Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Tony Evers, Governor
Dawn B. Crim, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
February 18, 2022

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions of the Board.

AGENDA

10:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-2)

B. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Board Members – Term Expiration Dates
   a. Kleppin, Susan – 7/1/2025
   b. O'Hagan, Tiffany – 7/1/2024
   c. Peterangelo, Anthony – 7/1/2023
   d. Walsh, Michael – 7/1/2024
   e. Weiss, Shana – 7/1/2023
   f. Weitekamp, John – 7/1/2022
   g. Wilson, Christa – 7/1/2025

C. Administrative Rule Matters – Discussion and Consideration
1) Phar 15, Relating to Compounding Pharmaceuticals **(3-22)**
   a. Review Public Hearing Comments and Respond to Clearinghouse Report
2) Pending or Possible Rulemaking Projects

D. Public Comments

ADJOURNMENT

NEXT MEETING: MARCH 3, 2022

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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 at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person.

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 deaf or hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, 608-266-2112, or the Meeting Staff at 608-266-5439.

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 **Administrative Rules Coordinator**	**02/08/22** **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

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
02/18/22	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Phar 15, relating to Compounding Pharmaceuticals** **a. Review Public Hearing Comments and Respond to Clearinghouse Report** **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 ☐ Closed Session	☐ Yes ☒ No	**N/A**

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

Attachments:
1. Phar 15 Rule Draft
2. Clearinghouse Report
3. Public Comments – Cardinal Health Nuclear & Precision Health Solutions

11) Authorization

Nilajah D. Hardin — 02/08/22

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

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to amend Phar 15.33 (10) and 15.37 (1); create Phar 15.30 (10m), (14g) and (14r), and 15.37 (5), (6), and (7); and repeal and recreate Phar 15.34, relating to compounding pharmaceuticals.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.01 (16)

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

Explanation of agency authority:

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. [s. 15.08 (5) (b), Stats.]

The board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961 and establish minimum standards for the practice of pharmacy. [s. 450.02 (3) (d) and (e), Stats.]

Related statute or rule: N/A

Plain language analysis:

The objective of the rule is to review the updated United States Pharmacopeia (USP) 795 and 797 standards, which originally had a publication date of June 1, 2019 with an anticipated official date of December 1, 2019. However, due to appeals filed, the 2019 revisions of the USP are currently on hold. The 2008 USP 795 and 797 are the current standard for pharmacy compounding until those 2019 standards are published and effective.

Even though the Board will not be moving forward with the 2019 revisions at this time, there are still updates that need to be made to Phar 15 to align it with the 2008 USP 795 and 797 chapters that are currently in effect. It is the Board's intent to amend Phar 15 without creating an unnecessary burden on Wisconsin pharmacies, while still aligning it with the current USP chapters. When new updated standards are available, the Board will consider opening a new scope statement to address any further changes if applicable.

Summary of, and comparison with, existing or proposed federal regulation:

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. For non-patient specific or "office use" of non-sterile compounded drugs, additional requirements apply. Among them, retrievable records must be maintained for at least 5 years and specific labelling requirements for office use. 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]

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. In addition, an FDA registered outsourcing facility must be licensed as a pharmacy in Iowa. [Iowa Administrative Code ss. 657.20.3, 657.20.4, and 657.20.6]

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. 333.17748]

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:

The Pharmacy Examining Board primarily utilized United States Pharmacopeia chapters 795 and 797 which are the recognized pharmacopeia standards.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The proposed rules were posted for a period of 30 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No economic impact comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis are attached.

Effect on small business:

These proposed rules do have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. and were submitted to the Small Business Regulatory Review Board for a determination on whether the rules will have a significant economic impact on a substantial number of small businesses. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; 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, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing on February 14, 2022 at 11:00 a.m., to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1 Phar 15.30 (10m), (14g), and (14r) are created to read:

Phar 15.30 (10m) "High-risk level compounded sterile preparations" means preparations compounded from non-sterile ingredients or from ingredients that are incorporated using non-sterile equipment before terminal sterilization, or from commercially manufactured sterile products that lack effective antimicrobial preservatives and whose preparation, transfer, sterilization, and packaging is performed in air quality worse than ISO class 5 for more than one hour. Water containing preparations that are stored for more than six hours before terminal sterilization are also classified as high-risk level compounded sterile preparations.

(14g) "Low-risk level compounded sterile preparations" means preparations compounded with aseptic manipulations entirely within ISO class 5 or better air quality using only sterile ingredients, products, components, and devices. The compounding process involves only transfer, measuring, and mixing, using no more than three commercially manufactured sterile products, and not more than two entries into one sterile container or package to make the compounded sterile preparations. The compounding process is limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

(14r) "Medium-risk level compounded sterile preparations" means preparations compounded under low-risk level conditions but which require multiple individual or small doses of sterile products to be combined or pooled to prepare compounded sterile preparations that will be administered either to multiple patients or to one patient on multiple occasions. The compounding process includes complex aseptic manipulations other than single volume transfer, and requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

SECTION 2 Phar 15.33 (10) is amended to read:

Phar 15.33 (10) Entry points on bags and vials shall be wiped with small sterile 70% isopropyl alcohol swabs or comparable method for disinfecting, allowing the isopropyl alcohol to dry before piercing stoppers with sterile needles and breaking necks of ~~ampuls~~ ampules. The surface of the sterile 70% isopropyl alcohol swabs used for disinfecting entry points of sterile package and devices may not contact any other object before contacting the surface of the entry point. Particle generating material may not be used to disinfect the sterile entry points of packages and devices.

SECTION 3 Phar 15.34 is repealed and recreated to read:

Phar 15.34 Immediate use compounded sterile preparations. Immediate-use compounded sterile preparations are exempt from the requirements described for low-risk level, Category 1, and Category 2 compounding sterile preparations only when all the following criteria are met:

(1) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package of sterile infusion solution or administration container or device.

(2) Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.

(3) During preparation, aseptic technique is followed and, if not immediately administered, the finished compound sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compound sterile preparations, and direct contact of outside surfaces.

(4) Administration begins not later than 4 hours following the start of the preparation.

(5) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared it, and the exact 4-hour BUD and time.

(6) If administration of the compounded sterile preparation has not begun within 4 hours following the start of preparation, it shall be promptly, properly, and safely discarded.

SECTION 4 Phar 15.37 (1) is amended to read:

Phar 15.37 (1) Sterility and stability considerations shall be taken into account when establishing a BUD. Either Category 1 and 2, or low, medium, and high risk compounding preparation standards may be used, but not a combination of the two within the same pharmacy. The following dates and times for storage and initiation of administration of the compounded sterile preparations shall apply:

(a) For compounded sterile preparations including components from conventionally manufactured products, the BUD shall not exceed the shortest expiration of any of the starting components. If the compounded sterile preparation includes non-conventionally manufactured products, the BUD may not exceed the shortest BUD of any of the starting components.

(b) For Category 1 compounded sterile preparations, one of the following:

1. May not exceed 12 hours when the preparation is stored at controlled room temperature.

2. May not exceed 24 hours when the preparation is stored in a refrigerator.

(c) For aseptically processed Category 2 ~~compounded~~ processed sterile preparations, one of the following:

1. No sterility testing performed or sterility testing not passed, and ~~Prepared~~ prepared with one or more nonsterile ~~ingredients~~ starting components, ~~which are sterilized with a validated sterilization procedure prior to compounding no preservative added and no sterility testing performed~~ one of the following:

a. Within 14 days when the preparation is stored at controlled room temperature.

b. Within ~~7~~ 4 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

2. ~~Prepared only with sterile ingredients, no preservative added and no~~ No sterility testing performed or sterility testing not passed, and prepared with only sterile starting components, one of the following:

a. Within ~~6~~ 4 days when the preparation is stored at controlled room temperature.

b. Within ~~9~~ 10 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

3. ~~Prepared only with sterile ingredients, preservative added and no sterility~~ Sterility testing performed and passed, one of the following:

a. Within ~~28~~ 30 days when the preparation is stored at controlled room temperature.

b. Within ~~42~~ 45 days when the preparation is stored in a refrigerator.

c. Within ~~45~~ 60 days when the preparation is stored in a freezer.

~~4. Prepared only with sterile ingredients, no preservative added and sterility testing, one of the following:~~

~~a. Within 28 days when the preparation is stored at controlled room temperature.~~

~~b. Within 42 days when the preparation is stored in a refrigerator.~~

~~c. Within 45 days when the preparation is stored in a freezer.~~

~~5. Prepared only with sterile ingredients, preservative added and sterility testing, one of the following:~~

~~a. Within 42 days when the preparation is stored at controlled room temperature.~~

~~b. Within 42 days when the preparation is stored in a refrigerator.~~

~~c. Within 45 days when the preparation is stored in a freezer.~~

(d) For Category 2 compounded sterile preparations, terminally sterilized by a validated procedure, one of the following:

1. ~~Prepared with no preservative and no~~ No sterility testing performed or sterility testing not passed, one of the following:

a. Within 14 days when the preparation is stored at controlled room temperature.

b. Within 28 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

2. ~~Prepared with no preservative added and sterility~~ Sterility testing performed and passed, one of the following:

a. Within ~~28~~ 45 days when the preparation is stored at controlled room temperature.

b. Within ~~42~~ 60 days when the preparation is stored in a refrigerator.

c. Within ~~45~~ 90 days when the preparation is stored in a freezer.

~~3. Prepared with preservative added and no sterility testing performed, one of the following:~~

~~a. Within 28 days when the preparation is stored at controlled room temperature.~~

~~b. Within 42 days when the preparation is stored in a refrigerator.~~

~~c. Within 45 days when the preparation is stored in a freezer.~~

~~4. Prepared with preservative added and sterility testing performed, one of the following:~~

~~a. Within 42 days when the preparation is stored at controlled room temperature.~~

~~b. Within 42 days when the preparation is stored in a refrigerator.~~

~~c. Within 45 days when the preparation is stored in a freezer.~~

SECTION 5 Phar 15.37 (5), (6), and (7) are created to read:

Phar 15.37 (5) For low-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 48 hours when the preparation is stored at controlled room temperature.

(b) Within 14 days when the preparation is stored at cold temperatures between 2 and 8 degrees Celsius.

(c) Within 45 days when the preparation is stored in a solid frozen state at -20 degrees Celsius.

(d) For products prepared in an airflow workbench not located in a buffer area, administration shall begin within 12 hours or less of preparation.

(6) For medium-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) within 30 hours when the preparation is stored at controlled room temperature.

(b) within nine days when the preparation is stored at cold temperatures between 2 and 8 degrees Celsius.

(c) within 45 days when the preparation is stored in a solid frozen state at -20 degrees Celsius.

(7) For high-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 24 hours when the preparation is stored at controlled room temperature.

(b) Within three days when the preparation is stored at cold temperatures.

(c) Within 45 days when the preparation is stored in a solid frozen state.

SECTION 6 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.

(END OF TEXT OF RULE)

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
January 18, 2022

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
20.165 (1) (g)

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 objective of this rule amend Phar 15 without creating an unnecessary burden on Wisconsin pharmacies, while still aligning it with the current 795 and 797 USP chapters.

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 proposed rules were posted for a period of 30 days on the Department of Safety and Professional Services' website to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No economic impact 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)
No economic or fiscal impacts are anticipated for specific businesses, sectors, ratepayers, local governments, or the state's economy as a whole. A total of $650.00 in one time costs are anticpated to be absorobed within the operating budget of the Department of Safety and Professional Services.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefits of implementing this rule is clear standards for the practice of pharmaceutical compounding until the next revision of USP chapters 795 and 797 occur. The alternative to implementing the rule is that Wisconsin Administrative Code Chapter Phar 15 would remain in conflict with current USP standards.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are clear standards for pharmaceutical compounding in Wiscsonsin.

17. Compare With Approaches Being Used by Federal Government

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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.

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. For non-patient specific or "office use" of non-sterile compounded drugs, additional requirements apply. Among them, retrievable records must be maintained for at least 5 years and specific labelling requirements for office use. 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]

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. In addition, an FDA registered outsourcing facility must be licensed as a pharmacy in Iowa. [Iowa Administrative Code ss. 657.20.3, 657.20.4, and 657.20.6]

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. 333.17748]

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

LCRC
FORM 2

Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **22-007**

AN ORDER to amend Phar 15.33 (10) and 15.37 (1); to create Phar 15.30 (10m), (14g) and (14r), and 15.37 (5), (6), and (7); and to repeal and recreate Phar 15.34, relating to compounding pharmaceuticals.

Submitted by **PHARMACY EXAMINING BOARD**

01-18-2022 RECEIVED BY LEGISLATIVE COUNCIL.
02-07-2022 REPORT SENT TO AGENCY.

SG:SM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☐ NO ☑

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☐ NO ☑

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE RULE 22-007

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Council Staff and the Legislative Reference Bureau, dated November 2020.]

2. Form, Style and Placement in Administrative Code

a. For the definition of "High-risk level compounded sterile preparations", consider modifying the last sentence to identify the defined term, perhaps changing the material to: ""High-risk level compounded sterile preparations" include water containing preparations that are stored for more than six hours before terminal sterilization."

b. For the definitions of "Low-risk level compounded sterile preparations" and "Medium-risk level compounded sterile preparations", the sentences within those definitions that begin with the material, "The compounding process …", appear to be substantive provisions that may not be appropriate to include within a definition. [s. 1.07 (1) (d), Manual.]

c. Is it necessary to specifically define "immediate use compounded sterile preparations", as that term is used in s. Phar 15.34? Also, presence or absence of a hyphen between "immediate" and "use" should be consistent. Presently, the rule text of s. Phar 15.34 uses the hyphen but s. Phar 15.34 (title) does not.

d. The treatment of SECTION 4 should more accurately describe the provisions of the existing code that are amended. Section Phar 15.37 (1) (a) and (b) are included but not changed by the proposed rule, so it appears the rule should treat only s. Phar 15.37 (1) (intro.,), (c), and (d). Also, in s. Phar 15.37 (1) (c) 1. (intro.), underscored material should follow stricken material at the beginning of the sentence. In s. Phar 15.37 (1) (c) 1. a., the treatment to revise the deadline to 14 days should be written "~~4~~ 14".

13 January 2022

Nilajah Hardin,
Administrative Rules Coordinator
Division of Policy Development
Department of Safety and Professional Services
PO Box 8366
Madison, WI 53708-8935
DSPSAdminRules@wisconsin.gov

Dear Board,

Cardinal Health Nuclear & Precision Health Solutions is pleased to submit comments to the Wisconsin Pharmacy Examining Board on the proposed revisions to regulations pertaining to sterile and nonsterile compounding in Wisconsin.

Cardinal Health can trace its lineage in the nuclear pharmacy industry back to the inception of centralized radiopharmacy practice in 1972. From that simple beginning, we have become one of the industry's leaders with 131 specialized radiopharmacies operating in 45 States, including 4 radiopharmacies in Wisconsin, located in Appleton, Madison, Marshfield, and West Allis.

As you are no doubt aware, the current (2012) USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations contains sections on hazardous drugs and radiopharmaceuticals that have been split out into three separate Chapters. In fact, there are four separate General Chapters that encompass sterile and nonsterile compounding. These are;

- <795> Pharmaceutical Compounding – Nonsterile Preparations
- <797> Pharmaceutical Compounding—Sterile Preparations
- <800> Hazardous Drugs—Handling in Healthcare Settings
- <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging

Radiopharmaceuticals at last have their own General Chapter. In June 2020 General Chapter <825> was made official. Nuclear pharmacy represents a very small percentage of all pharmacy practice settings. It is estimated that of more than 200,000 registered pharmacists only about 2,000 have the specialized training required to practice in nuclear pharmacy. Presently there are ~5 nuclear pharmacies in Wisconsin employing ~13 nuclear pharmacists and ~16 pharmacy technicians. This unique pharmacy practice was the first Board of Pharmacy Specialties (BPS) recognized practice area, initially recognized in 1978. It took another decade for the next specialty practice area to be recognized.

In Iowa, ARC 5352C became effective February 3, 2021, and amends Chapter 16, "Nuclear Pharmacy Practice". The amendment requires nuclear pharmacies to comply with the standards identified in USP General Chapter 825 which became official December 1, 2020.

In addition to Iowa, Washington, New Mexico, Mississippi, Connecticut and Ohio require compliance with the standards of USP <825. We would encourage the Wisconsin Pharmacy Examining Board to take this opportunity to ensure that citizens of Wisconsin receive the best radiopharmaceutical care possible by following the example of their neighboring state Iowa as well as the 5 other states listed in writing regulations that require adherence to the standards in USP <825>.

Thank you again for allowing us to provide these comments on the proposed regulation changes. If you would like to discuss any of the above comments, please feel free to contact me at 614-757-3174.

Best regards.

Richard L. Green, BS Pharm, R.Ph. BCNP, FAPhA
Director of Radiopharmacy Practice
Quality & Regulatory Department
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CVSHealth

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Via Electronic Mail

February 10, 2022

Nilajah Hardin
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DSPSAdminRules@wisconsin.gov

RE: Chapter Phar 15 Compounding Pharmaceuticals-Sterile Compounding

Dear Nilajah Hardin:

I am writing to you in my capacity as Pharmacy Regulatory Affairs Director for CVS Health and its family of pharmacies located across the country. CVS Health would like to thank the Pharmacy Examining Board ("Board") for their constant vigilance to continuously improve regulations that enhance patient care and guide the practice of pharmacy in Wisconsin. Through our integrated offerings across the spectrum of pharmacy care, we are uniquely positioned to provide greater access to care, engage plan members in behaviors that improve their health, and lower overall costs for health plans and their members. CVS Health provides multiple points of care to patients via our retail, mail, infusion, long-term-care, specialty pharmacies and Minute Clinics.

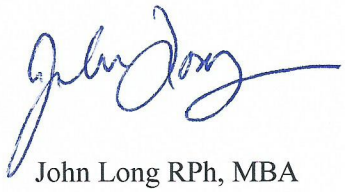
Based on the proposed revisions to Chapter Phar 15 from the Pharmacy Examining Board, CVS Health would like to provide the following comments on the new/amended rules.

While reviewing the Pharmacy Examining Board's draft language, there appears to be some confusion over the objective of the rule change. Specifically, the Board stated that it will not be moving forward with rulemaking to align with the 2019 revisions of the United States Pharmacopeia ("USP") chapter 797 at this time, because due to appeals filed, the 2019 revisions of USP 797 are currently on hold. In fact, the USP had published a newer proposed revision to the standard in 2021, which is still currently in the public comment period. However, the Board has included language specifically from the 2019 revision in contradiction of it's published intent. Specifically, Phar 15.37 uses "Category 1 and 2" as a basis to

establish beyond-use-dates. These "Categories" do not exist in the context of the current version of USP 797, but rather is language borrowed from the 2019 version that was never published. In essence, these Categories, without definition, are yet to become an applicable standard from the USP. Furthermore, if the Board is utilizing proposed/future revisions of the USP as a basis for this proposed rule, the newest revision contains 3 Categories, not 2.

This mix in terminology will create confusion to the pharmacy staff members and therefore, CVS Health requests clarity. CVS Health appreciates the opportunity to submit feedback on these Phar 15 rules in Wisconsin. If you have any questions, please contact me directly at 614-572-9008.

Best regards,



John Long RPh, MBA

cc: Jameson Whitney, Esq.

TO: John Weitekamp, Chairman
Pharmacy Examining Board

FROM: Danielle Womack, Vice President of Public Affairs
Pharmacy Society of Wisconsin

DATE: 14 February 2022

SUBJECT: Clearinghouse Rule 22-007 (Phar 15), Relating to Compounding Pharmaceuticals

On behalf of the Pharmacy Society of Wisconsin's nearly 4,500 members, I would like to thank you for the opportunity to share our thoughts on Phar 15 relating to compounding and for accepting stakeholder input throughout the entire rulemaking process.

The Pharmacy Society of Wisconsin is dedicated to patient safety and recognizes the need for updated regulations on compounding. We appreciate the Board's stance of updating the chapter despite the moving target of USP Standards to ensure Phar 15's alignment with 2008 USP Standards.

Based upon a review of CR 22-007 and consultation with our member experts, we have the following recommendations:

- Phar 15.30 through 15.36 use terminology such as "stored in a refrigerator" and "stored in a freezer" but do not dictate a specific temperature range. Beginning with Phar 15.37, the terminology refers to specific temperatures for refrigerated and frozen products.

  We recommend that the Board consider using consistent terminology to clarify appropriate temperature requirements across the chapter. By streamlining the language, pharmacies will better develop and maintain workflows and create standard operating procedures to ensure medications are stored appropriately.

- The revised Phar 15.34 states that no more than three commercially manufactured "packages" may be used in immediate-use compounding. There are settings in which more than three vials or packages of three or fewer products may be commonly mixed; this would no longer be allowed. The 2019 and 2021 proposed <797> revisions both use language specifying that immediate use compounds must not be prepared using more than three different sterile *products*.

  We recommend that the Board change the word "packages" to "products" to reflect better the requirements of USP <797> and contemporary practice.

Thank you for the opportunity to provide comments on the Phar 15 revisions and your consideration of our recommendations. I am happy to answer any questions you may have.

From: Brian Koenig
To: DSPS Admin Rules
Subject: USP 795, 797, 800, 825 & WI PHARM 15
Date: Monday, February 14, 2022 6:44:24 PM

Dear Board.

Thank you for the opportunity to talk in the public Pharmacy Board meeting as a guest. I do apologize if my selection of time to speak was in the wrong location per your meeting protocols.

As asked by Nilajah Hardin to summarize, my concern was if the WI Pharmacy Board have any plans to add to the current WI PHARM 15 or to adopt what will be federally approved in future months by the USP and FDA. As I read the current PHARM 15, it doesn't reconcile with the current USP 797 v2008 which is enforceable nor any of the proposed versions like 2019 and 2021. The lack of reconciliation can lead pharmacies to invoke standards that are not as stringent as what is currently enforceable on the federal level. For example, I do not believe the current PHARM 15 discusses testing the PEC (cleanbenches, BSC, isolators) nor the SEC (classified cleanrooms) on a semiannual basis, viable sampling protocols, nor HD compounding in details that are already established in the enforceable USP 797 v2008. I read several years back, that for federal monies to be received for pharmacy compounding, the pharmacy compounding facility must adhere to USP documents or similar. This being a document from the CMS and published in the public domain.

Some of the discussion afterwards today in which the public could not participate, was centered on why a blanket statement can not be used for compounding pharmacies to adhere to the most current enforceable version of USP 795, 797, 800, and 825. I would state that like the WI State Regulation SPS 332.24 Ventilation [29 CFR 1910.94} which is basically WI chemical fume hood operational requirements, that you could consider the adoption of the USP compounding documents and then add statements that the WI Pharmacy Board considers essential. These additional requirements could help to resolve concerns of "should" aspects to "shall" aspects as mentioned in today's meeting. One such requirement that is currently in WI PHARM 15 in which I would professionally recommend to remain a part of WI PHARM 15 is the requirement of a CNBT certified or similar technician to test/certify these compounding facilities.

If I can clarify or be of any additional assistance, please contact me.

As the former owner of Wisconsin Air Flow, Inc that worked in this area of test/certification, member on 2 of the CETA application guide taskforces involved in USP compounding protocols and over 30 years of experience in this field I the State of Wisconsin, I would be happy to be of any professional assistance in this endeavor to bring Wisconsin PHARM 15 compounding regulations to reconciling or exceeding the federal standards.

Brian L Koenig, PE, MBA, CNBT
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Technical Safety Services