Date: May 25, 2018
To: Oregon Board of Pharmacy
From: Mo Klein
Subject: Hearings Officer’s Report on Rulemaking Hearing

Hearing Date: May 23, 2018
Hearing Location: Portland State Office Building, Room 1A
Title of Proposed Rules:

- The composure and function of the Public Health and Pharmacy Formulary Advisory Committee
  OAR 855-019-0460
- Amend naloxone prescribing rules related to possession, distribution and counseling
  OAR 855-080-2200
- Repeals outdated and adopts new drug compounding rules
  Repeal: 855-045-0200 through 855-045-0630

The rulemaking hearing on the proposed rules was convened at 9:30 a.m. People were asked to sign the registration list if they wished to comment on the proposed rules and were informed of the procedures for making comments. They were also told that the hearing was being recorded.

Copies of the proposed rules were available for attendees.

Attendance included about 20 public, 8 OBOP Staff, 6 OBOP Board members

The following pages include a staff response to the comments collected during this rulemaking cycle, summaries of the oral and written comments, and copies of all written comments. An audio file is available of the hearing which includes all oral comments.
Summary of Oral Comments
Rulemaking Hearing May 23, 2018; 9:30 a.m.
Audio file available

Formulary Committee

None

Naloxone

Rob Nutt, Oregon Department of Corrections
Asked a question, can Naltrexone could be included in the Naloxone rule.

Compounding

Eric Lintner, Consonus Health
Extra licensing for Sterile Compounding.
Primarily a question from Eric regarding the proposed inspections. He wonders how they will work, what is the entity who will inspect, will there be an extra cost for the inspection, what type of inspection will be required. Depending on what this inspection will include, it may be onerous. (No written comments submitted.)

Dan Rackham, Samaritan Lebanon Community Hospital
Does not think these rules are ready for implementation. There are many questions on the rules as written. He submitted a written comment with details.
Also questions on a BUD for repackaged injectable opioids, during a current shortage, from 30 hours to 6 days. This is sterile compounding.

Adam Gustafson, Natalie Gustafson, Lloyd Center Pharmacy
Submitted a written comment that is a detailed look at the proposal, with many specific questions and suggestions for rewording. Their first proposal is to refer to the USP standards, if that is not possible, they suggest a detailed overhaul of the language to ensure a workable set of rule for compounding.

Jacob Thompson, Providence Health and Services
Submitted a written testimony. Looks at USP as the gold standard, would encourage ‘meet the current USP standards’. Also, does not like the portion that allows compounding for items not commercially available. Would like OBOP to allow a better method to get proposed rules to stakeholders, and allow time for their review and discussion.

Kyle Mulder, Technical Safety Services
Sent a comment on the self-checklist being out of date
Marty Hiers, NW Compounding Pharmacy (Roseburg OR)
Intention is great, but pitfalls in wording. One fear is that the final wording of USP is not known. Also, the cost of compliance of USP is not known. The container closures are requested by patients, which may pose issues. The “difficult to compound” may cause issues. A committee may be warranted for review of the new rules. He does not see the benefit of many of the items being proposed.

Eric Lintner (2nd comment), Consonus Health
Certification - Past issues have been with companies not following the existing rules. Seems unfair and expensive to add additional regulation to the companies following the rules. Does not see improved safety for patients by the new rules. Supports USP as a better solution, for interpretation and compliance, vs each state having their own different rules.
Summary of Written Comments

Naloxone Rule
None

Formulary Committee Rules
None

Compounding Rules

Summary of each response

AAD and ASDSA (Dermatologists) – does not want physician offices to be under the purview of OBOP, encourages OBOP to wait until the USPs are finalized, would like a longer time period for ‘immediate use’, and is concerned that the cost to comply with regulations in offices will be extremely high.

ASPS PSF (Plastic Surgeons) – would like to see office (non-sterile) compounding not included in rules. Suggests that physicians keep a log in patients’ medical record that covers medications that were compounded.

CVS (Paul) – Encourages OBOP to refer to USP instead of creating their own language. They do support the registration of compounders, and the inspection of the same. They have submitted several language changes if OBOP determines to move forward with their own compounding language.

Lloyd Center Pharmacy (Gustafson) – Listed many issues with the proposed text for compounding, on a section by section basis.

Lloyd Center Pharmacy (2)(Gustafson) – concern with outside agency inspections, and does not think inspecting only in-state, sterile, compounders provides a level playing field. Would like to see all compounders inspected, including out of state.

NW Compounding (Marty Hiers) – concern about inspection by non-OBOP personnel, also isn’t convinced USP 795 and 797 are going to be helpful to Oregon Compounders. Does not think the proposed Oregon rules are ready to adopt as more clarification is required.

Kaiser Permanente Foundation (Jaeger) – suggested word changes to several rules.

Laatsch (for ASPS) – question – Will changes regulate physician in-office compounding?

Legacy Health- supports compliance with USP 795, 797, and all applicable chapters of USP. They encourage simplifying and removing other proposed rules. They encourage the formation of an administrative rule advisory committee.

Mulder – Include compliance to USP 797 to keep OR regulations current. Also mentions that our “self-checklist” is out of date given requirements of 797.

Mulder(2) – Lists several items that are not clear in 797 including air pressure, temperature, HEPA

NCPA – Has provided several specific word changes to proposed rules.
OSHP – Does not support the current proposal for compounding rules. Suggests an advisory committee for future input on the rules, and is happy to assist.

Providence Health (Thompson)-Supports referring to USP 795 and 797. In the case OBOP moves forward with their own specific rules, new wording, and concerns are listed to be considered. Providence also suggest that a Rules Advisory Committee be formed to evaluate any additional rules beyond rules 855-045-0520.

Rackham – Provided a redlined copy of the proposed rules. The comments were based on an older revision of the proposed rules, but most comments were regarding the current version.

Rackham(2) – Representing 13 hospitals and health systems, a request is made to change the beyond use date to 6 days from the current 30 hours for injectable opioids being repackaged by and for hospital and health systems.
Attachment 1—Written Comments received by OBOP
May 23, 2018

Oregon Board of Pharmacy
Portland State Office
Building, Conf. Rm 1A
800 NE Oregon Street, Suite 150
Portland, OR 97232

RE: Compounding proposal, OAR 855-045-0200; OAR 855-045-0500 through 855-045-0630

Dear Members of the Oregon Board of Pharmacy:

On behalf of the undersigned organizations, representing approximately 200 dermatologists in Oregon and approximately 14,000 dermatologists nationwide, we appreciate the opportunity to provide comments to the Oregon Board of Pharmacy ("Board") on proposed rules governing compounding set forth in OAR Chapter 855. We urge the Board to refrain from adopting any changes to the compounding rules due to this issue being unresolved at the national level and impact on patient access.

As dermatologists who diagnose and treat more than 3,000 skin diseases, including skin cancer, eczema, infections, psoriasis, immunologic diseases, and many genetic disorders, we rely heavily on compounded medications. Prescribing and/or directly administering compounded medications allows us to tailor treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The compounding in which dermatologists engage involves low-risk practices, such as compounding or administering mixing FDA-approved medications, diluting steroids for intralesional injections, and administering topical medications. A widely used local anesthetic in surgical dermatologic procedures is lidocaine with epinephrine mixed with a small amount of sodium bicarbonate in order to buffer the solution and make the injection much less painful.¹

While we believe that the regulation of compounding in physician offices for their patients should be under the purview of the state medical board, it is essential that state

boards of medicine work collaboratively with the state pharmacy boards and other federal and state policymakers concerning the development of in-office preparations.

**National Context**

Concurrently, multiple stakeholders, such as the U.S. Food and Drug Administration (FDA), U.S. Pharmacopeia (USP), and Federation of State Medical Boards are scrutinizing the safety of in-office preparations and developing policy in order to prevent tragedies like those that occurred at the New England Compounding Center. This scrutiny extends to common simple practices in dermatology, such as buffering lidocaine and reconstituting botulinum toxin. Ready availability of these preparations is important to avoid disruption of medical procedures, maintain clinic flow and to prevent medical waste.

Unfortunately, relevant policymakers, such as FDA or USP, have not provided our organizations data to support mandating physicians who prepare low-risk medications in their offices to obtain the same equipment and comply with the same process as large compounding facilities. We believe the FDA is considering infection control breaches in outpatient settings as reported by the U.S. Centers for Disease Control and Prevention (CDC); however, the CDC examples are not specific or unique to the preparation of in-office compounded medications.2

The Board has relied on USP policy as it develops its own compounding rules. USP is currently reviewing and potentially revising Chapter 797 governing Pharmaceutical Compounding—Sterile Preparations. We have communicated our concerns to USP that the Cundell data, which has been used to support its proposed revisions to Chapter 797 on Pharmaceutical Compounding—Sterile Compounding, is not representative of clinical settings nor is it relevant to the types of drugs compounded by dermatologists in the office setting.3 We have attached for your consideration a list of relevant studies that refute the Cundell data.4 After receiving more than 8,000 comments, some of which opposed the burdensome requirements on physicians, USP is expected to release a second revised draft for stakeholder input in July 2018. Moving forward with the proposal before USP finalizes its revisions of Chapter 797 is premature and has the potential to create inconsistency and confusion in the regulation of compounding drugs.

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Lastly, in its recently issued 2018 Compounding Policy Priorities, the FDA acknowledges a need to revise draft guidance documents, acknowledging the negligible patient risk in the contexts discussed in this letter:  

These guidance documents will be followed by revised draft guidance describing examples of conditions that the FDA considers to be insanitary and in violation of the FD&C Act. This guidance will address concerns raised by some providers who compound small quantities of drugs in their offices for patient use, and as part of their routine clinical practice. This came up in the setting of certain dermatological procedures, for example. The FDA plans to better define the circumstances under which we believe drugs are being mixed and applied in a manner that creates negligible patient risk, and therefore wouldn't be subject to the same compliance policy under the agency's risk-based approach to implementing these requirements.

"Immediate Use"

Section 855-045-0620 would define “immediate-use provisions” in accordance with USP standards. It is our understanding that USP will be proposing a one-hour exemption from compliance with its Chapter 797 Pharmaceutical Compounding – Sterile Preparations. This timeframe would severely impact patient access. Many dermatologists compound drugs, such as buffered lidocaine, at the beginning of the day. This is particularly true for Mohs micrographic surgery (“Mohs surgery”), which may require a patient to spend several hours in the office. For the reasons set forth below, “immediate use” should exceed 24-hours.

Mohs surgery is a specialized surgery used exclusively to treat skin cancer. Mohs surgery is an outpatient procedure that entails staged excision of skin cancer while sparing normal skin. This procedure necessitates re-administration of lidocaine to the area until microscopic clearance of the tumor and closure are completed.

Two recent studies demonstrate extremely low levels of adverse events and no anesthesia toxicity. The Alam study, a 23-center study including nearly 21,000 Mohs procedures, found 149 adverse events and no deaths were reported. It demonstrates that lidocaine toxicity is not an issue, particularly in a Mohs procedure where a large volume of 1% lidocaine is used. The Alam study demonstrates that Mohs surgery is safe, with a very low rate of adverse events, an exceedingly low rate of serious adverse events, and an undetectable mortality rate.

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5 https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm592795.htm
In addition, a 2012 prospective multicenter cohort study further demonstrates the safety of Mohs surgery with the patient under local anesthesia. It included 1,550 patients with 1,792 tumors, resulting in no major complications during Mohs surgery or reconstruction. Minor complications were rare and occurred at a rate of 2.6%.  

Given the shortage of manufactured lidocaine with epinephrine, dermatology practices are adding epinephrine to lidocaine and other local anesthetics themselves for pain control and vasoconstriction. Pate et al. (2016) found that syringes filled with lidocaine; lidocaine and epinephrine; lidocaine with sodium bicarbonate; and lidocaine, epinephrine, and sodium bicarbonate and stored for up to four weeks, when prepared using aseptic technique and when stored in controlled room and controlled cold temperatures, are not prone to bacterial or fungal contamination. Zero of the 160 samples showed growth where streaked. This study had a larger sample size than a 1999 study, which found that 36 syringes of buffered lidocaine with epinephrine and sodium bicarbonate stored in room temperature were also not prone to bacterial or fungal contamination.

In both studies, multi-dose vials are used. According to CDC, multi-dose vials typically contain an anti-microbial preservative to help prevent the growth of bacteria. In addition, lidocaine and other local anesthetics used in dermatology have antimicrobial properties.

**Economic Impact**

The Board estimates that the fiscal and economic impact could cost less than $100,000 or more than a $1,000,000 depending on current readiness. While we support the Board’s efforts to ensure the safety of sterile compounded products, it is not reasonable to expect dermatologists who prepare simple compounds or dilutions used for intradermal or subcutaneous injections to adhere to the same standards as large compounding facilities. Dermatologists would be forced to close their offices due to the inability to incur such costs. We are extremely concerned that moving forward at this juncture will disrupt patient access to medications that have been safely prepared by dermatologists in their offices for years. For these reasons, we urge the Board to reject the amendments to the compounding regulations until such stakeholders finalize the appropriate level of oversight based on scientific evidence in order to improve the safety of in-office preparations.

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ATTACHMENT:

We appreciate the opportunity to provide these comments. Should you have any questions, please do not hesitate to contact Lisa Albany, director of state policy for the American Academy of Dermatology Association as staff representative for the undersigned organizations at (202) 842-3555 or lalbany@aad.org.

Sincerely,

[Signature]

Suzanne Olbricht, MD
President
American Academy of Dermatology Association

[Signature]

Lisa M. Donofrio, MD
President
American Society for Dermatologic Surgery Association
May 22, 2018

Oregon Board of Pharmacy  
c/o Mo Klein  
800 NE Oregon St., Suite 150  
Portland, OR 97232

RE: Proposed Changes to OAR Chapter 855

Dear Members of the Oregon Board of Pharmacy:

I am writing on behalf of the American Society of Plastic Surgeons (ASPS) regarding the proposed changes to Oregon Administrative Rules (OAR) Chapter 855. ASPS is the largest association of plastic surgeons in the world, representing more than 94 percent of all board-certified plastic surgeons in the United States – including 83 board-certified plastic surgeons in Oregon. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

We appreciate the Oregon Board of Pharmacy’s (Board) effort to take a formal position on physician compounding. However, it is important to note that the legislative and regulatory backlash against in-office compounding began not as a result of physicians mishandling compounded medications, but rather as the result of the contamination of compounded products made by a compounding pharmacy. Therefore, we have outlined several sections of the proposed changes that we believe should either be amended or removed to better reflect the position of physicians on this issue.

855-045-055 would require all compounders to adhere to guidelines of the current edition of the United States Pharmacopeia (USP) Chapters 795 and 797, as well as all applicable chapters of USP and USP-NF related to the compounding practices at any location. Many pharmacy boards rely on United States Pharmacopeia (USP) policies to dictate physician compounding, but the Food and Drug Administration (FDA) has acknowledged the need to revise draft USP guidance documents related to compounding. Furthermore, in order to justify the adverse impact to physicians that onerous compounding rules may have, state pharmacy boards have cited a 2012 Centers for Disease Control and Prevention (CDC) study\(^1\) that examines the use of single-use vials. This is misleading, as physician in-office compounding is typically performed by using multiple-dose vials, which are designed for multiple uses and include preservatives and manufacturer-specific expiration dates to ensure safety. ASPS recommends that the Board postpone the adoption of 855-045-055 until the updated guidance documents are written in order to reduce creating an undue burden on physicians who routinely compound drugs and medicine in a safe and sanitary manner that minimizes patient risk.

855-045-0530(5)(b) includes language that allows the compounding of a commercially-available drug product if it is not reasonably available in the market in time to meet the patient’s needs. Further restricting physicians’ ability to mix a drug such as lidocaine – which is listed as currently in shortage by the FDA – would limit treatment options for patients who are in need of these compounds. Therefore, we thank the Board for recognizing the difficulties that physicians face when dealing with drugs that are not commercially-available. Examples of mixtures that our physicians prepare – for which there are no commercially-available alternatives – on a frequent (often daily) basis are: sterile local anesthetics with sterile sodium bicarbonate to alleviate injection pain; sterile lidocaine with sterile bupivacaine for injection for longer-acting anesthesia; and lidocaine with triamcinolone when injecting hypertrophic/keloid scars to alleviate injection pain.

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\(^1\) [https://www.cdc.gov/injectionsafety/PDF/CDC-SDC-Position05022012.pdf](https://www.cdc.gov/injectionsafety/PDF/CDC-SDC-Position05022012.pdf)
855-045-0570 creates various recordkeeping requirements of compounders in Oregon. While ASPS appreciates the reasoning behind 855-045-0570, this rule places an unnecessary administrative burden on physician offices. Therefore, we respectfully request that the Board lessens this requirement by requiring physicians to keep a log of medications that were compounded in the patient’s medical record. This would provide physicians with easily-accessible information if they would need to contact affected patients due to a recall.

Rules 855-045-0600 through 855-045-0630 cover the practice of sterile compounding. ASPS understands the Board’s need to cover this practice for pharmacists and pharmacy personnel; however — as our physicians do not perform sterile compounding — we respectfully request that you exempt physicians from these requirements.

For the reasons outlined above, we urge you to amend the proposed changes to OAR Chapter 855. Thank you for your consideration of our position on this important issue. Please do not hesitate to contact Patrick Hermes, Director of Advocacy and Government Relations, at phermes@oplasticsurgery.org or (847) 228-3331 with any questions.

Sincerely,

\[Signature\]

Lynn Jeffers, MD
Board Vice President of Advocacy & Health Policy
American Society of Plastic Surgeons
May 21, 2017

Marcus Watt, RPh
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

Re: Proposed Rule Amendments in Division 045 pertaining to Sterile and Non Sterile Compounding

Dear Executive Director Watt:

I am writing to you in my capacity as Sr Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points to care to patients in the state of Oregon through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the Oregon State Board of Pharmacy proposed rule amendments in Division 045 pertaining to sterile and non-sterile compounding. We would also like to thank the Board for their vigilance in continuously improving the laws and regulations that guide pharmacists, pharmacy interns and pharmacy technicians serving Oregon patients.

CVS Health appreciates the Board’s proposed language requiring adherence to guidelines of current edition of United States Pharmacopeia Chapters 795 and 797, as well as all applicable Chapters of USP and USP-NF related to the compounding practices at any location. USP standards and guidelines are set by the Expert Compounding Committee which is comprised of 18 members, 10 of which are pharmacists. The committee is charged with developing new and to revise existing compounding related general chapters describing quality and practice standards for compounding of sterile and non-sterile preparations. As this is a committee of experts tasked to set the quality and practice standards for compounding, we feel that requiring adherence to these guidelines is sufficient for compounders to ensure proper and safe preparation. Also, with USP chapters 795, 797 and 800 currently under review and revision, significant changes in standards could occur before these are finalized and published. By requiring adherence to USP, this will be more efficient for the Board as changes to USP will cause additional amendments to this division be made. Therefore, we request the Board to consider removing the remaining sections, except registration outlined in OAR 855-045-0520 of the proposed amended division 045.

We would also request the Board amend language in OAR 55-045-0500(1) that requires an out of state compounding to follow their home state compounding rules or those of Oregon, whichever are more stringent. By nature of being a nonresident pharmacy, the pharmacy is required to follow the laws and regulations of the state in which they reside. Proposed OAR 855-045-0520 addresses registration requirements and requires an inspection and/or accreditation by a Board approved entity every 3 years to continue shipping sterile compounds and providing preparations to patients in Oregon. This inspection review will provide adequate assurances that compounding is being completed in a safe and quality manner.

Suggested Language:
855-045-0500
Compounding - Purpose

(1) These rules apply to any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for the use by a patient located in Oregon. Any person located outside Oregon must follow the compounding rules of their home state, or these rules, whichever are more stringent.
Should the Board feel compelled to move forward with promulgating the remaining sections of Division 045, rather than requiring adherence to USP, we ask the Board to consider the following amendments:

**855-045-0560 Compounding – Quality Controls**
CVS Health understands the importance of a patient level recall, when needed, and has policies and procedures set in place for pharmacy staff to follow in the unlikely event this may occur. In lieu of reporting any patient level recall to the Board, we suggest that the recall information be retained for a period of 2 years at the pharmacy where it can be made available during inspection. We are unclear of the intent of the Board with the reporting of this information and do not find it to be necessary, if the patient is made aware of the recall and provided with the correct preparation. This would be similar to guidelines outlined in OAR 855-041-1036 regarding proper storage of drugs and the steps to take in the event of a temperature excursion.

**Suggested Language:**
855-045-0560
Compounding - Quality Controls
(3) The pharmacist-in-charge must establish a written adverse event reporting process and recall procedure. The recall procedure must include notification to the Board in the event of a patient-level recall.

**Beyond Use Dating**
Finally, we also request the Board consider amending language or removing “time” from the definition of Beyond Use Date and also the BUD labeling requirements for when a drug is added to a parenteral solution. California is the only state we are aware of that includes “date and time” as an optional element in their definition of beyond use date. Specifically, California Code of Regulations 1735.1 Beyond Use Date “means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).” CCR 1735.4 requires labeling in California to only include the “beyond use date” for the preparation. Therefore, we suggest amending the language to either remove time or something similar to California for BUD and labeling.

**Suggested Language:**
855-045-0510
Compounding - General Definitions
(2) "Beyond-Use Date" and "BUD" means the date and time after which a compounded product must not be used (or stored or transported). The date is determined from the date and time the preparation is compounded, according to risk level.

OR

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

855-045-0550
Compounding - Labeling
(2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the compounded drug dispensed or distributed must contain the following, at a minimum:
(b) The beyond use date, to include date and time;
CVS Health appreciates the opportunity to submit comments for the proposed amendment of these rules. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,

Lauren Paul, PharmD.
Sr Director, Pharmacy Regulatory Affairs
CVS Health
From:
Lloyd Center Pharmacy
438 E Burnside St
Portland, OR 97214
(503) 281-4161

May 23, 2018

RE: Comments on Division 045 Proposed Changes

To:
Oregon Board of Pharmacy
800 NE Oregon St, Suite 150
Portland, OR 97232-2162
(971) 673-0001

Dear Oregon Board of Pharmacy,

Enclosed, please find our comments on the proposed rule changes to Division 045.

We are happy to chat further about these comments or other issues relating to Division 045, so please don't hesitate to contact us if you have any questions.

Best regards,

Natalie Gustafson
Natalie@LCRX.com
Lloyd Center Pharmacy
1) General comment on the rules (not related to any specific section)

Comments:
1A) Timing of enforcement
Upon passing of these rules, there is no specification about how long pharmacies will have before they must comply with the changes. Pharmacies will need time to interpret these new Board requirements, and time to come into compliance. Many of the changes are difficult, time intensive, expensive to implement, and will require third party consulting services which in current market conditions have long lead times. Providing a timeline for when enforcement will begin following the adoption of these rule changes will be needed, as it is unrealistic to say they will be enforceable from day 1.

These rules also do not provide the Board for any flexibility on when they will start to enforce either these rules, or future updates to USP chapters. As currently written, the Board must enforce whichever version of the specified USP chapters is currently active. There are currently major revisions in the pipeline for many USP chapters relating to compounding, and given the current wording the Board would have no option to delay enforcement if it deemed necessary based on community need. As an example, revisions to both USP <795> and <797> are being made right now, with an expected final publication date of June 1, 2019. USP has stated that these chapters will become “official” on December 1, 2019, just six months after publication. There are many changes being made in these chapters that will require expensive and time consuming renovations to buildings, and six months is likely not enough time for everyone to interpret the changes, come up with a plan for how to comply, and make the necessary infrastructure renovations in order to meet the new standards.

These rules do not allow the Board to selectively enforce certain parts of USP chapters if it deems relevant to do so. There are many significant upcoming changes to USP, and if the Board is going to enforce all relevant USP chapters for compounding, they may find that some of the changes may take our communities longer to implement or are infeasible to implement. With the current wording of the rules, the Board is required to enforce all of USP, even if it deems it to be in patient’s best interest to selectively enforce parts.

1B) FDA guidance documents
Some of the rules are based on FDA guidance documents, which are not legally enforceable. The guidance documents are not based on USP, and have actually been found to be an overreach of the FDA’s authority based on its interpretation of the Drug Quality and Security Act (DQSA).
1C) Reducing redundant wording
These rules seem to be requiring enforcement of USP. We suggest that when possible, the relevant USP chapter(s) are referenced, instead of rewriting parts of the chapters into the Board rules. Some of the wording of the Board rules differs from the wording of the USP chapters. Sometimes this is intentional, and sometimes this is because parts of USP are being summarized as Board rules. When summarizing USP, it would be preferable if the chapter is just referenced. This change will make Board rules easier to follow, and the Board rules will not become outdated as quickly when USP chapters are updated. For example, <795> and <797> are under revision and will have major changes in the next year, which will drastically change the language in the chapters.

2) Section 855-045-500 Compounding - Purpose

*Quote:* "(3) All drug compounding must adhere to guidelines of the current edition of the United States Pharmacopoeia Chapters 795 (USP <795>) and 797 (USP <797>), as well as all applicable Chapters of USP and USP-NF related to the compounding practices at any location. This includes but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 1072, 1116, 1160, 1163, 1211, and 1229.5."

*Comments:*
2A) We have concerns about the wording here. Specifically, the part that says "as well as all applicable chapters of USP and USP-NF related to the compounding practices at any location," and the reference to chapters above 1000. We believe the word "applicable" is too vague and may imply more chapters than the Board intends. Many chapters in the USP are for general notice only and contain no mandatory requirements. This is true of most chapters in the 1000 range.

For clarity, here is a quote directly from USP explaining that chapters beginning with 1000 are not mandatory except for in certain situations (from the USP Compounding Compendium, General Notices section):

"As stated in General Notices, general chapters numbered from 1000 to 1999 are considered interpretive and are intended to provide information on, give definition to, or describe a particular subject. They contain no mandatory requirements applicable to any official article unless specifically referenced in General Notices, a monograph, or a general chapter numbered below 1000."

By stating both "all applicable Chapters of USP and USP-NF" as well as specifically listing chapters in the 1000 range (1072, 1116, 1160, 1163, 1211 and 1229.5), the new rules could be interpreted as requiring compliance with all chapters above 1000, even those that USP itself does not necessarily require compliance with.
In addition, with big changes coming to USP in the next year, as well as unknown changes in the future, we suggest minimizing the inclusion of chapters above 1000 from the new rules in order to keep Oregon rules consistent with USP language.

**Suggestion:** Re-write as: "(3) All drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP <795>) and 797 (USP <797>)." Or include the chapter definition from USP so that you don’t need to use the word “applicable” in the definition of which USP chapters must be followed.

2B)
There is no verbiage in the new rules regarding timing of enforcement. Specifically, providing the Board with the ability to delay enforcement of a current or future USP chapter in order to allow pharmacies time to get in compliance. Many of the changes in USP chapters relating to compounding have required huge changes in infrastructure, big additional expenses to daily operation, and significant process and training changes. With the current wording of the Order, the Board does not have an option to delay enforcement even if it wanted to. This would be true of the current USP chapters as written, or hypothetical changes years in the future.

**Suggestion:** Provide wording that allows the Board to delay enforcement of all or part of updates made to a current or future USP chapter if it seems relevant given circumstances in the community.

3) **Section 855-045-0510 Compounding- General Definitions**

3A)
**Quote:**
(1) "Batch" means any specific quantity greater than one of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation carried out during a single time period."

**Comments:**
This definition of Batch is ambiguous. Specifically, the part that says “greater than one of a drug.” One capsule? One gram? One kilogram? One milliliter? One liter? One syringe? One container? One vial? One quantity needed for patient dispensing?

**Suggestion:**
There are multiple ways to interpret this, and changing the wording to clarify what you mean here would be helpful.

3B)
**Quote:**
(2) "Beyond-Use Date" and "BUD" means the date and time after which a compounded product must not be used (or stored or transported). The date is determined from the date and time the preparation is compounded, according to risk level."

Comments
We have a wording concern here. Specifically relating to the part that says "(or stored or transported)."

The wording of this definition produces some challenging situations by saying that after the BUD has been reached a product may not be stored or transported.

Some examples:
(a) This definition is saying that the day a product reaches its BUD, it must be destroyed. This would preclude a pharmacy from having a quarantined bin for drug destruction where drugs are stored after BUD has been reached prior to being destroyed. Many compounds already have short expiration dates. This definition would mean that pharmacies would need to destroy drugs every day, instead of at regular intervals which are more conducive to workflows (once a week, twice a month, etc.). This destruction is not practical as most pharmacies use reverse distributors or third parties to destroy their drugs. Pharmacies complying with USP <795> and <797> will have SOPs that address how drugs to be destroyed should be quarantined with clear labeling to prevent risk of using or dispensing.

(b) Some drugs are destroyed by third parties or reverse distributors. After BUD has been reached, as per this definition, we would not be allowed to "transport" these drugs to be safely destroyed by a third party.

The section in USP <795> on Stability Criteria and Beyond Use dating says: "The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded." USP's definition is safer, and does not include a mention of "or stored or transported."

Suggestion:
Use the USP definition of BUD, and remove the "or stored or transported" reference in the BUD definition.

3C)
Quote: "(3) "Hazardous Drug" means any drug identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control or any drug that meets at least one of following six criteria. (a) Carcinogenicity. (b) Teratogenicity or developmental toxicity. (c) Reproductive toxicity in humans. (d) Organ toxicity at low doses in humans or animals. (e) Genotoxicity. (f) New drugs that mimic existing hazardous drugs in structure or toxicity."
Comments:
We are concerned with a hazardous drug being defined by an Oregon Board of Pharmacy Rule. Specifically, the concern is that there has been much debate about the definition of a "hazardous drug." Since USP is now using NIOSH to specify what drug is hazardous, there has been increased pressure for NIOSH to adjust its hazardous drug categories. If/when a change in the definition of a hazardous drug occurs, a new definition would be in conflict with the Oregon Board of Pharmacy rule.

We recognize that the wording used in the OBoP rule is taken from current USP text, but the definition is still rather vague. Specifically, NIOSH and USP (e.g. upcoming USP <800>) do not treat all hazardous drugs as equal, but the OBoP rule does not seem to differentiate.

Suggestion:
If OBoP would like to have USP followed, it may be simpler to just reference a USP or a NIOSH definition of hazardous drugs to reduce risk of conflicting definitions in the future.

4) Section 855-045-0520 Compounding- Registration

4A)
Quote: “855-045-0520 (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 and ambulatory and residential patient.”

Comments:
The wording here is confusing. There is perhaps a typo in this part “if dispensing to both and ambulatory and residential patient.”

Suggestion:
We believe the Board meant “an” not “and” in the quoted sentence, but clarification here is requested.

4B)
Quote: (2) In addition to obtaining an Oregon drug outlet registration, all compounding pharmacies must either pass an inspection by a Board approved entity or must receive accreditation by a Board approved entity, every 3 years at a minimum, in order to distribute or dispense sterile compounded preparations into and within Oregon.”

Comments:
First, a question: What is considered a Board approved entity? Is a Board inspector a “Board approved entity?” What about JCAHO, PCAB or similar third party inspectors? Would this be required for infusion or satellite pharmacies?
Second, a concern: We believe it is inappropriate to only require an inspection or accreditation for pharmacies that dispense sterile compounded preparations. There are significant safety, quality and potency concerns related to non-sterile compounding pharmacies as well, and the Board should require inspection to protect Oregon patients. There are many non-sterile compounding pharmacies nationally, some that dispense very large volumes, and they should be held to the same standards of patient care and safety.

Given that the Board does not typically inspect pharmacies in other states, it seems even more important to require inspections at regular intervals.

Third, another concern: depending on the definition of what a "board approved entity" is, we feel that inspection every 3 years may be too infrequent. The Oregon Board inspects resident pharmacies every year. If the Oregon Board requires this for all resident Oregon pharmacies, why not require this of non-resident pharmacies as well? This new rule of requiring an inspection only every 3 years could lead to non-resident pharmacies being less regulated than resident pharmacies (which is likely true in our current laws as well).

We do not feel it is fair or appropriate for non-resident pharmacies to have less inspections and less oversight than resident pharmacies.

**Suggestion:**
For the safety of Oregon patients, require the regular inspections for both non-sterile and sterile compounding pharmacies.

And if an Oregon Board Pharmacy Inspection is a "Board Approved Entity," then consider reducing the time interval that inspections are required from 3 years to 1 year in order to place non-resident pharmacies on the same level as resident pharmacies.

5) Section 855-045-0530 Compounding- General Requirements

5A)
**Quote:** "(3) The equipment, components, devices, and utensils used for compounding of a drug preparation must be of appropriate design and capacity and must also be designed to protect the compounder from hazardous materials... A pharmacy must comply with all applicable USP standards commensurate with level of compounding being performed."

**Comments:**
How do you define "protect from hazardous material" for equipment or utensil? To our knowledge this is not language from USP. The concern is that by providing these kind of statements out of context from USP chapters that these become challenging to enforce or define.
This section also states that the "pharmacy must comply with all applicable USP standards." If the Board would like for the rules to follow USP chapters, then perhaps it is simpler to just refer to the relevant USP chapter that the Board would like followed. We are not sure the added complexity and ambiguity of (3) is helpful.

**Suggestion:**
Remove (3), or refer to the relevant USP chapter on hazardous handling and safety.

5B)
**Quote:** (4) Any compounding activity that is not pursuant to a valid prescription or an order to prepare for administration and for a specific patient is considered to be manufacturing, and any person engaged in manufacturing must be registered in accordance with Division 060, with the following exceptions: (a) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on a history of receiving valid prescription drug orders for the compounded or sterile prepackaged drug product.

**Comments:**
We believe the wording which differentiates manufacturing versus compounding in anticipation is not appropriate. The Board’s definition of anticipatory compounding more closely resembles FDA wording, instead of what is in USP. Specifically, the USP defines compounding as "the preparation, mixing, assembling, altering, packaging, and labeling of a drug or device or other article, as the result of a practitioner’s order or in anticipation of such an order based on routine, regularly observed prescribing patterns."

Part of our concern with this wording is in the logistics of how compounding works. Here is an example to illustrate our concern.

**Situation 1:** Imagine a doctor calls in a new compounded prescription for a new patient. The prescription is for a capsule, is a formula that has never been made before, has no refills, and has a quantity of 30. Most common compounding equipment for capsules requires you to make 100 capsules at a time. The remaining 70 capsules may never get used, but the encapsulation machine is designed to make 100 at a time, so we make 100, dispense 30 to the patient, and put 70 on our shelf in case we get another order for them before they reach BUD.

**Situation 2:** Imagine situation 1, but instead of a capsule it was an rapid dissolve tablet (RDT). RDT molds have a pre-defined number of “wells” in them, and they all must be filled in order to accurately make the RDTs. So we would need to make 96 RDTs in order to fill a prescription for 30.

In both these situations, we are concerned that the extra stock generated in the normal compounding process would have to be destroyed if following “strict” anticipatory compounding rules, since more stock was made than was needed for the prescription, and there is no history of orders for this formula. This is a huge waste, and we believe goes against the spirit of the
anticipatory compounding rules. Adjusting the wording in this rule to be less restrictive would help to allow for realistic compounding logistics in our pharmacies.

**Suggestion:**
Replace the following words:
"based on a history of receiving valid prescription"

with the USP wording: "based on routine, regularly observed prescribing patterns."

**5C)**

**Quote:** "(6) Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has been withdrawn or removed from the market for safety or efficacy reasons is prohibited."

**Comments:**
We suggest removing terminology based on FDA guidance documents.

While we agree in restricting items that are withdrawn due to safety, efficacy is a more challenging situation. Utilizing off-label uses for drugs is a standard practice for prescribers. The wording in this rule which prevents compounding a drug that has been removed for efficacy reasons comes from an FDA guidance document, which is not enforceable, not part of federal law and is subject to change. We do not see a reason for including the "efficacy" portion of this rule, as it is challenging to define "efficacy." We believe that practitioners should be allowed to prescribe what they feel is best for the patient as long as it is safe for the patient. Additional restrictions should not be placed on practitioners or compounding pharmacies.

**Suggestion:**
Remove the prohibition on compounding drugs removed from the market for efficacy.

6) Section 855-045-0540 Compounding Personnel and Responsibilities

**6A)**

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

**Comments:**
The wording in this section is somewhat vague. For example, "such products" could be interpreted to mean that technicians must be trained in all tasks, even if their job responsibilities only include a subset of tasks. We are sure that the intention of the Board was to limit individuals from performing tasks they have not been trained to do, and not require everyone
know everything. A change in wording will help accomplish this. USP has relevant wording which is better: “Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties.”

In addition, the part of the rule which states “including theoretical principles and practical skills of manipulations” is vague and potentially all encompassing. We suggest narrowing the training requirements to be more practical.

**Suggestion:**
Replace with USP wording: “Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties.”

**6B) Quote:** “(2) All personnel must possess the education, training and competency necessary to properly and safely perform compounding duties”

**Comments:**
We are concerned that this quote is too vague, for two reasons.

First, education could imply the need for a formal education (such as a degree or a formal certificate from an institution). We suspect that the Board is not requiring formal education, but is instead requiring proper training and knowledge, which can be obtained via on the job resources as opposed to institutions of higher learning or approved continuing education.

Second, it says “perform compounding duties” and not “assigned duties.” As with our previous comment, this could be interpreted to mean that all personnel must know how to do all duties, which is unrealistic (and we believe not what the Board intends).

There are multiple references in <795> and <797> to ensure proper training and competency, so we do not believe the Board needs to include rules specifying training requirements. This is already accomplished by requiring USP <795> and <797> compliance, so these rules are redundant.

**Suggestion:**
Since training is already required and defined in USP <795> and <797>, and the Board requires <795> and <797> compliance, we suggest removing training from Board rules.

If you would like to keep training requirements in the Board rules, we suggest removing the word “education” and adding the words “assigned duties” to the quote in order to reduce ambiguity. So it would read: “All personnel must possess the training and competency necessary to properly and safely perform their assigned duties.”
7) **Section 855-045-550 Labeling**

7A) **Quote:** "(1) In addition to the labeling requirements as specified in Division 41, the label of a compounded drug or medication order dispensed or distributed must contain the following, at a minimum (a) The generic or official name of each active ingredient"

**Comments:**
The common challenge with compounded medications is that many compounded formulas have so many ingredients that they will not fit on a label. Pharmacy dispensing software, even pharmacy dispensing software designed for compounding, is often inadequate at handling very long drug combinations.

**Suggestions:**
For names that will not fit on a label affixed to a container, allow an accompanying labeling or separate paperwork included with the prescription to contain the complete drug ingredient list if it is impractical to put on the label affixed to a vial.

Allow common acronyms. For instance, "dehydroepiandrosterone" is almost always referred to as "DHEA." Based on the current language it appears that acronyms are not allowed.

7B) **Quote:** "(1) In addition to the labeling requirements as specified in Division 41, the label of a compounded drug or medication order dispensed or distributed must contain the following, at a minimum (c) The name of the base or diluent"

**Comments:**
Adding the name of all bases or diluents would be challenging. For instance, an oral suspension that contains both Ora-Sweet and Methylcellulose 1% gel would have to list out all those ingredients. No compounding software is set up to handle this type of labeling requirement. Currently, diluents and inactive ingredients only have to be listed on sterile compounded medications per USP. In order to accomplish this for sterile items, we have to manually type out on separate labeling software that is not linked to patient or prescription information which increases risk for error. There is currently no practical way to have this information listed on a prescription label.

**Suggestion:**
Do not require additional labeling requirements such as base or diluent to non-sterile compounded medications.

7C) **Quote:** "(2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the
compounded drug dispensed or distributed must contain the following, at a minimum (a) The name, quantity and concentration of the drug added and the primary solution

Comment:
We believe the wording here may be confusing. Should the label say the final concentration of the ingredients? Or the concentration of the ingredient that was added? If the latter, this could lead to some confusing labels, which we believe is not what the Board is hoping to accomplish with this rule.

7D)
Quote: "(2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the compounded drug dispensed or distributed must contain the following, at a minimum (b) The beyond use date, to include date and time"

Comment:
We do not believe that adding the time to a BUD is applicable in all situations. For example, the "time" of expiration for a compounded sterile item that has 45 day dating is not useful.

Also: how is "time" defined? From the moment a compound has begun to be prepared? From the time it has been sterilized? From the time it is completely finished and prepared for dispensing? Some compounds require hours to be completed from start to finish. It can be difficult to track down to this level.

Suggestion:
If you want time to be included on the label, we suggest adding wording to the rules such as "when appropriate, an in-use time should be included on the label." This wording is consistent with proposed updated USP <797> (not finalized yet, so this may change). Or you could simply reference the USP chapter.

7E)
Quote: (2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the compounded drug dispensed or distributed must contain the following, at a minimum (c) Recommended frequency/schedule for administration

Comment:
Recommended frequency/schedule for administration is not a labeling requirement in USP. This type of information could vary or should be indicated by directions on the prescription. This wording also seems like it could be inappropriate in a hospital setting, such as if the bag or vial states one frequency but the physician order is for a different frequency. We think including this information on the label could lead to increased mistakes.
Suggestion:
Remove the requirement for “frequency/schedule for administration” from the label for safety and logistic reasons.

7F)
Quote: (2) In addition to the labeling requirements as specified in Division 41, whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the label of the compounded drug dispensed or distributed must contain the following, at a minimum (e) The name or initials of person performing admixture

Comments:
We do not believe that the name or initials of the person performing the admixture should be on the label, for several reasons.

First, from a safety standpoint, there is already a lot of information on the label. The name or initials of the person that performed the admixture serves no utility to either accurately describe the medication, or ensure that it is being used/administered correctly. Therefore, we believe it will be a distraction on the label. We believe it is important to only include relevant information on the label for safety reasons, and to prevent adding additional text that does not increase patient safety.

Second, this information is already required to be documented in the compounded preparation record. The goal of tracking who performed admixture is mostly for quality control and quality assurance purposes. This information should be retrievable for these purposes, but it does not belong on the label.

Third, what if multiple people were involved in compounding? Should all names be on the label, or just the “final” admixture technician?

Fourth, there is already a requirement to include the verifying pharmacist initials (which we also believe is likely not a beneficial piece of information to include on the label as this is more used for QC/QA purposes too, though we recognize is a current USP requirement). Also including the admixture name will cause more confusion.

Suggestion:
Do not require the name of the person performing the admixture to be on the label.

8) Section 855-045-570 Compounding- Records

8A)
Quote: "(4) Records for compounding must utilize a master formulation record. All master formula records must be developed and approved by the pharmacist for compounded preparations, and records for all preparations must contain, at a minimum..."
Comments:
Master formulation records can often be developed by or in collaboration with appropriately trained technicians or interns, with a final approval done by a pharmacist. This wording restricts development to pharmacists only.

As an example: imagine a formula being created that is a slight change in concentration of an existing formula. A trained technician or intern could create this new formula from the existing formula, and then give it to the pharmacist for final approval.

Allowing technicians to enter formulas initially is similar to how technicians are used in other parts of the pharmacy. Technicians routinely enter prescriptions into the computer, fill the prescription, and then a pharmacist does final verification. Math and calculations are a regular part of a technician’s responsibilities in all pharmacy settings. It is normal pharmacy procedure to have a pharmacist verify technician work, instead of performing all tasks from start to end.

Suggestion:
Change the quote to remove the word “developed,” and include the word “prior to dispensing.” Such as:

“(4) Records for compounding must utilize a master formulation record. All master formula records must be approved by the pharmacist for compounded preparations prior to dispensing, and records for all preparations must contain, at a minimum…”

8B)
Quote: "(5) Any compounded product must be documented and the unique compounded preparation record, must include but not be limited to the following: (j) Physical evidence of the proper weight of each ingredient"

Comments:
We are concerned with the possible misinterpretation of the words "physical evidence."
Specifically, three big problems:

First, analytical scales that are attached to a computer have their data recorded electronically when capturing tares and weights for an ingredient. In this situation, there is no “physical evidence” of the measurements because it is stored in a computer.

Second, liquid measurements, such as those measured in milliliters will prove a challenge. Analytical scales are of course not capable of measuring volumes, so there is no electronic weight that can be stored electronically or printed to paper. Liquids are measured using devices like graduated cylinders or syringes. Procedures can be used in these situations such as a second check to verify the quantity before writing down the weight on a worksheet, but it is unclear if this is considered “physical evidence.”
Third, the rule specifies "weight," which implies mass. This excludes volume measurements.

**Suggestion:**
Remove the word "physical evidence" to reduce confusion, and replace with the word "documentation" and remove "weight" and replace with "amount." This would make the rule read: "...documentation of the proper amount of each ingredient."

Or perhaps since this is covered in USP chapters, the Board rules can simply refer to the relevant chapters.

8C)
**Quote:** "(5) Any compounded product must be documented and the unique compounded preparation record, must include but not be limited to the following: (k) Duplicate label as described in the Master Formulation Record"

**Comment:**
Question regarding this item. Certain softwares provide a barcode that allows this label to be pulled up electronically and reviewed or printed as needed. In this instance, would all labels need to physically be printed and attached to the compounding record, or would a barcode suffice?

8D)
**Quote:** "(5) Any compounded product must be documented and the unique compounded preparation record, must include but not be limited to the following: (m) Results of quality control procedures (e.g. weight range of filled capsules pH of aqueous liquids)"

**Suggestion:**
Minor grammatical error. Missing comma between "capsules" and "pH".

9) **Section 855-045-0600 Sterile Compounding- Purpose**

9A)
**Quote:** "The minimum standards of the current edition of the United States Pharmacopeia Chapter <797> and all other applicable USP Chapters regarding sterile compounded products must be met unless requirements listed are more stringent."

**Comments:**
We have the same concerns with this rule as we have expressed previously. Specifically:
These rules do not provide the Board for any flexibility on when they will start to enforce either these rules, or future updates to USP chapters. There are currently major revisions in the pipeline for many USP chapters relating to compounding, and given the current wording the Board would have no option to delay enforcement if it deemed necessary for the community.

These rules do not allow the Board to selectively enforce certain parts of USP chapters if it deems relevant to do so. There are many significant upcoming changes to USP, and if the Board is going to enforce all relevant USP chapters for compounding, they may find that some of the changes may take our communities longer to implement or are infeasible to implement. With the current wording of the rules, the Board is required to enforce all of USP, even if it deems it to be in patient’s best interest to selectively enforce parts.

**Suggestion:**
To help allow for future unknown situations and to give pharmacies the time to prepare for changes, add wording that (a) specifies when enforcement begins on these new rule changes, (b) allows for the board to delay enforcement of current or future USP chapter changes if it deems necessary, and (c) allows the Board to selectively enforce all or part of current or future USP changes if it deems necessary.

**10) Section 855-045-0610 Sterile Compounding- Personnel Compounding Sterile Preparations (CSPs)**

**10A)**

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

(a) Fundamentals of sterile compounding manipulations;
(b) Responsibilities of compounding personnel;
(c) Purpose and utilization of policies and procedures;
(d) Use of all applicable equipment and supplies, to include automated compounding devices;
(e) Facility and personnel environmental sampling metrics, to include but not limited to:
(A) Garbing competency;
(B) Hand hygiene and proper work practices competency, via gloved fingertip sampling;
(C) Media-fill testing of aseptic manipulation competency, at least annually for low and medium-risk level compounding and semi-annually for high-risk level compounding; and
(D) Cleaning and disinfecting competency, to include surface sample testing;
(f) Understanding of primary and secondary engineering controls, such as function, use, testing, and certification;
(g) Assignment of BUDs;
(h) Quality assurance, quality releases and final checks of CSPs"

**Comments:**
The wording of this rule is too broad and confusing. Specifically:

- "Final checks of CSPs";
The training requirement reads as if all personnel, including temporary personnel, must be trained in "final checks of CSPs." Technicians should not need training in final checks of CSPs.

- **"Use of all applicable equipment and supplies."**
  - "Applicable" is a vague term and could be interpreted to mean the use of all equipment in the sterile lab, even those that are not part of an employees responsibilities. A line such as "Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties" is more appropriate. "Assigned duties" is more specific and limits the scope of their training to those tasks which they are involved in.

- **"(C) Media-fill testing... for low and medium-risk... and... high-risk..."**
  - The terminology from current <797> of low, medium and high-risk compounding will be removed when <797> is updated. They are defining the types of sterile compounding differently. It may not be beneficial to include soon to be outdated terminology in rules.

- **"(e) Facility and personnel environmental sampling metrics, to include but not limited to: (D) Cleaning and disinfecting competency, to include surface sample testing."**
  - The wording here is too all encompassing and again makes it sound like all sterile compounding personnel need to understand everything. Not all technicians will necessarily be involved in environmental monitoring. We think this is another great place to use of the word "assigned duties", instead of requiring everyone to know everything. "Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties"

- **"(i) For non-sterile-to-sterile batch compounding, written policies and procedures must include:¶ (A) Process validation for chosen sterilization methods; and¶ (B) End-product evaluation, quantitative, and qualitative testing"**
  - The location of this part is confusing as it is referring to SOPs about batch compounding, and not personnel training. We do not think this rule belongs under the topic of "Documented training for each personnel... must include." We are wondering if this was placed here in error and it belonged elsewhere in the rules?

**Suggestion:**
Many suggestions were included within the bulleted list above.

In general, much of this section was too vague and could be interpreted to mean that all staff must know every responsibility. If this section remains, we suggest using wording which includes "assigned duties" to make it more clear.
This section also covers topics that are explicitly described in USP chapters, so it seems simpler to refer to the USP chapter here and get rid of this section entirely from the Board rules. This will also make the Board rules simpler and consistent with USP when USP chapters are updated.

10B)

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

**Comments:**
This rule is almost certainly illegal. Specifically, the rule states that the PIC must be able to perform every sterile compounding duty supervised. This precludes any person with a disability, injury, or other physical limitation from legally being a PIC of a compounding pharmacy.

From a practical standpoint, this rule is also overly broad. It is reasonable to expect the PIC to understand all of the sterile responsibilities and techniques in compounding. But it is impractical to expect a PIC to be able to perform every technique on their own. A PIC can safely and competently supervise sterile compounding if they understand how a technique should be done even if they are unable to perform the technique themselves. For an extreme example, imagine a one armed PIC.

In addition, as mentioned before the word "education" is overly broad in this context and should either be removed or clarified.

**Suggestions:**
Re-word this section to remove the requirement that a PIC be able to “perform” the duties, and remove the word “education” as it is overly broad. Specifically:

"(5) The Pharmacist-In-Charge (PIC) must possess the training and proficiency necessary to properly and safely supervise sterile compounding duties."

10C)

**Quote:** "(8) A pharmacy technician who compounds sterile preparations must: (a) Possess the education, training and proficiency as required to properly and safely perform compounding duties undertaken"

**Comments:**
We have the same concerns here about the word "education" as we have had elsewhere in the rules. It is too broad, not defined, and not necessary for the position.

**Suggestion:**
Remove the word “education” from this section.
11) Section 855-045-0620 Microbial Contamination Risk Levels and Beyond-Use-Dates

Comments:
We are not clear as to the purpose of this section being in the Board rules. These areas are already covered in <797>, and the proposed changes to <797> will remove the "low/med/high" risk level definitions. Referencing relevant USP chapters should be sufficient here.

Suggestion:
Remove this section, which will be outdated soon, and reference relevant USP sections instead.
Hello!
Thank you for giving us the opportunity to speak at the rule hearing meeting this morning.

One of the items that was clarified for us at the meeting was what the board meant in 855-045-520 about a "board approved entity." Thanks for the clarification!

This email is an additional comment on the proposed rule changes to Division 045, specifically as it relates to 855-045-0520.

Here is the relevant quote from the rules:

**Quote:** (2) In addition to obtaining an Oregon drug outlet registration, all compounding pharmacies must either pass an inspection by a Board approved entity or must receive accreditation by a Board approved entity, every 3 years at a minimum, in order to distribute or dispense sterile compounded preparations into and within Oregon.

**Comments:**
At the meeting, the board clarified that the annual Board inspection is not considered a "Board approved entity" when the rules are referencing a required inspection or accreditation every 3 years for pharmacies that perform sterile compounding.

In our written comments previously submitted, we discussed this quote as part of our item "4B." This comment is an expansion on our previous written comments now that we understand the Board's intent better.

Specifically, we are concerned that only sterile pharmacies are required to have third party inspections every 3 years. We believe that this ruling should be extended to non-sterile pharmacies as well for patient safety and requirements consistency. We have several reasons for this:

1) Given that the Board does not inspect non-resident pharmacies, it seems important to require third party inspections/accreditation to all non-resident compounding pharmacies, and not just those shipping sterile prescriptions into Oregon. There are many non-sterile compounding pharmacies nationally, some that dispense very large volumes or that are in states with minimal Board oversight. Requiring inspection or accreditation would help address differences in state inspection and help protect Oregon patients.

2) Pharmacies that do both sterile and non-sterile compounding are unable to be inspected or accredited by third parties for just their sterile activities. Third party inspectors (correctly) require inspection/accreditation of non-sterile compounding activities if it is also being performed at the pharmacy. They also charge additional fees for everything they are inspecting, so inspecting a "sterile and non-sterile" pharmacy will be substantially more expensive and time consuming than inspecting just a "sterile" pharmacy.

In practice, this rule is requiring compounding pharmacies that are both "sterile and non-
sterile" to be inspected or accredited for non-sterile compounding activities, while "non-sterile only" pharmacies do not have any third party inspection or accreditation requirements. We believe that it makes sense to hold non-sterile compounding to consistent standards and oversight among pharmacies.

Thus, "sterile and non-sterile" compounding pharmacies will have an increased financial, logistical and time burden to not only be inspected for their sterile operations, but also for their non-sterile operations. For this reason we believe the distinction between sterile and non-sterile compounding as it relates to inspection and accreditation is not appropriate.

We see several possible solutions to this, which are outlined in our Suggestions below.

**Suggestion:**

A) **Non-resident pharmacies:** Since the Board is not able to physically inspect non-resident pharmacies, we think that all compounding pharmacies (both sterile and non-sterile) should be required to have third party inspection or accreditation. This will help to account for differences in quality and quantity of inspections in other states.

B) **Resident pharmacies:** Since the Board is able to physically inspect resident pharmacies, we see two options available:

1. If the Board feels third party inspection and accreditation is required, then all compounding pharmacies (both sterile and non-sterile) should be required to have it.

2. If the Board feels that third party inspections or accreditation is too big of a burden for resident pharmacies that are inspected annually by the Board, then they can remove the requirement for resident compounding pharmacies to undergo third party inspection/accreditation.

Either way, we believe that both sterile and non-sterile pharmacies should be treated the same from a third party or accreditation requirements.

Thank you for your time! Please feel free to reach out to us with any questions.

Adam Gustafson
Lloyd Center Pharmacy
503-281-4161
To whom it may concern,

When I was first made aware of the proposed changes to the Oregon State pharmacy rules in regards to compounding I was excited. We have needed clarification and unification for a long time and I welcomed the clarity and increase in patient safety that I hoped it would bring. Unfortunately, I hadn’t reviewed the proposed rules much before it became apparent that the target I was hoping for had been missed.

The proposed rules by the board have me concerned in a few areas, specifically, the inspection by an outside entity, the adoption of the difficult to compound list and some other minor things. I don’t see the need to have a separate outside entity carry out an inspection for sterile compounding if there is a clear set of rules for it and the board inspectors are already inspecting it. This seems like a way to force pharmacies to become accredited and pay an additional cost for no purpose and makes it appear as though the board inspectors are not qualified enough to carry out a full inspection. The difficult to compound list is still pending has been a source of contention and controversy since its first proposal and depending on how it is adopted could severely limit or altogether end patients access to a vast majority of compounds, at least the ones we currently do. Other things like needing times on BUD and the names and concentrations of base solutions or creams is just tedious and unnecessary, even commercial products don’t do that on their labels.

Using USP 795 and 797 as guidelines for rules for Oregon is a great place to start. However they are constantly changing and currently both have drafts that are pending approval. By adopting them in their entirety I feel it is going to hamstring pharmacies in Oregon and the board and make us subject to an ever increasingly difficult to understand and overbearing set of basically federal rules. There are many specifics I can site such as BUD for non sterile items and the testing needed to extend them beyond the very short ones set out in 795, or the ambiguity of what separates a sterile compounding area from a non-sterile compounding area. Overall, the basic backbone of them is solid but we should set them for us and not just follow whatever current guidelines are proposed for USP.

The adoption of USP 800 confuses and frustrates me greatly. My understanding is that the boards purpose is the safety of patients. USP 800 is basically a workplace and environmental rule set. I have not seen any justification for its existence other than theoretical issues that in my 15 years of compounding what we do have never happened. I am sure that in some cases like with chemo drugs it is totally warranted but some of the safety measures required for hormones and other items are way over the top. The only thing USP 800 would do in my practice is cost 10s or thousands of dollars to implement, restrict access to medications and greatly increase costs to patients.

While appreciate the effort that has gone into these proposed rules I don’t feel they are at a point to be adopted. I think that with a little bit of work form a rules committee and some more time and input from the community a rule set that is specific for Oregon could be adopted without all the confusion and waste that is associated with the federal guidelines. As it stands now these rules depending on some of the clarification and interpretation would at best increase the cost of medications to patients and at worst put me completely out of business eliminating access to many patients medications for very little benefit.

George Hiers
Northwest Compounding Pharmacy
541-672-8399
KLEIN Mo * BOP

From: Katie E Jaeger <Kay.E.Jaeger@kp.org>
Sent: Monday, May 21, 2018 11:00 AM
To: PHARMACY RULEMAKING * BOP
Cc: Tabitha L Fridriksson
Subject: OBOP-Comments for Division 45 Rulemaking

Kaiser Permanente Foundation Healthplan of the Northwest
500 NE Multnomah St, Suite 100
Portland, OR 97232

Attn: Oregon Board of Pharmacy

Thank you for the opportunity to comment on the proposed rulemaking regarding Division 45 Compounding rules.

855-045-0550
Compounding - Labeling
(2) (a) The name, quantity and concentration of the drug added and the primary solution;

KP comment: Propose that we do not add all of this information to the label. The space on a label is limited. The source information of the compound is maintained on the compounding log. The additional information does not reflect the final product and can lead to patient confusion and a patient safety risk.

855-045-0610
Sterile Compounding - Personnel Compounding Sterile Preparations (CSPs)
(3) Documented training for each person, including temporary personnel, must be performed and completed by the PIC or other supervising pharmacist prior to sterile compounding or supervising the preparation of sterile preparations, and must include, at a minimum:

KP comment: Propose change in language to include: Documented training and competence for each person, including temporary personnel, must be verified by the PIC or other supervising pharmacist prior to sterile compounding or supervising the preparation of sterile preparations, and must include, at a minimum:

(n) Hazardous drug material handling.

KP comment: Propose change in language to include: Hazardous drug material handling and disposal.

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

KP comment: Suggest adding record retention period.

Thank you for your consideration,

Katie Jaeger, CPA
Pharmacy Regulatory-Northwest Region
(503)261-2138 [office] Cell phone: (503)-758-6887
(503)261-7567 [fax]
This document has been created as part of the Quality Assurance/Peer Review Process at Kaiser Permanente under the protection of ORS 41.675 and RCW 4.24.250 and 70.41.200(3).

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From: Christian Laatsch
To: PHARMACY RULEMAKING * BOP: PHARMACY BOARD * BOP
Subject: Proposed amendments to Chapter 855
Date: Thursday, May 10, 2018 9:14:25 AM

To whom it may concern:

We received notice of the board’s proposed amendments to rules related to compounding in Oregon. Are these changes restricted to pharmacies/pharmacists only, or would they also regulate physician in-office compounding?

Thank you in advance for any information you may be able to provide.

Christian Laatsch
Government Affairs Associate
American Society of Plastic Surgeons
claatsch@plasticsurgery.org
Work: (847) 228-3326
Cell: (262) 353-2715
Legacy Health
Pharmacy Services
1015 NW 22nd Avenue
Portland, OR 97210

To: Mo Klein
   Project Manager
   Oregon Board of Pharmacy

Re: Draft Rules for Compounding

Legacy Health Pharmacy Services has reviewed the Oregon Board of Pharmacy's proposed compounding rules and would like to provide further comment and encourage the formation of an administrative rule advisory committee (RAC) to further assist with safe compounding within the State of Oregon. We share similar concerns expressed at today's Rules Hearing around proposed / draft language that differs from current and draft USP < 795>, < 797> and < 800> standards.

Legacy Health's hospital pharmacies are committed to compliance and patient safety with our nation's standards for sterile and non-sterile compounding. We would encourage the Oregon Board of Pharmacy to simplify the proposed compounding rules by adopting proposed language in OAR 855-045-0500 (3) "all drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP < 795>) and 797 (USP < 797>) as well as all applicable Chapters of USP and USP-NF related to the compounding practices at any location. By adoption of this language and removing other proposed rules, OBOP will be able to maintain current ruling based upon our national standards, (i.e. USP).

We support the Oregon Board of Pharmacy's mission "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." We believe that adoption of the proposed rule 855-045-0500 is in alignment with this mission. If the Oregon Board of Pharmacy deems it necessary to have additional rules for compounding, we hope that the pharmacy compounding community will be able to participate in the drafting of these rules through a rule advisory committee.

Thank you for your consideration.

Sincerely,
(electronic signatures)

Kathleen Stoner
Legacy Health
Vice President of Pharmacy

Michelle Murray
Legacy Health
Director, Clinical and Quality Improvement

Carl Heisel
Legacy Health
Director, Legacy Emanuel Medical Center
The simple inclusion of compliance to USP 797 is the best way to keep OR regulations current.

I do suggest a significant review and expansion of the compounded sterile products section of the self checklist. Currently it still refers to the 24hr BUD rule, as well as not addressing many items that are required for a USP 797 compliant compounding suite or segregated compounding area.

Thank you,

Kyle Mulder
NSF, CETA CNBT, NEBB CPT CP
Controlled environment specialist
Technical Safety Services LLC Oregon
(503) 421-4634 Mobile
(800) 877-7742 Main office
kmulder@techsafety.com

For more information about TSS, please visit www.techsafety.com
FYI from Kyle Mulder.

I believe (based on his second sentence) that this is Rulemaking Commentary as well.

IFEST is the Institute of Environmental Sciences and Technology. RP is Recommended Practices.

-----Original Message-----
From: Kyle Mulder <KMulder@techsafety.com>
Sent: Wednesday, May 23, 2018 3:09 PM
To: fiona.karbowicz@state.or.us
Subject: OR regulation clarification suggestions

Fiona,
Good to see and talk with you today. Sorry to send this to you and not the comment email, but I’m running very short on time. I’ll send a PDF of that gap analysis over to you very soon.

A few of the hot topics that are not outlined well in current 797:

Ante room pressure requirement. Some people read the chapter and think the buffer room only has to be positive to the general area, but there shall be a differential between each ante room to general of minimum 0.020” water column. The non-hd shall be 0.020” to ante and HD rooms are -0.010” to -0.030” to ante or wherever they are accessed from. Airflow displacement should be discouraged (40 fpm or meat curtains).

Airflow visualization studies (often called smoke studies). Clearly required at no frequency in 797 and 800 in the hoods. Some people want to make those required every 6 months, I think that is bad and could write a book to you as to why. I suggest airflow visualization be required for hoods AND rooms every 4 years or when changes are made to layout, HVAC or process.

Turbulent flow ISO 5 areas are not allowed in 797, but people are still using turbulent flow isolators as well as poorly designed integrated iso 5 areas.

HEPA filter integrity for the clean rooms is suggested in current 797, I am told it will be required in new 797. It would be nice to just be able to do it and stop the back and forth arguing with clinical I/Q, who believe it is required now.

Room temp. Currently 797 says should be below 20 C, 800 says shall, new 797 will likely be shall. Clarifying now might help a lot of poor, sweaty techs (and certifiers).

Dynamic vs static viables and non viable sampling. There is no question that dynamic/operational (should be called operational really) is the requirement, but it’s not done at MANY locations.
That’s it for certification stuff. There are tons of cleanroom construction issues, but an IEST RP is being created that would be very easy to reference once it is complete and it would address all those issues.

As always let me know if you have any questions,

Kyle Mulder
NSF, CETA CNBT, NEBB CPT CP
Controlled environment specialist
Technical Safety Services LLC.
(503) 421-4634 mobile
(800) 877-7742 main office
Kmulder@techsafety.com<mailto:Kmulder@techsafety.com> email

For more information about TSS, please visit: https://www.techsafety.com<https://www.techsafety.com/>
May 23, 2018

Mo Klein
800 NE Oregon Street
Suite 150
Portland, OR 97232

RE: Notice of Proposed Rulemaking OAR 855-045-0500 through 855-045-0630

Dear Mr. Klein:

Thank you for the opportunity to provide comments to the Oregon Board of Pharmacy on proposed rulemaking for drug compounding, OAR 855-045-0500 through 855-045-0630.

The National Community Pharmacists Association represents the interests of America’s community pharmacists, including the owners of more than 22,000 independent community pharmacies across the United States and 125 independent community pharmacies in Oregon. Together they represent an $80 billion health care marketplace and employ 250,000 people.

According to a recent NCPA member survey, more than 88 percent of our members provide some form of compounding services. NCPA supports the principle that pharmacist-compounded medications are customized medications and that compounding is a necessary service to meet the needs of patient care. NCPA also supports safety and quality in compounding activities and encourages compounding pharmacists to become accredited by the Pharmacy Compounding Accreditation Board to promote these conditions. We believe it is critical to balance the standards and expectations of safety and quality with patient care needs and access to medications.

After reviewing the proposed rules, NCPA would like to present the following questions and comments for discussion.

1. Oregon Board of Pharmacy enforcement of USP General Chapter <800> upon finalization of proposed rules

Proposed OAR 855-045-0500 (3)(4) states: “All drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP <795>) and 797 (USP <797>), as well as any applicable Chapters of USP and USP-NF related to the compounding practices at any location. This includes but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 1072, 1116, 1160, 1163, 1211, and 1229.5. (4) Compounding pharmacies and personnel must comply with federal and state regulations regarding compounding and handling hazardous drug products.” Further, proposed OAR 855-045-0530 (3) states: “The equipment, components, devices, and utensils used for compounding of a drug preparation must be of appropriate design and capacity and must also be designed to protect the compounder from hazardous materials.
Minimum standards for pharmacies and equipment are dependent on the risk level of the products being prepared. A pharmacy must comply with all applicable USP standards commensurate with level of compounding being performed. USP General Chapter <800> is notably missing from the listing of applicable chapters but seems to be indirectly referenced in other proposed rules.

NCPA encourages the Oregon Board of Pharmacy to delay implementation and enforcement of USP <800> until December 1, 2019 to align with USP implementation of the chapter.

2. Clarification of the definition of "batch" and the connection to the requirements for non-sterile-to-sterile batch compounding

Proposed OAR 855-045-0510 (1) defines “batch” as “any specific quantity greater than one of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation carried out during a single time period.” Proposed OAR 855-045-0610 (1) states “For non-sterile-to-sterile batch compounding, written policies and procedures must include: (A) process validation for chosen sterilization methods; and (B) End-product evaluation, quantitative, and qualitative testing.” As it is currently written, the proposed rules seem to indicate that any non-sterile-to-sterile preparation of more than one vial or container would require sterility and end-product testing. NCPA is concerned that this requirement could have a substantial negative impact on patient care and access. For example, preservative-free dosage forms are individually packaged and would seem to require sterility and end-product testing under the proposed rules. The delayed access and increased cost associated with these requirements could prevent patients from receiving their much-needed medications. USP General Chapter <797> currently indicates sterility testing and bacterial endotoxin (pyrogen) testing should be done for high-risk level CSPs prepared in batches of more than 25 identical containers.

NCPA recommends the following change to proposed OAR 855-045-0610 (1): “For non-sterile-to-sterile batch compounding written policies and procedures must include: (A) process validation for chosen sterilization methods; and (B) End-product evaluation, quantitative, and qualitative testing when appropriate.”

3. Clarification of the general requirements related to sterility of ingredients in compounded products

Proposed OAR 855-045-0530 (2) states: “The accuracy of identities, concentrations, amounts, purity, and sterility of ingredients in compounded products must be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers. (a) If the correct identity, concentration, amount, purity, and sterility of ingredients and components of compounded products cannot be confirmed, such ingredients and components must be discarded immediately.” Many ingredients used in compounded products are not sterile. This proposed rule seems to prohibit the use of any non-sterile ingredient in a compounded product.

NCPA recommends the following change to proposed OAR 855-045-0530 (2): “The accuracy of identities, concentrations, amounts, purity, and sterility (where applicable) of ingredients in
compounded products must be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers. (a) If the correct identity, concentration, amount, purity, and sterility (where applicable) of ingredients and components of compounded products cannot be confirmed, such ingredients and components must be discarded immediately.

4. Clarification of the definition of the phrase “strength of significance”

Proposed OAR 855-045-0530 (5) states: “A drug product that is commercially available may only be compounded if: (a) It is medically warranted by the prescribing practitioner to provide an alternate ingredient, dosage form, or strength of significance, for an identified individual patient; or (b) The commercial product is not reasonably available in the market in time to meet the patient’s needs.” What does the Oregon Board of Pharmacy consider a “strength of significance”?

NCPA recommends the following change to proposed OAR 855-045-0530 (5): “A drug product that is commercially available may only be compounded if: (a) It is medically warranted by the prescribing practitioner to provide an alternate ingredient, dosage form, or strength of significance, for an identified individual patient; or (b) The commercial product is not reasonably available in the market in time to meet the patient’s needs.”

5. Clarification of FDA identification of drug products prohibited in compounding for human use

Proposed OAR 855-045-0530 (6) states: “Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has been withdrawn or removed from the market for safety or efficacy reasons is prohibited.” NCPA is concerned that the intent behind the current wording of this proposed rule could be misconstrued, and drug products nominated for addition to the FDA Difficult to Compound List or to the Code of Federal Regulations under 21 C.F.R. §216.24 could be considered to meet this qualification and be prohibited prematurely.

NCPA recommends the following change to proposed OAR 855-045-0530 (6): “Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding included on the Difficult to Compound List or that has been included in 21 C.F.R. §216.24 withdrawn or removed from the market for safety or efficacy reasons is prohibited.”

6. Clarification of personnel compounding duties

Proposed OAR 855-045-0540 (2) states: “All personnel must possess the education, training and competency necessary to properly and safely perform compounding duties undertaken or supervised.” NCPA supports appropriate authorization of personnel before compounding duties are undertaken.
NCPA recommends the following change to proposed OAR 855-045-0540 (2): “All personnel must possess the education, training and competency necessary to properly and safely perform compounding duties undertaken or supervised or authorized to undertake.”

7. Clarification related to labeling of compounded drug products

Proposed OAR 855-045-0550 (1)(c) and (d) state: “The name of the base or diluent” and “The dosage form or route of administration” must be contained on the label of a compounded drug or medication order. While including the base or diluent makes sense when related to a cream, ointment, solution, or suspension, is this proposed rule intended to include all excipients used in capsules? NCPA is also concerned that the dosage form alone does not always imply one route of administration. For example, a gel could be applied topically, rectally, vaginally, or orally.

NCPA recommends the following change to OAR 855-045-0550 (1)(c): “The name of the base, or diluent, or primary excipient.” NCPA recommends the following change to proposed OAR 855-045-0550 (1)(d): “The dosage form or and route of administration.”

NCPA appreciates the opportunity to share our questions, comments, and recommendations with you. If you have any questions or would like to discuss our comments further, please contact me at 703-600-1179 or alliejo.shipman@ncpanet.org.

Sincerely,

Allie Jo Shipman
Associate Director, State Government Affairs
Position Statement on Proposed Division 045 Compounding Rules Draft

The Oregon Society of Health-System Pharmacists does not support the rules as proposed by the Oregon Board of Pharmacy.

The Oregon Society of Health System Pharmacists (OSHP) has heard from licensees and OSHP members stating concerns with the proposed Division 045 Compounding Rules Draft set for rulemaking. Based on concerns about the impact to licensees and costs associated with adoption of these rules, OSHP opposes the current draft going into rule. We suggest further input from licensees be considered by OBOP, possibly through creation of a Rules Advisory Committee.

We appreciate the work of OBOP and would be happy to assist in identifying subject matter experts to participate in an advisory committee. Thank you for considering this input.

Sincerely,

Dan R

Dan Rackham
OSHP President 2017-18
May 22, 2018

TO: Mo Klein  
Project Manager  
Oregon Board of Pharmacy

FROM: Jacob Thompson, PharmD, MS  
Regional Director of Pharmacy Operations & Compliance  
Providence Health & Services – Oregon

RE: Rule Making for Drug Compounding Rules

Thank you for the opportunity to comment on the proposed rules regarding the 4/26/2018 “Filing Caption: Repeals outdated and adopts new drug compounding rules” within Chapter 855-045. I am providing comments in my capacity as Regional Director of Pharmacy Operations & Compliance representing Providence Health & Services – OR. As the largest health system in the State of Oregon, it is important that we maintain our Values of Compassion, Dignity, Justice, Excellence and Integrity. Providence Health & Services prides our Value of Excellence as “We set the highest standards for ourselves and our ministries. Through transformation and innovation, we strive to improve the health and quality of life in our communities. We commit to compassionate, safe and reliable practices for the care of all.” Aligning with Excellence, Providence Health & Services agrees with the Board that “all compounding must adhere to the guidelines of USP 795 and 797” as these guidelines are important to maintaining patient safety throughout the compounding process. Providence Health & Services consider the United States Pharmacopeia (USP) as the “Gold Standard” for sterile and non-sterile compounding. We believe it is important to follow the most up to date USP guidelines and specifically support the rule 855-045-0500 (3): “All drug compounding must adhere to guidelines of the current edition of the United States Pharmacopeia 795 (USP <795>) and 797 (USP <797>).”

We do have a few concerns with the proposed rules that we hope the Board will address:

1) While the rules do require adherence to the current edition of USP <795> and USP <797>, the proposed rules still have specifics called out separately throughout. USP chapters are currently under review in 2018 and thus could include updates that could counter the rules being proposed. Our recommendation is to remove all proposed rules except 855-045-0500 and 855-045-0620.

If the Board does not support our first concern and recommendation, we hope the Board will address these additional concerns:

2) Rule 855-045-0510 (2) and 855-045-0550 requires date and time for “Beyond-Use Date(s).” USP defines BUDs as “the date after which a compounded preparation shall not be used; determined from the date the preparation is compounded.” USP chapters do not require time and it is not commonly used practice to include both date and time when applying beyond-use dates when using extended dating (e.g. 28 days, etc...). Our recommendation is to remove “time” from this rule and apply the USP definition verbatim.

3) Rule 855-045-0520 (2) refers to “a Board approved entity, every 3 years,” but this list was not attached to the proposed rules, not made available in the February or April agenda, nor was it easily accessible online. It is not possible to understand this impact without the list of “Board approved entities”. Our recommendation is to share this list for comment so outlets can assess the impact of this rule.
4) Rule 855-045-0530 (5) requires “a drug product that is commercially available may only be compounded if it is medically warranted or not commercially available in a reasonable time. Drug manufacturers continue to buy generic drugs to only create an oligopoly and raise drug prices. This is done for compounded products as well. For example, dexmedetomidine (Precedex®) makes a commercially available 100 ml (4 mcg/ml) and 50 ml (4 mcg/ml) for $75.85 and $41.71 (VAC pricing). However, the generic vial and base solution cost less than $5. This product is used over 10,000 times for our institutions. It is common practice for pharmacies (institutional, 503A and 503B) to compound commercially available products. USP <797> does not require this rule or its intent. Our recommendation is to eliminate 855-045-0530 (5).

5) Rule 855-045-0540 (5)(a) states that “a pharmacist who engages in compounding must: Perform and document the review and verification of each step of the compounding process.” It is common practice for a pharmacy technician to perform steps of the compounding process with pharmacist verification at the end of the process or at key points in the compounding process. It would be extremely burdensome for a pharmacist to perform each step of a compounding process. Our recommendation is to eliminate 855-045-0540 (5)(a).

6) Rule 855-045-0540 (5)(b) states that “a pharmacist who engages in compounding must: provide written information about the compounded preparation’s active ingredient(s) to the patient at the time of dispensing.” It is unclear if this rule was meant for institutional pharmacies who compound or just retail pharmacy outlets. It would be extremely burdensome for a pharmacist to notify every patient in the institutional outlet (“inpatient”) or retail outlet (“ambulatory infusion centers”) when their medication was compounded. Our recommendation is to eliminate 855-045-0540 (5)(b).

7) Rule 855-045-0560 (3) requires notification to the Board in the event of a patient-level recall. Providence Health & Services has policies and procedures in place when recalling medications. Some of these notifications are not due to a compounding error, but due to manufacturer recalls. There are many unmet questions on this notification. Does one patient recall require a notification to the Board? How quickly? What types of records are required? Our recommendation is to eliminate “The recall procedure must include notification to the Board in the event of a patient-level recall.”

8) Rule 855-045-0570 (2)(b) requires a pharmacist to sign off on competency, training, and education for personnel. It is common practice across the State and US for pharmacy technicians to be the trainers of pharmacists and pharmacy technicians who compound. These technicians are often the ones actually compounding and are expected to be our subject matter experts when appropriately educated. Our recommendation is to change the rule to include pharmacy technicians who are trained or educated by a PIC or pharmacist.

9) Rule 855-045-0570 (5)(j) requires documentation of “physical evidence of proper weight of each ingredient.” It is not practical for every ingredient to have documentation of proper weight, as often volume is sufficient. Requiring physical evidence would be extremely costly for outlets in Oregon. Additionally, it is not clear if a pharmacist signature would suffice this rule or if actual documentation of the physical weight or volume is necessary (i.e. picture or scale recordings). Again, requiring documentation of a picture or scale recordings would be extremely costly for outlets in Oregon. Our recommendation is for the rule to be changed to “physical evidence of proper weight or volume of each ingredient” and that a pharmacist signature be acceptable.

10) We are concerned that there may be other aspects of the proposed rules that could impact the practice of pharmacy across the state. While these rules have been discussed since the first of the year, it has been difficult to facilitate conversation on the
rules since they were not published until 4/26/18. This has left very little time for necessary review with other professional colleagues within the state and with subject matter experts across the country. As stated in the Notice, these rules could have significant practice and fiscal impact across the state. If the rules are going to go beyond compliance with current USP chapters, our recommendation is for a Rules Advisory Committee be formed to evaluate any additional rules beyond rules 855-045-0520.

We appreciate the work of the Board and its mission. Thank you for the opportunity to provide comment on these proposed rules.

Sincerely,

JACOB M. THOMPSON
To: Oregon Board of Pharmacy

From: D. Rackham

Several pharmacists and pharmacy managers involved in sterile and non-sterile compounding reviewed the Division 045 Compounding Rules Draft. On their behalf, I respectfully submit the following comments, suggestions for edit and questions on the draft rules:

855-045-0520

(2) In addition to obtaining an Oregon pharmacy drug outlet registration, all compounding

77 pharmacies must either pass an inspection by a Board approved entity or must receive

78 accreditation by a Board approved entity, every 3 years at a minimum, in order to

79 distribute or dispense sterile compounded preparations into and within Oregon.

855-045-0530

99 (1) All active pharmaceutical ingredients must be obtained from an FDA and Board

100 registered manufacturer.

(2) (b) Ingredients that do not have expiration dates assigned by the manufacturer or

124 supplier, must be labeled on the container with the date of receipt and must be assigned an

125 expiration date not to exceed two years after receipt of the component.

(5) (b) The commercial product is not reasonably available in the market in time to meet the

167 patient's needs.
855-045-0550

(B) For a sterile compounded product, in the absence of stability and sterility testing, USP 797 limits the BUD of a compounded sterile product to the following, based on risk level:

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Controlled Room Temperature</th>
<th>Cold Temperature</th>
<th>Frozen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Use</td>
<td>1 hour from start of compounding</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Low – Segregated Compounding Area</td>
<td>12 hours or less from compounding</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Low</td>
<td>48 hours</td>
<td>14 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Medium</td>
<td>30 hours</td>
<td>9 days</td>
<td>45 days</td>
</tr>
<tr>
<td>High</td>
<td>24 hours</td>
<td>3 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

Commented [DR6]: This is being outdated in new USP 797 draft and categories, definitions and BUDs are changing. Support referencing 797 standards rather than using specifics to allow for changes over years.

(2) (d) The scheduled time for administration;
(2) (h) The name or initials of the verifying pharmacist;

855-045-0580

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

(4) (B) Mixing temperatures or other environmental controls;
(4) (C) Duration of mixing; and
(4) (A) Generic name and quantity of and concentration of each active ingredient;

370 (a) Name, strength, and dosage form of the preparation;
380 (f) Name of the person who prepared the preparation, name of the person who performed

Commented [DR7]: Why is this needed on the label? Human readable wording describes difficulty dealing with sending out multiple doses at a time and patients will be confused. A patient will not be digging through to look for the Tuesday 5am dose, they will just get one every 8 hours. Why is this necessary on an IV product and not oral products?

Commented [DR8]: Is an electronic link to who verified acceptable?

Commented [DR9]: Can a technician conduct the training and RPh validate?

Commented [DR10]: Are we expected to record the temperature of the mixing room on a master formulation record each time we mix?

Commented [DR11]: Why must this be recorded and to what level of detail is needed? Hours, minutes, seconds?

Commented [DR12]: Not sure if form should be here, but line 325 is identical and includes “form”
381 the quality control procedures, and name of the compounder who approved the
382 preparation;

390 (j) Physical evidence of the proper weight of each ingredient;

Commented [DR13]: Does technician/pharmacist initials suffice here? Or do we need 3 initials now?

Commented [DR14]: Is this for sterile and non-sterile or non-sterile only? What's an example of what OBOP would like to see for this?

855-045-6510

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

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

Commented [DR15]: Can a technician do this? Says must be performed and completed by a pharmacist, but technicians are often a better choice.

Commented [DR16]: For how long?

(a) The PIC must not be in charge of more than one licensed compounding pharmacy
492 at a
time. The PIC must be on site at that pharmacy for a minimum of twenty hours
493 per week.
494 For DISCUSSION:
495 • Does the Board want to keep this requirement?

Commented [DR17]: Yes, we agree with this requirement and think it should be kept.

496 If so, does the Board want to include waiver language for a specific pharmacy to
test if
498 waiver, per specific circumstances (to be outlined by the Board, such as rural location)?

(7) (b) Successfully complete the required competency training appropriate for the type of compounding performed or supervised;

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

570 • Does this need to be further defined?

571 • Does the Board want to require end product testing for certain batch sizes (for example, if Batch Size > ___ , compounder must perform...)

573 • Does the Board want to require an Annual Report for all compounding pharmacies to notify OBOP about details such as batch sizes, % of compounding performed patient specific vs. non-patient specific, etc.?

855-045-0620

594

595 Microbial Contamination Risk Levels and Beyond-Use-Dates

596

597 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

599 Level CSPs are determined by the potential for microbial contamination during...
600 preparation, and High-Risk Level CSPs by the potential for not being properly sterilized
601 before administration to patients. These risk levels, including Immediate-use provisions,
602 are defined, and products must be prepared and managed per current USP standards.

Commented [DR20]: These definitions (low, medium, high risk) are changing in the new USP 797 draft so best not to use them or will need to be updated when 797 draft final.
May 22, 2018

Dear Oregon Board of Pharmacy,

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

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

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

The request for 6 day beyond use dating at room temperature comes from the latest draft USP 797 guidelines. These guidelines classify CSPs prepared in a cleanroom environment as category 2 CSPs and may be given a 6 day beyond use date if prepared from only sterile starting components.\(^1\) For your reference, the second page of this letter includes the Table from the draft standards with inclusion of 6 day room temperature beyond use dating.

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

Thank you for considering this request.

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

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

Sincerely,

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

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

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

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

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

Staff recommends that the proposed compounding rules not be adopted at this time, but be re-evaluated via Board discussion at the June 2018 meeting.

Expectation of full compliance with the USP Chapter standards is not negotiable, as exhibited by the Pew Charitable Trusts report, *State Oversight of Drug Compounding*, published in February 2018. Oregon is only one of a handful of states that has yet to require full compliance with the USP standards, and our patients deserve the care and drug safety they have come to rely on from the pharmacy profession.

Staff is not recommending a Rules Advisory Committee. The Board and staff identify and utilize the necessary tools for the rule writing process including workgroups, national meetings, conversing with local pharmacists at professional society meetings, roundtable meetings, coalition meetings, and annual pharmacy inspections. For the rewrite of Division 045 (compounding rules), rule drafts have been informed by a great deal of stakeholder input and subject matter expertise.

In the early part of the process, staff held two compounding work group meetings (April 2014 and July 2014). To gain insights from other states and the federal oversight of compounding policy and regulation, staff participated in all six of the FDA’s 50 State Compounding Conferences, held in December 2012, March 2014, March 2015, November 2015, September 2016 and September 2017.

Additionally, staff have conversed regularly with licensees via phone and email and at association meetings, pharmacy roundtable meetings, coalition meetings and numerous pharmacy inspections, gaining insights to current compounding processes in Oregon, as well as the challenges licensees face when complying with USP Chapter standards.

The proposed rules are the compilation of all these efforts as well as input/policy directives from the Board at meetings since 2012.