**STATE OF WISCONSIN**
**PHARMACY EXAMINING BOARD**

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| **IN THE MATTER OF RULEMAKING** | **:** | |
| **PROCEEDINGS BEFORE THE** | **:** | **REPORT TO THE LEGISLATURE** |
| **PHARMACY EXAMINING BOARD** | **:** | **CR 24-092** |

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## I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

## II. REFERENCE TO APPLICABLE FORMS: N/A

## III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

## IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

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 Pharmacopeia (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. The Board will request approval from the Attorney General, as required by s. 227.21 (2), Stats., prior to submission of this rule for final adoption and publication.

## V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Pharmacy Examining Board held a public hearing on February 20, 2025 on CR 24-092. The following people either testified at the hearing, or submitted written comments:

- Danielle Womack, Vice President of Public Policy and Advocacy for the Pharmacy Society of Wisconsin

The Pharmacy Examining Board summarizes the comments received either by hearing testimony or by written submission as follows:

- The Pharmacy Society of Wisconsin submitted the following comments:
    - Is it the Board's intent to require compliance with USP General Chapter 800, whether they compound or not?
    - Can a pharmacy document a different timeframe or do 14-day beyond-use dates for flavoring under Phar 15.02 (1)(b) required?
    - What patient protection is offered if flavoring is not considered compounding?
    - What grounds does the Board have for disciplinary action for failure to meet "should" standards under USP General Chapter 797?

- Does USP General Chapter 797 being incorporated by reference into the Administrative Code mean that compliance is required with all other USP chapters cited in that chapter?
- Will copies of the incorporated chapters be available through the Legislative Reference Bureau?
- How should pharmacies label non-patient-specific or office use compounding products?

The Pharmacy Examining Board made the following modifications to its rule-making proposal based on public comments:

- Phar 15.02 (1) (b) is revised to read "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 a shorter beyond-use-date has been documented."
- The following has been added to section Phar 15.03: "**(2)** DIFFERING REQUIREMENTS. **(a)** Where any Board rule in this chapter differs from a requirement within a standard referenced in this chapter, the Board rule shall govern.

  **(b)** Except as provided in par. (a), where a provision of this chapter prescribes a general requirement and another provision of this chapter prescribes a specific or more detailed requirement regarding the same subject, the specific or more detailed requirement shall govern.

  **(c)** Except as provided in pars. (a) and (b), where different sections of this chapter specify conflicting requirements. The most restrictive requirement, as determined by the Board, shall govern."

## VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

**Comment 2b:** "Should the material created in s. Phar 15.03 either be moved to, or at least referenced within, current s. Phar 10.03? Additionally, it is confusing that the provisions says it only "may" be considered a violation. Does that give adequate notice to practitioners about what is required?"

**Response**: The board accepts this comment and would like to note that the standards being incorporated are already required by the United States Food and Drug Administration, so there should be no need to give notice to licensees.

**Comment 2c:** "The agency could consider whether an initial applicability clause should be added to the proposed rule, if there could be circumstances in which the new rule could apply to compounding that was initiated before the effective date of the rule. [s. 1.06 (3), Manual.]"

**Response**: The board accepts this comment and would like to note that standards being incorporated are already required by the United States Food and Drug Administration, so there should be no need an initial applicability clause.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

## VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

| | | |
|---|---|---|
| IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD | : | PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 24-092) |

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.

ANALYSIS

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

**Statutory authority:** ss. 15.08 (5) (b), 227.21 (2) (a), and 450.02 (3) (d) and (e), Stats.

**Explanation of agency authority:**
Section 15.08 (5) (b), Stats. states that "[t]he 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 227.21 (2)(a), Stats. states that "[e]xcept as provided in s. 601.41 (3) (b), to avoid unnecessary expense an agency may, with the consent of the attorney general, adopt standards established by technical societies and organizations of recognized national standing by incorporating the standards in its rules by reference to the specific issue or issues of the publication in which they appear, without reproducing the standards in full."

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 Pharmacopeia (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. The Board will request approval from the Attorney General, as required by s. 227.21 (2), Stats., prior to submission of this rule for final adoption and publication.

**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 to 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, Louisiana, 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 was 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. No comments were received.

**Fiscal Estimate and Economic Impact Analysis:**
The Fiscal Estimate and Economic Impact Analysis is attached.

**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) 266-2112.

**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; email at DSPSAdminRules@wisconsin.gov.

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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, "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 drug with a beyond-use date no greater than 14 days past the date the flavoring agent is added if the drug is required to be stored in a refrigerator. A different beyond-use date or alternate storage conditions may be indicated if such variation is supported by peer-reviewed medical literature or manufacturer's recommendations. The pharmacist shall electronically or manually document that a flavoring agent was added to a drug.
- **(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 July 1, 2020, is incorporated by reference into this chapter.
**(4)** RADIOPHARMACEUTICALS. USP-NF general chapter 825, official as of January 1, 2024, is incorporated by reference into this chapter.

**Note:** Copies of the above standards are on file in the office 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.** (1) UNPROFESSIONAL CONDUCT. Noncompliance with ch. Phar 15 shall be considered a violation of s. Phar 10.03 and may result in disciplinary action by the Board against a credential holder.
**(2)** DIFFERING REQUIREMENTS. **(a)** Where any Board rule in this chapter differs from a requirement within a standard referenced in this chapter, the Board rule shall govern.

**(b)** Except as provided in par. (a), where a provision of this chapter prescribes a general requirement and another provision of this chapter prescribes a specific or more detailed requirement regarding the same subject, the specific or more detailed requirement shall govern.

**(c)** Except as provided in pars. (a) and (b), where different sections of this chapter specify conflicting requirements. The most restrictive requirement, as determined by the Board, shall govern.

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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This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Dated 4/21/2025 Agency _____

Member
Pharmacy Examining Board

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

# ADMINISTRATIVE RULES
## Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
12/09/24

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 15

4. Subject
Compounding Pharmaceuticals

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
s20.165 (1) (hg)

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
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

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule was posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
DSPS estimates a total of $5,955.00 in one-time costs for implementing this rule. The one-time staff costs support 0.1 limited term employee to undertake tasks such as rule drafting, regal review, training on new rules, and updating forms and website.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is that there will be clear and up to date standards fo pharmaceutical compounding, safe handling of hazardous drugs, and radiopharmaceuticals in Pharmacy practice.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are increased safety in pharmacy practice in Wisconsin .

17. Compare With Approaches Being Used by Federal Government

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# ADMINISTRATIVE RULES
## Fiscal Estimate & Economic Impact Analysis

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18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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)].

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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]

| 19. Contact Name | 20. Contact Phone Number |
|---|---|
| Nilajah Hardin, Administrative Rules Coordinator | 608-267-7139 |

This document can be made available in alternate formats to individuals with disabilities upon request.

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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# ADMINISTRATIVE RULES
# Fiscal Estimate & Economic Impact Analysis

## ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

**STATE OF WISCONSIN**
**DEPARTMENT OF JUSTICE**

**Josh Kaul**
**Attorney General**

**17 W. Main Street**
**P.O. Box 7857**
**Madison, WI 53707-7857**
**www.doj.state.wi.us**

**Lara Sutherlin**
**Administrator**
**Division of Legal Services**
**sutherlinl@doj.state.wi.us**
**608/224-4929**

May 14, 2025

John Weitekamp, R.Ph.
Chairperson
Pharmacy Examining Board
4822 Madison Yards Way
PO Box 8366
Madison, WI 53708-8366

Re: Incorporation by Reference of Standards and Technical Materials into Wis. Admin. Code ch. Phar 15

Dear Chairperson Weitekamp:

By letter of April 22, 2025, the Pharmacy Examining Board proposed to incorporate by reference certain standards into the Wisconsin Administrative Code, Chapter Phar 15, relating to compounding pharmacies. The Pharmacy Examining Board represents that the relevant standards were created by the United States Pharmacopeia (USP), which is a nationally recognized technical society and organization.

The Pharmacy Examining Board represents that pursuant to Wis. Stat. § 15.08(5)(b), the Pharmacy Examining Board is required promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, including compounding pharmacies. Wisconsin Stat. § 450.02(3)(d) states that the Pharmacy Examining Board "may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961." Similarly, Wis. Stat. § 450.02(3)(e) states that the Board "may promulgate rules establishing minimum standards for the practice of pharmacy." The Pharmacy Examining Board further represents that incorporation by reference of the pertinent standards is necessary to avoid unwarranted expense, be more efficient, and create less confusion.

I am aware that the proposed rule package is posted online at: https://dsps.wi.gov/Documents/BoardCouncils/PHM/20240829PHMRulesFullPacket.pdf, and that the pertinent section of Wis. Admin. Code ch. Phar 15 identifies how the incorporated material may be obtained and states that the material is on file at the office of the legislative reference bureau and online at https://usp.org.

Pursuant to the Attorney General's Authority under Wis. Stat. § 227.21(2), the following standards are approved for incorporation by reference:

| **Proposed Code Section** | **Author of Standard** | **Name of Standard** |
|---|---|---|
| Phar 15.02(1) | USP | Pharmaceutical Compounding – Nonsterile Preparations (USP General Chapter 795) |
| Phar 15.02(2) | USP | Pharmaceutical Compounding – Sterile Preparations (USP General Chapter 797) |
| Phar 15.02(3) | USP | Safe Handling of Hazardous Drugs (USP General Chapter 800) |
| Phar 15.02(4) | USP | Radiopharmaceuticals (USP General Chapter 825) |

For these reasons, the Attorney General consents to the incorporation of these standards in the agency's rules by reference.

Sincerely,

*/s Lara Sutherlin*

Lara Sutherlin
Administrator
Division of Legal Services

LS:LEM