Date:  September 25, 2019
To:  Oregon Board of Pharmacy
From:  Rachel Melvin, Hearings Officer

Subject:  Hearings Officer’s Report on Rulemaking Hearing

Hearing Date:  September 24, 2019
Hearing Location:  Portland State Office Building, Room 1D

Title of Proposed Rules:
•  Divisions 006 and 045 – Drug Compounding and Definitions
•  Divisions 019 and 020 – Pharmacist Prescribing Authority & Formulary

The rulemaking hearing on the proposed rules was convened at 1:30PM. Nine people provided oral testimony on purposed rules; Divisions 006 and 045 Drug Compounding and no one appeared to provide comment on purposed rules, Divisions 019 and 020. The hearing was closed at 2:05PM. The hearing was recorded and copies of the proposed rules were available for attendees.

Attendance included 26 public, 4 OBOP Staff, and 3 OBOP Board members

Summary of Comments

•  Karen Collell, Broadway Pharmacy, new independent pharmacy in Coos Bay – Would like the Board to consider that accreditation should be not required for “on-the-spot / just-in-time” traditional compounding in rural communities.
•  The following people provided written testimony and utilized the open comment period to reiterate/emphasize certain points: Mike Millard (OSHP), Jackson Leong, Mark Cushing (Animal Policy Group), Tyler Treharne, Natalie Gustafson, Michele Koder, Rob Geddes and Luke Eilers.

Items reiterated/emphasized include:
•  Accreditation costs will limit patient access to medications
•  Interprets the elimination of Shared Services agreements for humans as a requirement for registration as an FDA 503B Outsourcing Facility. This will impact small rural hospitals in Oregon and specialty clinics that may care for patients when patient specific pharmacy services are not available
• The need for OBOP to permit non-patient specific anticipatory “own-use” compounding, regardless of physical distance
• Inspection team is capable of identifying compliance with USP standards; accreditation is not necessary
• Legal concerns with excluding the non-resident pharmacies from providing non-patient specific veterinary medications, including lack of access. Of the 18 specifically identified veterinary drugs, there is not an Oregon pharmacy capable of providing all 18
• Favors accreditation for all locations as a way to ensure non-resident pharmacy safety
• Favors accreditation for locations to create a way to maintain a high level quality/safety
• Requiring accreditation for minimal amounts of simple compounding creates a barrier to access, especially to indigent patients
• Accreditation does not make sense for typical compounding at community pharmacies and accreditation entities do not actually have standards to address this type of traditional compounding
• Favors requiring non-resident compounding pharmacies to obtain 503B in order to provide non-patient specific drugs into Oregon; correction of the record provided by another testimony, Oregon pharmacies can provide those veterinary drugs

Summary of Written Comments

All written comments received by the public comment deadline date of 9/24/19 at 4:30PM have been provided in their entirety to the Board and are summarized below. 26 comments were received in response to the August 16, 2019 Notice of Proposed Rulemaking (sent via email, USPS mailed to all Rulemaking interested parties and posted on the Board’s website).

RULES PROPOSED: Compounding
AMEND: 855-006-0005

Luke Eilers, R.Ph
Commented in regards to a reasonable timeframe for accreditation and compliance enforcement. He provided background and suggestions.

Rob Geddes, Pharm D. – On behalf of Albertson’s Companies, Inc.
They are supportive of these regulations generally and they provided helpful background information from the standpoint of the community pharmacy setting, where simple, nonsterile compounds are provided routinely to patients in Oregon. They request the Board exclude community pharmacies from the accreditation requirement particularly due to costs. Additionally, they provided a number of suggestions for policy and rule language edits.
Michele Koder, Pharm D. - On behalf of Multnomah County Health Dept.
While they appreciate the intent and value of the proposed changes, they oppose the requirement for accreditation due to cost and Federally Qualified Health Center (FQHC) status.

Marc Rizzo, Pharm D.
He believes Compounding needs more oversight but strongly believes there should be exceptions and suggested replacing accreditation with mandatory training, similar to the contraceptive training and asked that we consider the patients in rural communities that will be negatively impacted by the current proposed rules.

Michael Blaire, R.Ph – On behalf of Wedgewood Pharmacy
Believes that purposed rules fail to address existing limitations on compounded office use dispensing for animal health, limiting veterinarians to in-state pharmacies only. Requests revised rules to allow any pharmacy that complies with regulations be permitted to provide compounded (non-patient specific) medications for veterinary office use.

Natalie Gustafson, R.Ph – On behalf of Lloyd Central Compounding Pharmacy
Supports accreditation requirement for standardization and safety and suggests up to 18 months lead-time for compliance. Additionally, she provided a number of suggestions for policy and rule language edits.

Eric Lintner, R.Ph- with Consonus Pharmacy Services
He applauds efforts to align rules more closely with USP, but has some concerns over wording and is opposed to additional requirements for compounding accreditation for pharmacies that are already in compliance with all existing rules. Additionally, he provided a number of suggestions for language edits and posed some questions for the Board to address.

OSHP Board of Directors
OSHP is in support of the proposed rules and feels that critical practices must be permitted under OAR to protect the health and safety of Oregonians receiving prescriptions for compounded drug products. They provided policy items for the Board’s consideration and are seeking clarification on a number of rules prior to Board adoption.

Lorri Walmsley, R.Ph- On behalf of Walgreens
They are supportive of the majority of the proposed rule language and provided a number of suggestions for language modifications for the Board’s consideration. They believe the cost of accreditation or inspection will limit patient access.

Lis Houchen, - On behalf of NACDS (National Association of Chain Drug Stores)
They provided specific details regarding their concerns with the proposed rule changes. They stated that USP announced plans to reconsider and potentially revise the standards due to the number of appeals and strongly encouraged the Board to delay making any revisions until USP completes their revision initiatives. They provided suggestions for language edits for the Board’s consideration. We believe the cost of accreditation or inspection by a board-approved
entity will create a significant cost barrier for pharmacies to participate in compounding of nonsterile preparations and will limit access to these products in Oregon.

Alan Matarasso – On behalf of the American Society of Plastic Surgeons (ASPS)  
They asked that the proposed rules be amended by allowing physicians to be exempt from recordkeeping requirements as well as more clarification around compounding in or outside of Oregon for those who plan to distribute in Oregon.

They share the Board’s concerns about safety of medications prepared and administered to patients and suggested that the Board set forth an exemption from requiring dermatologists to comply with Section 1.3 because they have engaged with USP regarding in-office preparation of drugs to establish a 12-hour exemption and pending testing results, state that USP will develop a monograph that would supersede Chapter 797.

Kevin Russell, R.Ph – On behalf of OSPA  
They give their full support to testimony submitted by OSHP and stated that their organization agrees with OSHP’s statements and take the same position on sterile compounding and shared services. They have some concerns related to non-sterile compounding in regards to regulatory burden, accreditation and added expenses and stated that it might lead pharmacies to discontinue compounding services and request that separate inspection or accreditation only be required for 503B outsourcing facilities.

Lauren Paul, PharmD – On behalf of CVS  
They have concerns with specific reference to multiple USP-NF chapters within the proposed rules regarding the expense and resources involved for accreditation for drug outlets that compound and believe that these rules will force some retail drug outlets to discontinue compounding services. They provided suggested language edits for the Board’s consideration.

John Girod M.D & Ryan Miller – On behalf of Cascade Infectious Diseases and Infusion, LLC.  
They stated that the proposed changes will have a significant negative effect on their patients and if the proposed rules are adopted in their current state, they might need to stop their infusion business.

Aaron Lopez- On behalf of Political Capital LLC.  
They provided reasons why the Board should consider requiring veterinarians to purchase their office-use stock from Oregon licensed, FDA registered outsourcing facilities regardless if the facility is located in state or out of state.

Kevin Smith, R.Ph  
They provided comments to current proposed language for the Board to consider and stated that adaptation of the Oregon compounding rules at this time may cause OR rules to not align with USP chapters, which was the intent of these rules. Additionally he is concerned about the
Carrie Reedy, Pharmacy Manager – Works with Samaritan Ambulatory & Home Infusion Svs. She agrees with the plan to allow pharmacies to either pass a board of pharmacy inspection on compounding or to have outside accreditation from an approved entity, but has concerns regarding the inspections being performed every 3 years, as well as the expense for accreditation will cause small compounding pharmacies out of business limiting access to patients in rural communities.

Tabitha Fridriksson, R.Ph- On behalf of Kaiser Permanente Northwest Region Provided concerns regarding proposed language in Division 006, definitions and is asking for clarification to proposed language related to registrations and records proposed language in Division 045. They provided recommended language revisions for the Board to consider.

Jackson Leong, R.Ph. He has concerns about the proposed language in regards to the inspection or accreditation portion of the language, as well as the costs involved with accreditation. He believes that Board’s current inspection process of using licensed pharmacists should be sufficient, whereas using an accredited 3rd party inspection will eliminate the important face to face relationship licensees currently have with the Board.

Tyler Treharne He feels the upcoming proposed changes are very good and constructive and that compliance with USP 795, 797, and 800 is necessary to make sure all pharmacies are compliant. He stated that he is strongly in favor of all pharmacies being accredited or inspected to maintain continuity, quality and believes doing away with shared services for human use.

Christina Barry, Pharm.D. Asked for clarification on several proposed language definitions. She asked for clarification on procedural processes and implementation timelines.

Ned Milenkovich – With Much Shelist, P.C. Attorneys at Law He is concerned that USP 795 does not explicitly address or mention flavoring and that USP’s stance would place costly regulatory burdens on many community pharmacies in Oregon that offer the service and would effectively eliminate flavoring, which will negatively affect pediatric medication adherence. He proposed language for the Board to consider that would exclude flavoring from the definition of compounding.

RULES PROPOSED: Prescribing
855-019-0264, 855-019-0470, 855-020-0110, 855-020-0200, 855-020-0300
REPEAL: 855-019-0264
Lauren Paul, PharmD – On behalf of CVS
They continue to support the Board’s efforts in adopting new recommendations for the formulary and protocol compendium. They provided rule language edits for the Board’s consideration.

Tabitha Fridriksson R.Ph – On behalf of Kaiser Foundation Health Plan and Hospitals of the Northwest
Kaiser Permanente asks the Board to consider removing language “face to face” related to patient assessment to allow for telehealth services.

Lis Houchen, - On behalf of NACDS (National Association of Chain Drug Stores)
NACDS supports policies that give patients more options, including Oregon’s new law authorizing pharmacists to prescribe and dispense certain FDA-approved drugs and devices. They commend the Board and PHPFAC for their hard work on this regulatory initiative.