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DATE: December 12, 2017

TO: The Honorable Stephen Nass, Senate Chair and Joan Ballweg, Assembly Chair
Members, Joint Committee for Review of Administrative Rules

RE: Clearinghouse Rule 16-085

Good Morning. My name is Philip Trapskin, I am a pharmacist at UW Health and Vice-Chair of the Wisconsin Pharmacy Examining Board. I am here today to testify for information only.

Background

The compounding of non-sterile preparations dates back to the origins of pharmacy. Only in the early 20th century do we start to see the compounding of sterile preparations with the first national standards described in the 1960s. Since that time pharmacy associations, the U.S. Food and Drug Administration (FDA), and United States Pharmacopeia (USP) have endeavored to standardize compounding best practices to safeguard the public. Unfortunately there have been dozens of examples of compounded preparations leading to illness, permanent injury and death. The highest profile case in recent history was the New England Compounding Center meningitis outbreak that infected 753 patients and caused the death of 64. Although Wisconsin was spared, multiple institutions used the services of this pharmacy prior to the outbreak.

Regulation of Compounding

Although the FDA plays a role, the oversight of compounding is left primarily to the state Boards of Pharmacy. Wisconsin is lagging behind other states in terms of contemporary rules for compounding practice and does not provide any prospective inspections of compounding practices. The only time a pharmacy is inspected in WI is when the pharmacy opens or if a complaint is submitted to the Board. In essence the practice of compounding is based on the honor system.

Phar 15

The attempt to update Phar 15 has been ongoing for almost 8 years and has used relevant USP chapters to guide the rule-writing process. As would be expected, as best practices evolve, so do the USP chapters relevant to compounding. The Pharmacy Examining Board did discuss adopting the relevant sections of USP by reference. However, the manner in which USP is worded reads more like guidance with language that is difficult to enforce (e.g. should, consider, may). The current draft was created trying to balance patient safety, regulatory burden, and evolving minimum standards.

Controversy

The Board continues to receive requests to simply adopt USP instead of writing specific rules. The Board does not feel this adequately protects the public and that some elements of USP create unnecessary regulatory burden (e.g. finger-tip sampling frequency). In addition, requirements of clean room design

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(sprinkler heads, use of displacement air) have been questioned by some pharmacists. In response to these concerns I cite the current USP language on these issues:

...The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area **shall be smooth, impervious, free from cracks and crevices,** and nonshedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents. Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame. Walls may be constructed of flexible material (e.g., heavy gauge polymer), panels locked together and sealed, or of epoxy-coated gypsum board. Preferably, floors are overlaid with wide sheet vinyl flooring with heat-welded seams and coving to the sidewall. **Dust-collecting overhangs, such as ceiling utility pipes, and ledges, such as windowsills, should be avoided. The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls shall be sealed.** The buffer area shall not contain sources of water (sinks) or floor drains. Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. Carts should be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility. Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection.

... For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. **Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area.**

... In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions...

In consultation with compounding experts, including those that server or have served on the USP Expert Committee on Compounding, the PEB feels that the current Phar 15 draft rule is consistent with what experts feel should be in place to protect the public.

Summary

In closing, I would like to thank the JCRAR for their consideration of this rule. The input of the legislature is always welcome, especially with an issue that impacts the public welfare of so many WI citizens.

Sincerely,

Philip J. Trapskin, PharmD, RPh

WHA A Valued Voice

PSW Pharmacy Society of Wisconsin

RWHC Your partner. Your source.

TO: Members, Joint Committee for Review of Administrative Rules

FROM: Jeremy Levin, Director of Advocacy – Rural Wisconsin Health Cooperative
Kyle O'Brien, Senior Vice President, Government Relations – Wisconsin Hospital Association
Danielle Womack, Director, Public Affairs – Pharmacy Society of Wisconsin
Ann Zenk, Vice President, Workforce & Clinical Practice – Wisconsin Hospital Association

DATE: December 8, 2017

RE: Clearinghouse Rule 16-085 Relating to Compounding Pharmaceuticals (Phar 15)

On behalf of our organizations and the members we represent throughout Wisconsin, we ask that you not allow CR16-085 that relates to compounding pharmaceuticals (Phar 15) to be promulgated in its current form. We ask that you send the rule back to the Pharmacy Examining Board (PEB) requesting modifications that would better harmonize Phar 15 with national standards that serve as the state standard for nearly every other state in the country. If state regulations diverge from national industry standards, our members could incur hundreds of thousands of dollars in renovations only to undergo additional renovations if and when state regulations either do not maintain up-to-date practices or conflict with national regulatory standards.

Our organizations are dedicated to patient safety and take pride in serving their communities. The United States Pharmacopeia (USP) has an almost 200-year history of standards development, where they follow a rigorous process that can take years to complete and involves many stakeholders—global experts in science and health, regulators, academics and industry. By working together, USP, industry and regulators help ensure drug quality and meet our shared goal of improving health for people around the world. For sterile compounding, regulators and accrediting bodies, such as the FDA, BQA, and Joint Commission find USP 797 regulations more than adequate to police hospital and community pharmacies to maintain good manufacturing practices. According to The Joint Commission, thirty-two states rely solely on USP regulations and, according to the PEW Charitable Trust study, at least fifteen other states require compliance equal to USP 797.

Further, according to the USP website, "[b]ased on the Expert Committee's evaluation of the public comments and significance of further revisions to the chapter, General Chapter 797 may be proposed for another public comment period." Therefore, not only is the current draft rule of Phar 15 based on a draft of USP 797, USP is openly stating that further revisions will be made, with a final regulation unlikely to be finished until 2019. If Wisconsin creates separate compounding guidelines, which will inevitably become outdated due to the administrative rules process, Wisconsin pharmacies will be forced to choose between following USP or Phar 15 guidelines.

We ask the Committee to request the following modifications to better align Wisconsin's state regulation with national best practices, protect patients and provide certainty to heavily regulated health care operators in this state.

1. Request the Pharmacy Examining Board to include a section at the beginning of this rule clearly stating the purpose of this regulation. Based on conversations stakeholders like WHA, PSW and RWHC have had with the PEB and the CR 16-085 administrative rule report to the legislature, we believe that purpose statement at the beginning of this rule should include the following: "Phar 15 is established to create a state regulatory standard that aligns with the United State Pharmacopeia Chapters 795 and 797. Pharmacy compliance with USP 795 and 797 meets the requirements established within this rule."

2. Remove provisions that are inconsistent with the USP 795 and 797 standard, including the requirement that sprinkler heads be flush with the ceiling and requirements that a door be installed separating the ante area and the buffer area. In both instances, change the rule to reflect the standards established in USP.

Thank you for your consideration. We respectfully request the Joint Committee for Review of Administrative Rules to take action to request these modifications and encourage the PEB to address outstanding issues raised by several stakeholders in this process. Please do not hesitate to contact us if you have any questions.