Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way, 2nd Floor
PO Box 8366
Madison WI 53708-8366

Phone: 608-266-2112
Web: http://dsps.wi.gov
Email: dsps@wisconsin.gov

**Tony Evers, Governor**
**Dan Hereth, Secretary**

# TELECONFERENCE/VIRTUAL
# PHARMACY RULES COMMITTEE
# of the
# PHARMACY EXAMINING BOARD
# Virtual, 4822 Madison Yards Way, Madison, WI
# Contact: Brad Wojciechowski (608) 266-2112
# February 29, 2024

*Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. A quorum of the Board may be present during any committee meetings.*

## AGENDA

## 9:00 A.M.

**OPEN SESSION – CALL TO ORDER**

**A. Approval of Agenda (1)**

**B. Approval of Minutes of January 18, 2024 (2)**

**C. Administrative Rule Matters – Discussion and Consideration (3-10)**
1) Phar 15, Relating to Compounding Pharmaceuticals
2) Pending or Possible Rulemaking Projects

**D. Public Comments**

**ADJOURNMENT**

## NEXT MEETING: APRIL 25, 2024

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, or reach the Meeting Staff by calling 608-267-7213.

**VIRTUAL/TELECONFERENCE**
**PHARMACY RULES COMMITTEE**
**MEETING MINUTES**
**JANUARY 18, 2024**

**PRESENT:** Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp

**STAFF:** Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Brenda Taylor, Board Services Supervisor; and other Department staff

## CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 9:00 a.m. A quorum was confirmed with four (4) members present.

## ADOPTION OF AGENDA

**MOTION:** Susan Keppin moved, seconded by Tiffany O'Hagan, to adopt the Agenda as published. Motion carried unanimously.

## APPROVAL OF MINUTES OF DECEMBER 7, 2023

**MOTION:** Susan Kleppin moved, seconded by Anthony Peterangelo, to approve the Minutes of December 7, 2023, as published. Motion carried unanimously.

## ADJOURNMENT

**MOTION:** Anthony Peterangelo moved, seconded by Susan Kleppin, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 9:53 a.m.

# State of Wisconsin
# Department of Safety & Professional Services

## AGENDA REQUEST FORM

| 1) Name and title of person submitting the request: | 2) Date when request submitted: |
|---|---|
| **Nilajah Hardin**<br>**Administrative Rules Coordinator** | **02/16/24**<br>**Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting** |

**3) Name of Board, Committee, Council, Sections:**

Pharmacy Examining Board Rules Committee

| 4) Meeting Date: | 5) Attachments: | 6) How should the item be titled on the agenda page? |
|---|---|---|
| **02/29/24** | ☒ Yes<br>☐ No | **Administrative Rule Matters – Discussion and Consideration**<br>**1. Phar 15, Relating to Compounding Pharmaceuticals**<br>**2. Pending or Possible Rulemaking Projects** |

| 7) Place Item in: | 8) Is an appearance before the Board being scheduled? *(If yes, please complete **Appearance Request** for Non-DSPS Staff)* | 9) Name of Case Advisor(s), if required: |
|---|---|---|
| ☒ Open Session<br>☐ Closed Session | ☐ Yes<br>☒ No | **N/A** |

**10) Describe the issue and action that should be addressed:**

Attachments:
1. Phar 15 Preliminary Rule Draft
2. Mississippi and Tennessee Compounding Language

Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

**11) Authorization**

Nilajah D. Hardin — 02/16/24

**Signature of person making this request** — **Date**

**Supervisor (if required)** — **Date**

**Executive Director signature (indicates approval to add post agenda deadline item to agenda)** — **Date**

**Directions for including supporting documents:**
**1. This form should be attached to any documents submitted to the agenda.**
**2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.**
**3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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| | | |
|---|---|---|
| IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD | : | PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE ) |

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PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate chapter Phar 15, relating to Compounding Pharmaceuticals.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** s. 450.01 (16), Stats.

**Statutory authority:** ss. 15.08 (5) (b), and 450.02 (3) (d) and (e), Stats.

**Explanation of agency authority:**
Section 15.08 (5) (b), Stats. states that "The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 450.02 (3) (d), Stats. says that the board "may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

Section 450.02 (3) (e), Stats. provides that the board "may promulgate rules establishing minimum standards for the practice of pharmacy."

**Related statute or rule:** N/A

**Plain language analysis:**
The Pharmacy Examining Board recently completed a revision to Wisconsin Administrative Code Chapter Phar 15 which became effective on August 1, 2022. The objective of this rule is to repeal and recreate the recent version of Phar 15 to incorporate by reference United States Pharmaceopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020.

**Summary of, and comparison with, existing or proposed federal regulation:**
The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, labeling requirements and may distribute compounded drugs in response to an order that is not patient specific. The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions.

**Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule:** N/A

**Comparison with rules in adjacent states:**
**Illinois**: For patient-specific prescriptions, sterile and unsterile pharmaceutical compounding is governed by the USP 42-NF 37 from the 2019 USP Compounding Compendium, except for USP Chapter 800. Additionally, all pharmacies that compound drugs must maintain a set of minimum standards and equipment. These requirements include a specific area for compounding materials, accurate scales or measuring equipment, a separate area for compounding, a record keeping system for tracking compounded drugs, drug distribution procedures, and labelling. Additional requirements for sterile compounding include current reference materials, pharmacist availability at all times to answer patient and health care professional questions, and emergency medications for adverse drug reactions to compounded sterile drugs. [Illinois Administrative Code s. 1330.640]. In Illinois, the definition of "compounding" excludes flavorings [225 Illinois Compiled Statutes 85 s. 3 (o)].

**Iowa**: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. Additionally, Iowa includes requirements for the use of flavoring agents. These requirements include that pharmacist may add flavoring in the amount of not more than percent of the total volume of the drug. The beyond-use date of the flavored drug must be no greater than 14 days and the pharmacist must document that a flavoring agent was added ot a drug. Compliance with USP Chapter 825 is not required, however Iowa does have its own rules for radiopharmaceuticals and nuclear pharmacy [Iowa Administrative Code ss.657.16 and 657.20].

**Michigan**: Michigan requires a pharmacy that provides compounding services to be licensed as a pharmacy and authorized to provide compounding services. The pharmacy must be accredited through a national accrediting organization and be in compliance with USP standards [Michigan Compiled Laws s. 333.17748a to c]. In Michigan, the definition of "compounding" does not include flavoring agents that are nonallergenic, inert, and not more than 5% of the drug's total volume [Michigan Administrative Rules R 338.501 (1) (e)].

**Minnesota:** Minnesota requires pharmacies compounding nonsterile drug preparations to follow USP chapter 795 standards. Pharmacies compounding sterile drug preparations are required to follow USP chapter 797 standards. [Minnesota Administrative Rules s.6800.3300]

**Summary of factual data and analytical methodologies:** In addition to the four adjacent states listed above, the Pharmacy Examining Board also reviewed statutes and regulations regarding compounding pharmaceuticals from other states including Arizona, California, Colorado, Connecticut, Idaho, Kentucky, Lousiana, Massachusetts, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wyoming.

**Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:**
The rule will be posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens.

**Fiscal Estimate and Economic Impact Analysis:**
The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

**Effect on small business**:
These rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

**Agency contact person**:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

**Place where comments are to be submitted and deadline for submission:**
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

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TEXT OF RULE

Section 1. Chapter Phar 15 is repealed and recreated to read:

## Chapter Phar 15
## PHARMACEUTICAL COMPOUNDING, SAFE HANDLING OF HAZARDOUS DRUGS, AND RADIOPHARMACEUTICALS

**Phar 15.01 Definitions.** In this chapter:
**(1)** "USP-NF" means the United States Pharmacopeia-National Formulary published by the United States Pharmacopeial Convention.

**Phar 15.02 Incorporation of Standards. (1)** PHARMACEUTICAL COMPOUNDING - NONSTERILE PREPARATIONS. USP-NF general chapter 795, official as of November 1, 2023, is incorporated by reference into this chapter, subject to the exception that nonsterile compounding does not include the addition of nonallergenic, therapeutically inert flavoring agents to a conventionally manufactured drug product. The pharmacist shall also comply with the following requirements when adding flavoring agents to a drug product:

(a) The pharmacist shall ensure that the flavoring agent is not more than 5 percent of the product's total volume.
(b) The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented.
(c) The pharmacist shall document the addition of flavoring as part of the prescription record. The documentation shall include the type of flavoring agent, manufacturer, lot number, and expiration date.
(d) A prescription is required before a pharmacist may add flavoring to an over-the-counter product.

**(2)** PHARMACEUTICAL COMPOUNDING - STERILE PREPARATIONS. USP-NF general chapter 797, official as of November 1, 2023, is incorporated by reference into this chapter.
**(3)** SAFE HANDLING OF HAZARDOUS DRUGS. USP-NF general chapter 800, official as of December 1, 2023, is incorporated by reference into this chapter.
**(4)** RADIOPHARMACEUTICALS. USP-NF general chapter 825, official as of December 1, 2020, is incorporated by reference into this chapter.

**Note:** Copies of the above standards are on file in the offices of the legislative reference bureau. A copy of the USP-NF can be purchased from the United States Pharmacopeial Convention at https://usp.org.

**Phar 15.03 Compliance.** Noncompliance with ch. Phar 15 may be considered a violation of s. Phar 10.03 and may result in disciplinary action by the Board against a licensee.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

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(END OF TEXT OF RULE)

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**From:** Tiffany OHagan
**To:** DeVoe, Whitney - DSPS; Hardin, Nilajah - DSPS; Wojciechowski, Brad - DSPS
**Subject:** Re: Simple compounding
**Date:** Monday, January 15, 2024 5:33:37 PM



This is what TN is working on

Authority: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.

Rule 1140-07-.09 Quality Assurance is amended by deleting the rule in its entirety, including the title, and substituting instead the following language, so that as amended, the new title and rule shall read:

1140-07-09 Nonsterile Simple Compounding Preparations

(1) The combining of commercially manufactured ready-to-use products shall be exempt from the 'Compounding Facilities' requirements in the USP 795 compounding standards if all of the following conditions are met:

(a) Only commercially manufactured ready-to-use products (that have not been manipulated) are used. Manipulation occurs when a change of a commercially available drug product occurs for patient-specific



needs beyond United States Food and Drug Administration approved labeling. Crushing, using a surfactant, diluting or using a dosage form that exists as a granule or powder is manipulating for the purpose of this section.

(b) Compounding is not prepared in anticipation of medication orders.

(c) Beyond Use Dates are assigned in accordance with the current standards of USP 795.

(d) The label complies with the labeling requirements as set forth in Tenn. Comp. R. and Regs. 1140-07-.06.

(e) The compounding record complies with the requirements as set forth in Tenn. Comp. R. and Regs. 1140-07-.02.

(2) Solely adding flavoring to medications is not considered compounding.

(3) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.

On Sat, Jan 13, 2024 at 2:56 PM Tiffany OHagan wrote:

> Hello,
> I found some simple compounding verbiage that may be useful. I have spoken to a few smaller independent pharmacies that do simple compounds (not large amounts of compounding, therefore not money makers that would make it a wise financial decision to continue -cost of USP subscription and other enhancements needed).
>
> Every pharmacy permitted by the Mississippi Board of Pharmacy engaged in the compounding of pharmaceuticals shall comply with USP 797 and 795 standards. The designated USP representative must be a pharmacist licensed in the State of Mississippi.
>
> 1. General Provisions
>
> C. For the purpose of this Article, the combining of commercially manufactured, ready to-use products shall be exempt from USP 795 compounding standards under the following conditions:
>
> i. No more than four (4) commercially manufactured ready-to-use products (that have not been manipulated) are used;
>
> ii. Compounding is not done in anticipation of medication orders;
>
> iii. Must follow USP 795 beyond use dates (BUDs);
>
> iv. A valid prescription shall serve as the compounding record;
>
> v. The prescription label shall comply with the labeling requirements as set forth in Article XIV of these regulations and also include:
>
> (1) Name of Preparation;
> (2) Strength and concentration of each component;
> (3) Beyond Use Date;
> (4) Special storage requirements, if applicable; and
> (5) Cautionary auxiliary labels, if applicable.
>
> Thank you,
> Tiffany