Minutes	**Oregon Board of Pharmacy – Rules Advisory Committee** **Drug Compounding – Division 045** **May 8, 2019; 1-4pm in Room 1B** **800 NE Oregon Street** **Portland OR, 97232**

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

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

❖ Committee Dialogue

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

Broad topic points shared by committee dialogue included:

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

	facility updates, etc. for compliance; Members seeking insights related to the Board's expectations for compliance in Oregon. Staff anticipates this may be similar to other rule/policy changes in the past – the Board allows a reasonable timeframe for a pharmacy to achieve compliance with new rules and plans to create an updated Self-Inspection Form for compounding to help with understanding and compliance expectations. ▪ Oregon Shared Services: General understanding related to the historic and current role that shared services for compounded products services (compounding batches of non-patient specific drug products), and the need to phase out shared service for human compounded drug products however, Members shared concerns related to ongoing confusion among some Oregon pharmacies and Oregon clinicians; agreement that streamlined Board processes for shared services allowance is needed, as well as a necessity for a consistent communication to impacted clinicians; current overall landscape permits the use of Oregon shared services for veterinary compounding for batches of non-patient specific drug products ▪ Patient Impacts: It is anticipated that compliance with USP standards will have a positive impact on the safety and quality of the drugs compounded for patients. It is assumed that at least some of the increased costs of doing business in the compounding realm may ultimately passed along to patients, estimated increase of 25%, though hospitals cannot pass along increases to patients due to primarily fixed reimbursements. Additionally, patients and clinicians may notice that certain drugs will have shorter expiration dates (BUDs) depending on the final language put forth by USP for dating standards. Some pharmacies may choose to stop compounding all together, though there may be an increase in FDA-approved kits to replace some frequently compounded items (i.e. magic mouthwash). ▪ Fiscal Impacts: The majority of the Committee's discussion directly or indirectly related to the costs to comply with USP Standards (and therefore also with Board rule). Compliance costs can be placed into two major categories: initial costs, such as facility remodels and ongoing costs, such as gowning/garbing items needed for daily compounding activities. It is anticipated that the costs to comply are high, ranging anywhere from an estimated $50,000 to more than $2,000,000 per location, depending on the current facility specifications and the type of compounding being performed. The Committee had a robust discussion related to the Board's proposed requirement to for a compounding pharmacy to be accredited by a Board approved entity, every three years at a minimum, and the related costs; not all accreditors are 'created equally' and the Board may not ultimately get the safety assurances they seek from this policy directive.
Good of the Order	The meeting concluded with general consensus related to the overall high fiscal realities of compliance with USP standards, and therefore with the Board's proposed rules. General agreement that Committee Members are willing to meet again, particularly if the USP standards published in June include unanticipated additional costs. Otherwise, the group may continue to meet, not as a RAC, but rather as a formal stakeholder group, to continue providing ongoing expertise and professional insights to the Board.

DIVISION 045- DRUG COMPOUNDING

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

OVERVIEW

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

OBOP MISSION STATEMENT

The mission of the Oregon State Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale and distribution of drugs.

RULES ADVISORY COMMITTEE (RAC)

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

RULES ADVISORY COMMITTEE - PURPOSE

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

A RAC's role is advisory only.

WHAT IS A RULE?

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

ORS 183.310(9)

WHEN IS A RULE REQUIRED?

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

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

WHERE ARE RULES FOUND?

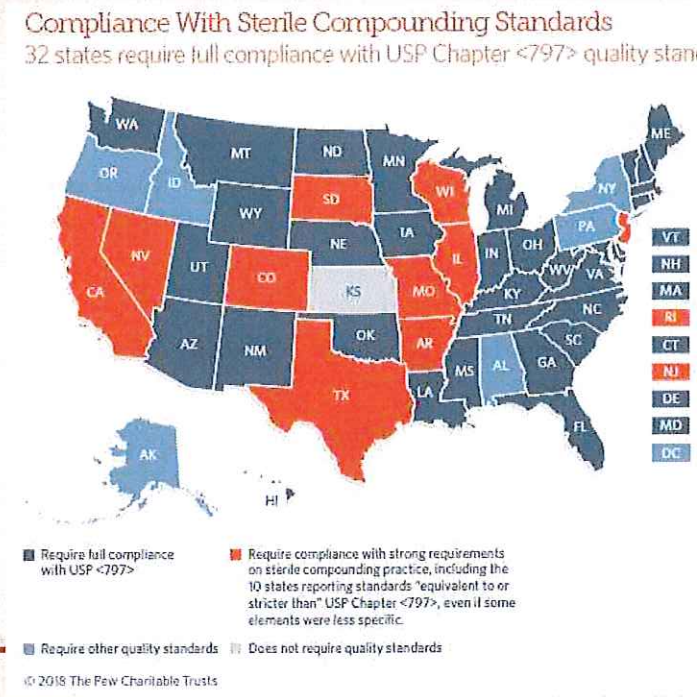
- **Oregon Administrative Rules (OAR)**-official compilation of rules & regulations having the force of law in Oregon
  - http://sos.oregon.gov/archives/Pages/oregon_administrative_rules.aspx

PROPOSED RULES - OBJECTIVES

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

HISTORICAL CONTEXT/CONSIDERATIONS

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



POLICY ITEM – SHARED SERVICES

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

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

USP

Note: The current version of General Chapters <795> and <797> published in USP-NF are official.

OBOP Timeframe:
June/August – Policy discussions; September – Rulemaking; October – Final adoption

https://www.usp.org/compounding/updates-on-standards

COMPLIANCE

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

COMMITTEE MEMBER SHARING & DIALOGUE

IMPACTS

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

COMMITTEE MEMBER DISCUSSION:

FISCAL IMPACT

FISCAL IMPACT STATEMENT – MAY 2018

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

FINAL THOUGHTS

THANK YOU VERY MUCH

We appreciate your participation in this important work!