MacLean @ 971-673-0001.*

Date: 10/26/2018

Request/Inquiry Type: Waiver

- ***Request:*** Deschutes County Health Services is registered with the Board as a Community Health Clinic, and operates from two locations (Redmond: CH-0000059 and Bend: CH-0000095).

  They request a waiver from OAR 855-043-0720 (Security) to allow the following persons access to the drug storage area:
  - Matt Palmer, Clinic Operations Supervisor
  - Ana Silveira, MA
  - Lucia Tapia, MA

  The MAs split their time evenly between the Bend and Redmond locations.

- ***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:

Matt Palmer, Public Health Vital Records and Clinic Operations Supervisor
Deschutes County Health Services
2577 NE Courtney Drive, Bend OR 97701
P: 541-385-1716 | matthew.palmer@deschutes.org

Memo

TO: Board Members

FROM: Chrisy Hennigan, Licensing Program Supervisor

DATE: January 11, 2019

RE: Annual LEDS checks vs. LEDS checks upon renewal - Policy Discussion

History:

- Per Board direction, staff completes annual "Oregon only" LEDS background checks on individuals.

- With the current online system, upon renewal, a daily LEDS batch file is created. After the renewal cycle is over, staff uploads the files to the LEDS system and then the results are reviewed by staff.

- With the change to biennial licensure, the staff uses the batch files created for the current year's renewal (either CPT or RPh), as well as the batch files from the previous year to run annual LEDS checks (either CPT or RPh).

- Due to time / staff resource constraints, this is normally done in the period of mid-November through mid to late January, which is several months after the license renewal.

- This results in approximately 15,000 LEDS results reviewed annually.

- This is also the same timeframe that the audit of over 1000 RPH or CPT's is being completed.

In preparation for the transition to the new MyLicense Office platform, we have the opportunity to streamline and automate the system where the LEDS batch files can be uploaded to the LEDS system upon renewal. A designated staff member would be able to review the results within days of the completion of a renewal.

This would:

- Expedite the review of the LEDS reports
- Reduce the number of LEDS checks done annually
- Free up staff resources for a timelier review of the audits after renewal

POLICY DISCUSSION ITEM:

Would the Board approve a change from annual LEDS checks to LEDS checks upon renewal?

Would a rule change requiring mandatory reporting of crimes other than misdemeanor convictions or felony convictions or arrest, within 10 days, be necessary?

Applicable Oregon Administrative Rules:

Pharmacists
855-019-0122
(2) A pharmacist will be subject to an annual criminal background check.

855-019-0205
(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.

(3) A pharmacist must report to the Board within 10 days if they:
(a) Are convicted of a misdemeanor or a felony; or
(b) If they are arrested for a felony.

Interns
855-031-0020
(11) an intern must report to the Board within 10 days if they are:
(a) Convicted of a misdemeanor or a felony; or
(b) Arrested for a felony.

Certified Oregon Pharmacy Technicians
855-025-0015
(2) (d) Be subject to an annual criminal background check.

855-025-0020
(3) A Pharmacy Technician or Certified Oregon Pharmacy Technician must report to the Board within 10 days if they:
(a) Are convicted of a misdemeanor or a felony; or
(b) If they are arrested for a felony.

BOARD OF PHARMACY
AY19 CASH FLOW - November 2018
OF Appn 30235

Budget Objects	REVENUE & EXPENDITURES	LAB ORBITS BUDGET	Rstars Financial Plan	EBoard or Adj Budget or Salary Pot	Adjusted Financial Plan	ACTUALS To Date	Unobligated Balance	% Expended
REVENUE								
0205	Other Business Licenses	4,431,667	4,431,667		4,431,667	3,327,934	1,103,734	75%
0210	Other NonBusiness Licenses and Fe	505,552	505,552		505,552	167,646	337,906	33%
0505	Fines and Forfeits	420,000	420,000		420,000	264,872	155,128	63%
0605	Interest and Investments	48,000	48,000		48,000	121,469	(73,469)	253%
0975	Other Revenue	39,700	39,700		39,700	72,594	(32,894)	183%
	SubTotal Revenue	5,444,919	5,444,919	0	5,444,919	3,954,515	1,490,404	73%
TRANSFERS								
2443	Transfer out to OHA--Workforce/PD	(409,357)	(409,357)		(409,357)	32,961	(442,318)	-8%
	SubTotal Transfers	(409,357)	**(409,357)**	**0**	**(409,357)**	**32,961**	**(442,318)**	-8%
TOTAL REVENUE & TRANSFERS		**5,035,562**	**5,035,562**	**0**	**5,035,562**	**3,921,554**	**1,932,722**	**78%**
PERSONAL SERVICES								
3110	Regular Employees	3,191,268	3,191,268	104,724	3,295,992	2,254,580	1,041,411.82	68%
	Board Member Stipends		-		0	-		
3160	Temporary Appointments	25,222	25,222		25,222	-	25,222	0%
3170	Overtime Payments		-		0	505	(505)	0%
3190	All Other Differential O/Class Lead V	183,457	183,457		183,457	138,108	45,349	75%
3210	Employment Relations Board Assess	1,083	1,083		1,083	721	362	67%
3220	Public Employees Retirement Contri	504,012	504,012	3,269	507,281	327,898	179,383	65%
3221	Pension Bond Contribution	195,224	195,224	(3,502)	191,722	139,877	51,845	73%
3230	Social Security Taxes	256,020	256,020		256,020	171,203	84,817	67%
3240	Unemployment Assessment		-		0	654	(654)	0%
3250	Workers' Compensation Assessment	1,380	1,380		1,380	702	678	51%
3260	Mass Transit Tax	20,334	20,334		20,334	14,272	6,062	70%
3270	Flexible Benefits	666,720	666,720	24,720	691,440	444,744	246,696	64%
3455	Vacancy Savings-ORBITS only	(169,448)	(169,448)	-	(169,448)	-	(169,448)	0%
3465	Reconciliation Adjustment-ORBITS only				0	-	-	0%
3470	Undistributed Personal Services-ORBITS				0	-	-	0%
3991	PERS Policy Adjustment-ORBITS				0	-	-	0%
	SubTotal Personal Services	**4,875,272**	4,875,272	129,211	5,004,483	3,493,264	1,511,219	70%
SERVICES AND SUPPLIES			Proj all					
4100	InState Travel	**102,270**	102,270		102,270	65,597	36,673	64%
4125	Out of State Travel	**15,724**	15,724		15,724	6,160	9,564	39%
4150	Employee Training	**52,335**	52,335		52,335	13,402	38,933	26%
4175	Office Expenses	**123,883**	123,883		123,883	56,829	67,054	46%
4200	Telecommunications	**43,879**	43,879		43,879	42,390	1,489	97%
4225	State Govt. Service Chgs.	**119,969**	119,969		119,969	130,341	(10,372)	109%
4250	Data Processing	**73,694**	73,694		73,694	50,910	22,784	69%
4275	Publicity & Publications	**37,712**	37,712		37,712	7,088	30,624	19%
4300	Professional Services	**402,408**	402,408		402,408	200,581	201,827	50%
4315	IT Professional Services	**353,340**	353,340		353,340	25,050	328,290	7%
4325	Attorney General	**326,595**	326,595		326,595	309,941	16,654	95%
4375	Employee Recruitment & Develop	**207**	207		207	-	207	0%
4400	Dues & Subscriptions	**4,583**	4,583		4,583	4,532	51	99%
4425	Facilities Rent & Taxes	**219,519**	219,519		219,519	134,564	84,955	61%
4475	Facilities Maintenance	**51**	51		51	116	(65)	228%
4525	Medical Supplies and Services	**1,110**	1,110		1,110	4,008	(2,898)	361%
4575	Agency Program Related S&S	**229,434**	229,434		229,434	140,715	88,719	61%
4650	Other Services & Supplies	**278,652**	278,652		278,652	238,887	39,765	86%
4700	Expendable Property	**10,499**	10,499		10,499	689	9,810	7%
4715	IT Expendable Property	**43,976**	43,976		43,976	4,553	39,423	10%
5550	Data Processing Software		-		0	-	-	0%
5600	Data Processing Hardware	**8,296**	8,296		8,296	-	8,296	0%
			-		0	-		
	SubTotal Services and Supplies	**2,448,136**	2,448,136	-	2,448,136	1,436,351	1,011,785	59%
SPECIAL PAYMENTS								
6085	Other Special Payments	11,991	11,991		11,991	-	11,991	0%
6443	Special Payments to OHA-HPSP		-		-	-	-	0%
	SubTotal Transfers	**11,991**	11,991	0	11,991	0	11,991	0%
Total Expenditures Budget		**7,335,399**	**7,335,399**	**129,211**	**7,464,610**	**4,929,616**	**2,534,994**	**66%**
					7,057,070			
	LAB % PS	66%			67%		Target	100%
	LAB % S&S	33%			33%			
	LAB % SP	0%			0%			

		Cash
AY17 Ending Cash Balance		4,794,930
Revenue less Expenditures	Actuals	
Total Revenue & Transfers	3,921,554	
Total Expenditures	(4,929,616)	
Total Revenues & Transfers less Expenditures	**(1,008,062)**	(1,008,062)
AY19 Cash Balance after the Fiscal Month Closed		**3,786,868**
Budgeted Revenues not yet received (zero) less Estimated Transfers to OHA-PMP & Workforce Data program to be mac		0
Budgeted Expenditures not yet spent		(2,534,994)
AY19 Estimated Cash Balance		**1,251,873**
Cash Balance Contingency (Months)		4.10 months