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Scott Walker, Governor
Laura Gutiérrez, Secretary

PHARMACY EXAMINING BOARD
Contact: Dan Williams (608) 266-2112
Room 121A, 1400 East Washington Avenue, Madison, WI 53703
January 9, 2018

Notice: 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 action and deliberation of the Board.

AGENDA

9:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. **Adoption of Agenda (1-4)**

B. **Approval of Minutes of December 19, 2017 (5)**

C. **Legislation/Administrative Rule Matters – Discussion and Consideration (6-59)**
1) Phar 15 Relating to Compounding Pharmaceuticals **(6-47)**
2) Phar 7 Relating to Practice of Pharmacy – Remote Dispensing **(48-59)**
3) Phar 17 Relating to Interns
4) Pharmacy Rules Projects
5) Update on Legislation and Pending or Possible Rulemaking Projects

D. **Pilot Program Matters – Discussion and Consideration**

E. **Speaking Engagements, Travel, or Public Relations Requests (60)**
1) Travel Report from the District IV NABP Annual Meeting – Toledo, OH – October 1-3, 2017
2) Pharmacy Society of Wisconsin Legislative Day – February 8, 2018 – Madison, WI

F. Informational Items – Discussion and Consideration

G. **Pharmacy Case Forfeitures – Discussion (61)**

H. **Wis. Admin. Code § Phar 6.07 Relating to Storage – Discussion and Consideration (62)**

I. **11:00 A.M. Public Hearing on Clearinghouse Rule 17-090 Relating to Authority and Definitions (63-69)**
1) Review and Respond to Clearinghouse Report and Public Hearing Comments

J. **NABP Appearance Regarding Programs and Services (70)**

K. **Administrative Updates – Discussion and Consideration (71-77)**
1) **Staff Updates**
2) **Election of Officers**
3) **Appointment of Liaisons and Alternates**

4) **Delegation of Authorities**
5) Board Member – Term Expiration Date
    a. Grace Degner – 7/1/2018
    b. Franklin LaDien – 7/1/2020 (reappointed, not yet confirmed)
    c. Terry Maves – 7/1/2018
    d. Thaddeus Schumacher – 7/1/2019
    e. Kristi Sullivan – 7/1/2020 (reappointed, not yet confirmed)
    f. Philip Trapskin – 7/1/2021 (reappointed, not yet confirmed)
    g. Cathy Winters – 7/1/2021 (reappointed, not yet confirmed)

L. Items Received After Preparation of the Agenda
1) Introductions, Announcements and Recognition
2) Election of Board Officers
3) Appointment of Board Liaisons
4) Administrative Updates
5) Education and Examination Matters
6) Credentialing Matters
7) Practice Matters
8) Legislation/Administrative Rule Matters
9) Informational Items
10) Disciplinary Matters
11) Presentations of Petitions for Summary Suspension
12) Petitions for Designation of Hearing Examiner
13) Presentation of Proposed Stipulations, Final Decisions and Orders
14) Presentation of Proposed Final Decision and Orders
15) Presentation of Interim Orders
16) Petitions for Re-Hearing
17) Petitions for Assessments
18) Petitions to Vacate Orders
19) Requests for Disciplinary Proceeding Presentations
20) Motions
21) Petitions
22) Appearances from Requests Received or Renewed
23) Speaking Engagement(s), Travel, or Public Relations Request(s)
24) Division of Legal Services and Compliance (DLSC) Matters
25) Prescription Drug Monitoring Program Information
26) Consulting with Legal Counsel
27) Liaison Report(s)
    a. Appointed to Controlled Substances Board per Wis. Stats. §15.405(5g): Philip Trapskin
    b. Continuing Education (CE) and Education and Examinations Liaison: Terry Maves
    c. Credentialing Liaison(s): Terry Maves, Cathy Winters
    d. Digest Liaison: Philip Trapskin
    e. DLSC Liaison: Thaddeus Schumacher, Cathy Winters
    f. Legislative Liaison: Philip Trapskin, Thaddeus Schumacher, Terry Maves
    g. Monitoring Liaison(s): Franklin LaDien, Cathy Winters
    h. PHARM Rep to State Council on Alcohol and Other Drug Abuse (SCAODA): Kristi Sullivan
    i. Pharmacy Rules Committee: Thaddeus Schumacher, Franklin LaDien, Philip Trapskin
    j. Professional Assistance Procedure (PAP) Liaison: Franklin LaDien
    k. Screening Panel: Franklin LaDien, Cathy Winters, Kristi Sullivan
    l. Pilot Program Report Liaison(s): Philip Trapskin, Cathy Winters

M. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

N. **Deliberation on Division of Legal Services and Compliance (DLSC) Matters**

1) **Administrative Warnings**
   a. 16 PHM 179 – (M.E.F.) **(78-80)**
   b. 16 PHM 220 – (A.C.M.) **(81-82)**
   c. 16 PHM 220 – (C.P.) **(83-84)**
   d. 16 PHM 220 – (H.N.H.) **(85-86)**
   e. 16 PHM 220 – (M.J.T.) **(87-88)**
2) **Stipulations, Final Decisions and Orders**
   a. 16 PHM 129 – Alvin A. Krause, R.Ph. **(89-95)**
   b. 16 PHM 155 and 16 PHM 176 – Shawnte L. Robinson, R.Ph. **(96-104)**
   c. 16 PHM 158 – Brandon L. Wendt, R.Ph. **(105-110)**
   d. 17 PHM 015 – Bentley Pharmacies, Inc. **(111-118)**
   e. 17 PHM 018 – Palm Beach Pharmaceuticals, Inc. **(119-124)**
3) **Case Closings**
   a. 16 PHM 220 **(125-129)**
   b. 17 PHM 054 **(130-133)**
   c. 17 PHM 098 **(134-137)**
4) **Monitoring (138-202)**
   a. Robin Block, R.Ph. – Requesting PIC Hours, Monitoring Interruption, Termination of Therapy, Reduction in Testing and Reporting Frequency **(140-168)**
   b. Dirk Larson, R.Ph. – Requesting Full Licensure **(169-202)**

O. **Credentialing Matters**

1) Application Review
   a. Recover Health Pharmaceutical Care **(203-245)**
   b. Wells Pharmacy Network, L.L.C. **(246-371)**
   c. Lincare Inc. **(372-422)**
   d. Mohammad El-Barbarawi **(423-455)**

P. Consulting with Legal Counsel

Q. Deliberation of Items Received After Preparation of Agenda

1) Education and Examination Matters
2) Credentialing Matters
3) Disciplinary Matters
4) Monitoring Matters
5) Professional Assistance Procedure (PAP) Matters
6) Petitions for Summary Suspension
7) Petitions for Designation of Hearing Examiner
8) Stipulations, Final Decisions and Orders
9) Administrative Warnings

10) Review of Administrative Warnings
11) Proposed Final Decisions and Orders
12) Orders Fixing Costs/Matters Related to Costs
13) Case Closings
14) Interim Orders
15) Petitions for Assessments and Evaluations
16) Petitions to Vacate Orders
17) Remedial Education Cases
18) Motions
19) Petitions for Re-Hearing
20) Appearances from Requests Received or Renewed

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

R. **Voting on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate**

S. Board Meeting Process (Time Allocation, Agenda Items) – Discussion and Consideration
1) Starting times for Rules Committee and Board meetings on February 22, 2018

T. Board Strategic Planning and its Mission, Vision, and Values – Discussion and Consideration

ADJOURNMENT

The Next Scheduled Meeting is February 22, 2018.

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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 1400 East Washington Avenue, 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. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

PHARMACY EXAMINING BOARD
TELECONFERENCE/VIRTUAL MEETING MINUTES
October 26, 2017

PRESENT: Grace Degner *(arrived at 10:41 a.m.)*, Franklin LaDien, Terry Maves, Thaddeus Schumacher, Kristi Sullivan, Philip Trapskin, Cathy Winters

STAFF: Dan Williams, Executive Director; Laura Smith, Bureau Assistant; Sharon Henes, Administrative Rules Coordinator, and other Department staff

CALL TO ORDER

Thaddeus Schumacher, Chair, called the meeting to order at 10:39 a.m. A quorum was confirmed.

ADOPTION OF AGENDA

MOTION: Franklin LaDien moved, seconded by Cathy Winters, to adopt the agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF OCTOBER 26, 2017

MOTION: Franklin LaDien moved, seconded by Cathy Winters, to approve the minutes of October 26, 2017 as published. Motion carried unanimously.

LEGISLATIVE/ADMINISTRATIVE RULE MATTERS

Phar 15 Relating to Compounding Pharmaceuticals – Response to Joint Committee for the Review of Administrative Rules

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to consider modifications to Clearinghouse Rule 16-085. Motion carried unanimously.

MOTION: Philip Trapskin moved, seconded by Terry Maves, to delegate to the Chair to respond to the Joint Committee for Review of Administrative Rules regarding Clearinghouse Rules 16-085. Motion carried unanimously.

ADJOURNMENT

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:07 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:
Sharon Henes **Administrative Rules Coordinator**	**20 December 2017** Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 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?
9 January 2017	☐ Yes ☐ No	**Legislation and Rule Matters – Discussion and Consideration** 1. Phar 15 Relating to Compounding Pharmaceuticals 2. Phar 7 Relating to Practice of Pharmacy – Remote Dispensing 3. Phar 17 Relating to Interns 4. Pharmacy Rules Projects 5. Update on Pending Legislation and Pending and Possible Rulemaking Projects

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes (Fill out Board Appearance Request) ☐ No	

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

11) Authorization

Sharon Henes — *20 December 2017*

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.

PHARMACY EXAMINING BOARD

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19 December 2017

Senator Stephen Nass, Senate Co-Chairperson
Joint Committee for Review of Administrative Rules
Room 10 South, State Capitol
Madison, WI 53702

Representative Joan Ballweg, Assembly Co-Chairperson
Joint Committee for Review of Administrative Rules
Room 210 North, State Capitol
Madison, WI 53702

RE: Clearinghouse Rule 16-085

Dear Senator Nass and Representative Ballweg:

I am writing to notify you that on December 29, 2017 the Pharmacy Examining Board met to consider your request. The Pharmacy Examining Board made the following motion:

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to consider modifications to Clearinghouse Rule 16-085. Motion carried unanimously.

The Pharmacy Examining Board plans to review CR 16-085 at a future meeting to consider any modifications.

Thank you.

Sincerely,

Chairperson

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
PHARMACY EXAMINING BOARD	**:**	**CR 16-085**

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 basis and purpose of the proposed rule is to update the non-sterile and sterile compounding rules. Following the New England Compounding Center meningitis outbreak in 2012 which affected 753 patients (64 patient deaths), the Pharmacy Examining Board recognized that Wisconsin's current rules have not been updated since 2000 and did not adequately address current practice or safety standards for compounding non-sterile and sterile pharmaceuticals.

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 January 17, 2017. The following people either testified at the hearing, or submitted written comments:

Danielle Laurent representing Pharmacy Society of Wisconsin
Jeremy Levin representing Rural Wisconsin Health Cooperative
Aaron Webb, Pharmacy Manager, University of Wisconsin Hospital and Clinics
Dawn Wypiszynski representing Morton LTC
Susan Kleppin representing Chartwell Midwest Wisconsin
Michelle Violi representing Women's International Pharmacy
Ronald Phillips representing Animal Health Institute
Jennifer Hoppe representing The Joint Commission
Jordan Lamb of DeWitt, Ross & Stevens representing Wisconsin Veterinary Medical Association

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

Several people recommended the Pharmacy Examining Board adopt U. S. Pharmacopeia chapters 795 and 797. The Board in formulating the rule considered the draft of the new chapter USP 797 and Phar 15 may contain items which will not be adopted in the final revision of chapter USP 797. Hospitals are required to meet USP chapters 795 and 797 to maintain accreditation.

There were comments submitted indicating that Phar 15 should only apply to bulk compounding pharmacies who sell their product to other pharmacies. Similar comments were made to exempt retail or hospitals from Phar 15 because those entities do not manufacture drugs.

Comments related solely to compounding for animal patients were received. The Animal Health Institute requested that Phar 15 not exempt compounding for animal patients from the non-patient specific compounding requirements in the proposed Phar 15.17 raising safety concerns, including food safety implications for food animals. The Wisconsin Veterinary Medical Association requested an exemption to the proposed Phar 15.17 to allow a veterinarian to dispense a non-patient specific compounded drug to a patient for a period of time not to exceed 10 days.

The Joint Commission provided information related to their new Medication Compounding certification program for the Board's consideration in reliance on their program to ensure that pharmacies providing compounding pharmaceuticals are complaint with the requirements contained in the proposed rules.

Please see the attached Appendix A for specific line item comments not addressed as general comments in this section.

The Pharmacy Examining Board explains modifications to its rule-making proposal prompted by public comments as follows:

The Pharmacy Examining Board is not adopting U.S. Pharmacopeia chapters 795 and 797 due to the difficulties associated with enforcing standards which are not itemized and read as recommendations or best practices. The Pharmacy Examining Board recognizes that the U.S. Pharmacopeial Convention is in the process of updating the U.S. Pharmacopeia chapter 797. The Board balanced safety concerns with the burden regulations place on pharmacies while creating the minimum standards in Phar 15 recognizing that other entities may require higher standards.

Pharmacies are not allowed to compound bulk pharmaceuticals and sell to other pharmacies. Outsourcing facilities are not required to be a licensed pharmacy and may or may not obtain prescriptions for individual patients (if dispensing to a patient than a prescription is required). Outsourcing facilities are required to register with the federal government and meet Current Good Manufacturing Practices. Outsourcing facilities currently are not licensed in Wisconsin and Phar 15 does not apply.

The Pharmacy Examining Board did not make any changes to the proposed Phar 15 for animal patients. The Pharmacy Examining Board based the decision on regardless of whether the patient is a human or animal, there are patient safety concerns as it relates to compounding pharmaceuticals.

Please see the attached Appendix A for modifications as a result of specific line item comments.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 5i: In s. Phar 15.20 (3), the board should review the provision for clarity and its relationship to other provisions in s. Phar 15.20. For example, in what circumstances may components be transferred to other containers? How does the transfer of components relate to the timeliness of usage of those components and the requirement that a component be stored in is original container under s. Phar 15.20(1).

Response: The Pharmacy Examining Board reviewed the provision and believes it is clear. There is no conflict with s. Phar 15.20 (1) and (3). If a component is transferred, it needs to be stored in a container providing a minimally equivalent integrity and an expiration date will need to be identified. The expiration date from the manufacturer or distributor as provided for in sub. (1) will no longer be automatically once the component has been transferred and will need an expiration assigned.

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:

The Small Business Regulatory Review Board provided a verbal statement that the rule will not have a significant economic impact on a substantial number of small businesses.

APPENDIX A

Comment: In Phar 15.01 (9) (c) clarify reconstituting versus compounding. Also clarify this relates to only non-sterile preparations.

Response: The Pharmacy Examining Board modified the paragraph to include these clarifications.

Comment: In Phar 15.11, the "equipment surfaces that contact components" is unnecessary and should be removed.

Response: The Pharmacy Examining Board removed this phrase.

Comment: The record for mixing instructions does not require all of the listed requirements, particularly in non-sterile compounding.

Response: The Pharmacy Examining Board removed the list and added to Phar 15.12 (5) the phrase, "pertinent to the replication of the preparation as compounded".

Comment: In Phar 15.13, clarify who conducts the final check verification.

Response: The Pharmacy Examining Board modified this section to read, "One or more pharmacists shall complete a verification of all of the following before dispensing." to allow for the multiple pharmacists in the process to complete the various verifications after each step. The Pharmacy Examining Board also clarified that if any discrepancy is found during any of the verifications the appropriate corrective action shall be taken before dispensing.

Comment: In Phar 15.14 (2) (d), the items listed as included in environmental monitoring are unnecessary. In Phar 15.14 (2) (m), there needs to be clarification.

Response: The Pharmacy Examining Board removed the list of items in Phar 15.14 (2) (d) and simplified Phar 15.14(2) (m) to "maintaining the integrity of any classified work area".

Comment: Recommend the label includes notification that the pharmaceutical was compounded.

Response: The Pharmacy Examining Board added a paragraph, "Indication that the preparation is compounded unless administered by health care personnel."

Comment: Recommend adding a provision to Phar 15.16 (2) about using professional judgement if USP or NF grade is not available.

Response: The Pharmacy Examining Board made this addition.

Comment: Several comments regarding clarification of Phar 15.17.

Response: The Pharmacy Examining Board clarified the introduction paragraph to address the non-patient specific compounding is pursuant to a non-patient specific order to be administered by the practitioner or practitioner's agent. In addition, the Pharmacy Examining Board removed the requirement that the order include the name of the compounded preparation's name due to lack of clarity as to what the name would be and added strength of the compounded preparation. The label should indicate "For Practitioner Administration Only – Not for Dispensing or Distribution" which replaced the word "use" with "administration". Lastly the Pharmacy Examining Board moved the provision related to recall to Phar 15.14 (2)(o) requiring there to be a policy for recall of any compounded preparation.

Comment: Recommend the primary engineering control be certified by the Controlled Environment Testing Association's national Board of Testing.

Response: The Pharmacy Examining Board included this entity but also created a provision allowing a different entity to be approved by the Board.

Comment: Recommend combining the donning of protective clothing and the hand hygiene procedure for clarity purposes.

Response: The Pharmacy Examining Board accepted the recommendation and made the clarification that sterile gloves shall be donned over the RABS gloves. In addition, the Pharmacy Examining Board made other clarifications as to clothing.

Comment: Several comments requesting clarification of the cleaning and disinfecting the compounding area and supplies.

Response: The Pharmacy Examining Board created definitions for cleaning and disinfecting and simplified the frequency and need to clean/disinfect the various areas.

Comment: Recommend adding to Phar 15.26 (3) a clarification regarding a preservative added by the compounder versus the vial already containing a preservative.

Response: The Pharmacy Examining Board added the phrase "added by the compounder".

Comment: Recommend adding to Phar 15.37 a provision relating to compounded sterile formulations with a preservative passing an antimicrobial effectiveness testing before dispensing.

Response: The Pharmacy Examining Board added Phar 15.37 (4).

Comment: Recommend clarification as to the compounding personnel required to complete training.

Response: The Pharmacy Examining Board revised Phar 15.38 (1) (intro) to include a listing of the compounding personnel required to complete training.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 16-085)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate ch. Phar 15 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:

This proposed rule repeals and recreates the Pharmacy Examining Rules related to compounding pharmaceuticals.

Phar 15.01 creates the definitions which will be used throughout the chapter.

Subchapter I are the general provisions which provide requirements for all types of compounding.

Phar 15.10 requires a facility which has a designated area for compounding and orderly placement of equipment, materials and components so that errors are minimized. The compounding area is to be maintained in a clean and sanitary manner, be easily accessible to hot and cold running water, soap and single-use towels and all compounding equipment, materials and components stored off the floor and in a way that prevents contamination.

Phar 15, 11 requires a pharmacy to possess equipment and drug preparation containers or packaging that is appropriate to the compounding performed at the pharmacy, minimize contamination and not alter stability of the compounded preparation. The equipment needs to be maintained consistent with the manufacturer's recommendations.

Phar 15.12 requires compounding documentation necessary to trace, evaluate and replicate the compounding steps throughout the process of a preparation to be maintained for a period of 5 years after the date of the last refill of the preparation.

Phar 15.13 requires a final check of the compounding, investigate any discrepancies and take corrective action before the prescription is dispensed.

Phar 15.14 requires all personnel involved in the compounding, evaluation, packaging and dispensing of compounded preparations be properly trained and competency tested for the type of compounding conducted. It is the managing pharmacist's responsibility to ensure personnel training and competency assessments are completed and documented. The pharmacy shall establish written policies and procedures governing compounding and reflect current compounding practice.

Phar 15.15 requires in addition to the regular labeling requirements, to include storage conditions, beyond use date and special handling instructions.

Phar 15.16 Active pharmaceutical ingredients or added substances shall be manufactured by an FDA registered facility or accompanied by a certificate of analysis and USP or NF monograph specifications when available. Components for human use may not be used if they have been withdrawn or removed from the market based by the FDA. Compounding for food producing animal use may not use any components prohibited for use in food producing animals.

Phar 15.17 Compounded preparations dispensed or distributed directly to a practitioner to be administered to an individual patient without a patient specific prescription shall meet the following: the prescription shall include the name, address, drug, quantity and purpose of the compounded preparation; the label shall include the practitioner's name and state "For Administration Only – Not for Dispensing or Distribution" and marked for "Single Dose Only" if the sterility or integrity is not maintained after the opening of the container; the pharmacist shall record the name and address of the location the compounded preparation was dispensed or distributed, the lot number and beyond use date; and there shall be a procedure for immediate notification to all practitioners of a preparation which is recalled.

Subchapter II provisions relate to non-sterile compounding.

Phar 15.20 allows components with an expiration date from the manufacturer or distributor may be used before the expiration date provided the component is stored in its original container and there is minimal exposure of the remaining component each time component is withdrawn from the container. Components without an expiration date assigned by the manufacturer or supplier shall be assigned an expiration date based upon the nature of the component and its degradation mechanism, the container in which it is packaged and the storage conditions.

Phar 15.21 requires the beyond use date not be later than the expiration date on the container of any component. In the absence of stability information the beyond use date if based upon the type of formulations. Assignment of the beyond use date includes an assessment of the need for antimicrobial agents or refrigeration to protect against contamination introduced during or after the compounding.

Subchapter III provisions relate to sterile compounding.

Phar 15.30 contains definitions of words used throughout the subchapter.

Phar 15.31 indicates the requirements necessary for the segregated compounding area and the classified area to ensure there is not contamination. The primary engineering control shall be certified prior to initial use and then every six months in addition to a redesign of facility, or the replacement or relocation of the primary engineering control.

Phar 15.32 indicates the personnel hygiene, garbing and protective gear required to ensure there is not contamination.

Phar 15.33 requires the compounding area to be cleaned and disinfected with designated minimum frequency. The pharmacy shall have written standard operating procedures which are followed by all compounding and environmental services personnel for cleaning and disinfecting the compounding area. Storage sites for the compounding ingredients and supplies shall remain free from dust and debris. Supplies and equipments removed from shipping cartons shall be disinfected. Entry points on bags and vials shall be disinfected before piercing.

Phar 15.34 requires urgent use compounded sterile preparations to be prepared within one hour and administration shall begin within one hour of the completion of the preparation. Aseptic technique shall be followed and procedures to minimize contamination. Unless immediately and completely administered or witnessed by the person who prepared the preparation, the preparation shall have a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who did the preparation and the 1 hour beyond use date and time.

Phar 15.35 indicates the sterilization methods for maintaining physical and chemical stability and the packaging integrity of the compounding sterile preparations. The sterilization methods are by filtration, steam heat or dry heat based upon the components utilized in the preparation. Dry heat depyrogenation shall be used to render glassware and other thermostable containers pyrogen free.

Phar 15.36 requires after the completion of compounding, the preparation shall be physical inspected and upon any observed defects be discarded or segregated in a manner which prevents it from being dispensed and pass a sterility test. Any preparation containing a preservative shall also pass an antimicrobial effectiveness testing before being dispensed.

Phar 15.37 indicates the requirements for establishing a beyond use date. Sterility and stability considerations shall be considered when establishing a beyond use date. Administration date and times based upon the requirements listed in the rule can't be exceeded or extended without verifiable supporting valid scientific sterility and stability information that applies to the specific preparation or compound. If the beyond use date is based upon storage in a freezer, the integrity of the container closure system with the specific preparation in it shall have been demonstrated for 45 days at frozen storage.

Phar 15.38 provides that the managing pharmacist, all pharmacists, technicians, interns and externs involved in compounding sterile preparations shall successfully complete didactic and practical training initially and then annually. All personnel shall be evaluated initially and annually on all of the following: visual observation of hand hygiene and garbing; visual observation of aseptic technique; gloved fingertip and thumb sampling; and media-fill tests. Records of the training and evaluations shall be maintained by the pharmacy for 5 years.

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

None. There is federal compounding regulation relating to outsourcing facilities.

Comparison with rules in adjacent states:

Illinois: Illinois requires a specific area for compounding; records to be kept of each compounded prescription and the components; reference books; and a pharmacy operations manual with policies and procedures pertinent to the complexity and size of the compounding operations. The pharmacy may compound drug products to be sued by practitioners in their office for administration to patients. Sterile compounding requires: a designated area of sufficient size to accommodate a laminar airflow hood, barrier isolation chamber and proper storage of drugs and supplies; the laminar airflow hood shall be certified annually; sink with hot and cold water; refrigerator and/or freezer with a thermometer or temperature recording device; current resource materials and texts; patient profile or medication system; specific labeling requirements including beyond use date and time; and compounding records are to be maintained for 5 years.

Iowa: Iowa requires compliance with United States Pharmacopeia, Chapters 795 and 797. In addition, an FDA registered outsourcing facility must be licensed as a pharmacy in Iowa.

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 by the Pharmacy Compounding Accreditation Board and be in compliance with United States Pharmacopeia standards. In addition, any outsourcing facility must be licensed as a pharmacy in Michigan.

Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow United States Pharmacopeia, chapter 795 standards and pharmacies compounding sterile drug preparations to follow United States Pharmacopeia, chapter 797 standards.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board primarily utilized United States Pharmacopeia chapters 795 and 797 which are the recognized pharmacopeial standards. In addition, the Pharmacy Examining Board reviewed the code of other states which have been revised since the New England Compounding Center meningitis outbreak in 2012.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The Board does not know how many or which pharmacies are compounding sterile pharmaceuticals and UPS 795 and 797 are the recognized pharmacopeial standards. Therefore the Board was unable to determine whether there will be an effect on small businesses. This rule was posted for 30 days for economic comments and none were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules were submitted to the Small Business Regulatory Review Board. The Small Business Regulatory Review Board determined the rules will not have a significant economic impact on a substantial number of small businesses. The Department's Regulatory Review Coordinator may be contacted by email at Kirsten.Reader@wisconsin.gov, or by calling (608) 267-2435

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. Repeals and recreates ch Phar 15 to read:

CHAPTER Phar 15
COMPOUNDING PHARMACEUTICALS

15.01 Definitions. In this chapter:
(1) "Active pharmaceutical ingredient" or "API" means any substance or mixture of substances intended to be used in the compounding of a drug preparation and that, when used in the compounding of a drug preparation, becomes an active ingredient in the preparation intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease in humans and animals or affecting the structure and function of the body.
(2) "Added substances" means ingredients that are necessary to compound a drug preparation that are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation.
(3) "Adverse drug event" means an injury resulting from the use of a drug.
(4) "Beyond use date" or "BUD" means one of the following:
(a) The date after which a non-sterile compounded preparation shall not be used.
(b) The date and time after which a sterile compounded preparation shall not be used.
(5) "Certificate of analysis" means a report from the supplier of a component, container or closure that accompanies the component, container or closure and contains the specifications and results of all analyses and a description.
(6) "Chemical stability" means each active pharmaceutical ingredient retains its chemical integrity and labeled potency, within specified limits.
(7) "Classified area" means a space that maintains an air cleanliness classification based on the International Organization for Standardization (ISO).
(8) "Component" means any active pharmaceutical ingredient, or added substances used in the compounding of a drug preparation.
(9) "Compounding" means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug delivery device, or a device in accordance with a prescription, or medication order. Compounding does not include repackaging. Compounding includes any of the following:
(a) Preparation of drug dosage forms for both human and animal patients.
(b) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
(c) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients. Notwithstanding this paragraph, the reconstituting, mixing, or storage and beyond use dating that is performed for non-sterile preparations in accordance with the directions contained in approved labeling provided by the manufacturer is not compounding.
(d) Preparation of drugs or devices for the purposes of, or as an incident to, research, teaching or chemical analysis.
(10) "Container-closure system" means the sum of packaging components that together contain and protect a dosage form, including primary packaging components and secondary packaging components.
(11) "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 68 degrees to 77 degrees Fahrenheit.
(12) "FDA" means the United States food and drug administration.

(13) "Freezer" means a place in which a the temperature is maintained between -13 degrees and 14 degrees Fahrenheit.
(14) "Microbiological stability" means sterility or resistance to microbial growth is retained according to specified requirements and antimicrobial agents that are present retain effectiveness within specified limits.
(15) "NF" means the National Formulary.
(16) "Physical stability" means the original physical properties, including appearance, palatability, uniformity, dissolution, and suspendability, are retained.
(17) "Refrigerator" means a cold place in which the temperature is maintained between 36 degrees and 46 degrees Fahrenheit.
(18) "Stability" means the extent to which a compounded preparation retains, within specified limits and through its beyond use date, the same properties and characteristics that it possessed at the time of compounding.
(19) "Therapeutic stability" means the therapeutic effect remains unchanged.
(20) "Toxicological stability" means no significant increase in toxicity occurs.
(21) "USP" means the United States Pharmacopeia.

SUBCHAPTER I – General

15.10 Facilities. A pharmacist engaged in compounding shall ensure all of the following:
(1) An area designated for compounding.
(2) Orderly placement of compounding equipment, materials, and components in order to minimize the potential for compounding errors.
(3) The compounding area is maintained in a clean and sanitary condition.
(4) The compounding area is easily accessible to all of the following:
(a) Hot and cold running water, exclusive of the bathroom sink.
(b) Soap or detergent.
(c) Single-use towels.
(5) All compounding equipment, materials and components shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage areas

15.11 Equipment and Drug Preparation Containers.
(1) A pharmacy shall possess equipment and drug preparation containers or packaging appropriate to the type of compounding performed at the pharmacy.
(2) Equipment and drug preparation containers or packaging used in compounding shall be of appropriate design and capacity, and shall be suitably stored in a manner to facilitate use, cleaning, maintenance, and protect it from contamination.
(3) Equipment and drug preparation containers or packaging used in compounding drug products shall be of suitable composition and may not be reactive, additive, adsorptive or absorptive so as to alter the stability of the compounded preparation.
(4) Equipment used in compounding shall be thoroughly cleaned and sanitized after each use, and when necessary, prior to use, according to written policies and procedures, in order to reduce bioburden and reduce the opportunity for cross-contamination.
(5) All equipment utilized in compounding preparations shall be inspected, maintained, calibrated and validated at appropriate intervals, consistent with manufacturer's

recommendations, to ensure the accuracy and reliability of equipment performance. Records shall be kept indicating the equipment was inspected, maintained, calibrated and validated.

15.12 Records of compounding. The managing pharmacist shall ensure written or electronic compounding documentation to systematically trace, evaluate, and replicate the compounding steps throughout the process of a preparation. The compounding documentation shall be maintained for a period of 5 years after the date of the last refill. The compounding documentation shall include all of the following:

(1) Official or assigned name, strength, and dosage form of the preparation.
(2) List of all APIs and added substances and their quantities.
(3) Vendor or manufacturer, lot number and expiration date of each APIs and added substances.
(4) Equipment and supplies needed to prepare the preparation.
(5) Mixing instructions pertinent to the replication of the preparation as compounded.
(6) Compatibility and stability information, including references or laboratory testing.
(7) Container or container-closure system used in dispensing.
(8) Packaging and storage requirements.
(9) Quality control procedures.
(10) Sterilization method when using non-sterile ingredients to make a sterile preparation.
(11) Total quantity compounded.
(12) Name of the person who prepared the preparation.
(13) Name of the person who performed the quality control procedures.
(14) Name of the person who approved the preparation.
(15) Date of preparation.
(16) Assigned control or prescription number.
(17) Assigned BUD.
(18) Copy of the label to dispense final product.
(19) Documentation of any adverse reactions or preparation problems reported by the patient or caregiver.

15.13 Quality control.

(1) One or more pharmacists shall complete a verification of all the following before dispensing:
- (a) Written procedures were followed in the compounding process.
- (b) Preparation instructions were followed.
- (c) Finished preparation appears as expected.
- (d) Label includes all required elements.
- (e) Quality control procedures were completed.
- (f) Compounding records are complete.

(2) A pharmacist shall investigate any discrepancies found during any of verifications and take appropriate corrective action before dispensing.

15.14 Training, Policies and Procedures. (1) TRAINING. All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained and competency is assessed for the type of compounding conducted. It is the responsibility of the managing pharmacist to ensure personnel training and competency assessments are completed and documented.

(2) POLICIES AND PROCEDURES. The pharmacy and managing pharmacist shall establish written policies and procedures governing all of the following:

(a) Personnel qualifications and training, responsibilities, and competencies.
(b) Personal hygiene, garb, garbing, and personal protective gear.
(c) Use and maintenance of compounding facilities and equipment, including applicable certifications.
(d) Environmental monitoring.
(e) Cleaning and disinfection of compounding area.
(f) Component selection.
(g) Sterilization and depyrogenation, if pharmacy does sterilization and depyrogenation.
(h) Documentation requirements.
(i) Establishing BUD.
(j) Reporting of adverse drug events.
(k) A risk management program, including documentation of incidents, adverse drug reactions and product contamination.
(L) A quality assurance program.
(m) Maintaining the integrity of any classified work areas.
(n) Handling small and large spills of antineoplastic agents and other hazardous substances.
(o) Notification to patients or practioners of a preparation which is recalled.
when there is potential for patient harm.

(3) REVIEW OF POLICIES AND PROCEDURES The policy and procedures shall be reviewed at least once every 36 months and shall be updated, on a continuous basis, to reflect current practice. Documentation of the review shall be made available to the board upon request.

15.15 Labeling. The label of a compounded preparation shall include all of the following:
(1) Labeling requirements in s. Phar 7.02 and 8.08.
(2) Storage conditions if other than controlled room temperature.
(3) BUD.
(4) Special handling instructions, when applicable.
(5) Indication that the preparation is compounded unless administered by health care personnel.

15.16 Component Selection. (1) Active pharmaceutical ingredients or added substances used in compounding shall be manufactured by an FDA registered facility or accompanied by a certificate of analysis.
(2) APIs and added substances shall meet USP or NF monograph specifications when monographs are available. A pharmacist shall use professional judgement in selection of APIs if USP or NF grade is not available.
(3) All components shall be stored and handled consistent with the manufacturer's labeling or USP or NF monographs and in a manner that prevents contamination and deterioration.
(4) A pharmacist compounding for human use may not use components that have been withdrawn or removed from the market for safety or efficacy reasons by the FDA. A pharmacist compounding for food producing animal use may not use components prohibited for use in food producing animals.

15.17 Non-patient specific compounding. Compounded preparations dispensed or distributed to a practitioner pursuant to a non-patient specific order to be administered by a practitioner or practitioner's agent shall meet all of the following:
(1) The order shall include the name and address of the practitioner, drug, strength, quantity and the purpose of the compounded preparation.
(2) The label shall include the practitioner's name in place of the patient's name and state "For Practitioner Administration Only – Not for Dispensing or Distribution". If the sterility or integrity of the compounded preparation is not maintained after the initial opening of the container, the label shall state "Single-Dose Only".
(3) The pharmacist shall record the name and address of the location the compounded preparation was dispensed or distributed, and the lot number and BUD of all preparations dispensed or distributed to the practitioner.

SUBCHAPTER II – Non-sterile Compounding

15.20 Component Selection. (1) Components with an expiration date from the manufacturer or distributor may be used before the expiration date provided all of the following:

(a) The component is stored in its original container under conditions to avoid decomposition.

(b) There is minimal exposure of the remaining component each time component is withdrawn from the container.

(2) Components without an expiration date assigned by the manufacturer or supplier shall be labeled with the date of receipt and assigned a conservative expiration date, not to exceed three years after receipt, based upon the nature of the component and its degradation mechanism, the container in which it is packaged and the storage conditions.
(3) Components transferred to another container which shall provide integrity that is minimally equivalent to the original container and shall be identified with all of the following:

(a) Component name.
(b) Original supplier.
(c) Lot or control number.
(d) Transfer date.
(e) Expiration date.

15.21 Assigning BUD. (1) The BUD shall not be later than the expiration date on the container of any component.
(2) Only in the absence of stability information that is applicable to a specific drug product and preparation, the maximum BUD for a non-sterile compounded drug preparation that is packaged in a tight, light-resistant container is as follows:

(a) For nonaqueous formulations stored at controlled room temperature, the BUD shall not be later than the time remaining until the earliest expiration date of any active pharmaceutical ingredient or 6 months, whichever is earlier.

(b) For water-containing oral formulations, the BUD shall not be later than 14 days when stored in a refrigerator.

(c) For water-containing semisolid mucosal liquid, topical or dermal formulations, stored at controlled room temperature, the BUD shall not be later than 30 days.

(3) Assignment of BUD shall include an assessment of the need for antimicrobial agents or storage in a refrigerator to protect against bacteria, yeast, and mold contamination introduced during or after the compounding process.

SUBCHAPTER III – Sterile Compounding

15.30 Definitions. In this subchapter:
(1) "Ante area" means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, labeling and other high particulate generating activities are performed. The ante-area is the transition area between the unclassified area of the facility and the buffer area.
(2) "Buffer area" means an ISO Class 7 or ISO Class 8 if using an isolator or cleaner area where the primary engineering control that generates and maintains an ISO Class 5 environment is physically located.
(3) "Category 1" means a compounded sterile preparation compounded with a primary engineering control in a segregated compounding area.
(4) "Category 2" means a compounded sterile preparation compounded with a primary engineering control in a classified area.
(5) "Clean" means to physically remove debris, dirt, dust, and other impurities from surfaces or objects using a cleaning agent with a detergent.
(6) "Compounded sterile preparation" means a compounded final preparation intended to be sterile through the BUD.
(7) "Compounded stock solution" means a compounded solution to be used in the preparation of multiple units of a finished compounded sterile preparation.
(8) "Critical site" means a location that includes any component or fluid pathway surfaces or openings that are exposed and at risk of direct contact with air, moisture or touch contamination.
(9) "Disinfect" means the killing of microorganisms when used according to the disinfectant's label.
(10) "HEPA" means high-efficiency particulate air.
(11) "ISO Class 5" means conditions in which the air particle count is no greater than a total of 3,520 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA-filtered air.
(12) "ISO Class 7" means conditions in which the air particle count is no greater than a total of 352,000 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA-filtered air.
(13) "ISO Class 8" means conditions in which the air particle count is no greater than a total of 3,520,000 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA-filtered air.
(14) "Isolator" means an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. An isolator uses only decontaminated interfaces or rapid transfer ports for materials transfer.
(15) "Primary engineering control" means a device or zone that provides an ISO Class 5 environment for sterile compounding.
(16) "Restricted access barrier system (RABS)" means an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress or egress of materials through defined

openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. RABS include compounding aseptic isolators and compounding aseptic containment isolators.

(17) "Sterility assurance level of 10^{-6}" means an equivalent to a probability that one unit in a million is nonsterile.

(18) "Segregated compounding area" means a designated, unclassified space, area, or room that contains a primary engineering control.

(19) "Urgent use compounded sterile preparation" means a preparation needed urgently for a single patient and preparation of the compounded sterile preparation under Category 1 or Category 2 requirements would subject the patient to additional risk due to delays.

15.31 Facility design and environmental controls. (1) GENERAL. Facilities shall meet all of the following requirements:

(a) Be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

(b) Be accessible only to designated personnel.

(c) Have a heating, ventilation, and air conditioning system controlling the temperature and humidity.

(2) SEGREGATED COMPOUNDING AREA. A segregated compounding area shall meet all of the following requirements:

(a) Be located in an area away from unsealed windows and doors that connect to the outdoors, or significant traffic flow.

(b) Be located in an area which is not adjacent to construction sites, warehouses and food preparation areas.

(c) Have a defined perimeter.

(d) Locate the primary engineering control at least one meter from any sink.

(3) CLASSIFIED AREA. A classified area shall meet all of the following:

(a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets shall be smooth, impervious, free from cracks and crevices and nonshedding.

(b) Work surfaces shall be constructed of smooth, impervious materials. All work surfaces shall be resistant to damage from cleaning and sanitizing agents.

(c) Junctures where ceilings meet walls shall be covered, caulked, or sealed to avoid cracks and crevices in which microorganisms and other contaminate can accumulate. All areas in ceilings and walls where the surface has been penetrated shall be sealed.

(d) Ceilings that consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic and shall either be caulked or weighted and clipped.

(e) Walls shall be constructed of a durable material, panels locked together and sealed or of epoxy-coated gypsum board.

(f) Floors shall have a covering that shall be seamless or have heat-welded seams and coving to the sidewall. There shall be no floor drains.

(g) All sprinkler heads shall be flush with the ceiling.

(h) Ceiling lighting fixtures shall have exterior lens surfaces which are smooth, mounted flush and sealed.

(i) Carts shall be constructed of stainless steel wire, nonporous plastic or sheet metal with cleanable casters.

(j) Tacky mats may not be used in a classified area.

(k) HEPA filters and unidirectional airflow shall be used to maintain the appropriate airborne particulate classification.
(L) The classified area shall measure not less than 30 air changes per hour of which at least half shall be HEPA-filtered fresh air.
(m) A minimum differential positive pressure of 0.02-inch water column is required to separate each classified area. A pressure gauge or velocity meter shall be used to monitor the pressure differential or airflow between classified areas with results documented at least daily.
(n) Devices and objects essential to compounding shall be located at an appropriate distance from the primary engineering control.
(o) The ante area and buffer area shall be separate rooms, with walls and doors between them and controls to prevent the flow of lower quality air into the higher ISO class areas. If a pass through is used, only one door shall be opened at a time.
(p) The ante area shall meet all of the following requirements:
1. Be capable of maintaining an ISO Class 8 air or higher.
2. Have a sink with running hot and cold running water.

(q) The buffer area shall meet all of the following requirements:
1. Be capable of maintaining an ISO Class 7 air or better.
2. Only contain any of the following:
a. Items, including furniture, equipment, and supplies, that are required for the tasks to be performed in the buffer area.
b. Items that are smooth, impervious, free from cracks and crevices, nonshedding, and easily cleaned and disinfected.
c. Items that have been cleaned and disinfected immediately prior to their being placed in the buffer area.
3. Does not contain any sinks.
4. Does not contain any course cardboard, external shipping containers and nonessential paper.

(4) PRIMARY ENGINEERING CONTROL. The primary engineering control shall be certified by an independent, qualified individual certified by the Controlled Environment Testing Association's National Board of Testing or another Board approved entity prior to initial use and then every six months. It shall also be certified when any of the following occurs:
(a) Redesign of the facility.
(b) Replacement of the primary engineering control.
(c) Relocation of the primary engineering control.

15.32 Personnel hygiene, garbing and protective gear. (1) Personnel suffering from rashes, sunburn, oozing tattoos or sores, conjunctivitis, active respiratory infection, or other active communicable disease shall be excluded from working in compounding areas until the condition is resolved.
(2) All personnel who engage in compounding sterile preparations shall comply with all of the following requirements before entering the compounding area:
(a) Remove personal outer garments, all cosmetics, exposed jewelry and piercings, headphones, ear buds, and cell phones.
(b) Abstain from eating, chewing gum or drinking in the compounding area or bringing food, gum or drink into the compounding area.

(c) Artificial nails, nail extenders or nail polish may not be worn while working in the compounding area. Nails shall be neat and trim.

(d) Don personnel protective equipment and perform hand hygiene in the following order:

1. Low-lint, disposable shoe covers.
2. Low-lint, disposable covers for head and facial hair that cover the ears and forehead and face masks.
3. Eye shields, if required due to working with irritants or hazardous drugs.
4. Wash hands and forearms up to the elbows with unscented soap and water for at least 30 seconds. Hands and forearms to the elbows shall be completely dried using either lint-free disposable towels or wipes.
5. Don low lint disposable gown or overalls.
6. Prior to donning sterile gloves, hand antisepsis shall be performed using an alcohol-based hand rub with sustained antimicrobial activity following the manufacturers labeled instructions and application times.

(3) Gloves on hands and gauntlet sleeves on RABS shall be routinely inspected for holes, punctures, or tears and shall be replaced immediately if any are detected. Sterile gloves shall be donned over the RABS gloves.

(4) Disinfection of contaminated gloved hands shall be accomplished by wiping or rubbing sterile 70% isopropyl alcohol on all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Routine application of sterile 70% isopropyl alcohol shall occur throughout the compounding process and whenever non-sterile surfaces, including vials, counter tops, chairs and carts, are touched.

(5) When compounding personnel exit the buffer or segregated compounding area, a gown may be removed and retained in the ante area or segregated compounding area if not visibly soiled, to be worn again during the same work shift. Coveralls, shoe covers, hair and facial hair covers, face masks, eye shields, and gloves shall be replaced with new ones before re-entering the compounding area.

(6) Garbing items, including gowns, shall be segregated and stored before use in an enclosure to prevent contamination.

(7) Visibly soiled gowns shall be changed immediately.

(8) Gloves shall be sterile and powder free and tested by the manufacturer for compatibility with alcohol disinfection.

15.33 Cleaning and Disinfecting the Compounding Area and Supplies. (1) Compounding personnel are responsible determining the cleaning and disinfecting products to be used and for ensuring that the frequency of cleaning and disinfecting compounding area is done.

(2) Compounding personnel shall clean in accordance with the following:

(a) Primary engineering control work surfaces, counters, floors and work surfaces in the buffer zone area, ante room and segregated compounding areas daily.

(b) Walls, ceilings and storage shelving monthly.

(c) When a spill occurs or the surface is visibly soiled.

(d) Sporicidal agents shall be used at least weekly to clean compounding areas.

(3) Compounding personnel shall disinfect in accordance with the following:

(a) Primary engineering control work surfaces at the beginning and end of each compounding business day and before each batch, but not longer than 4 hours following the previous disinfection when ongoing compounding activities are occurring.

(b) When microbial contamination is known to have been or is suspected of having been introduced into the compounding area.

(4) All cleaning and disinfecting practices and policies for the compounding area shall be included in written standard operating procedures and shall be followed by all compounding and environmental services personnel.

(5) Cleaning, detergents and disinfection agents shall be selected and used with consideration of compatibilities, effectiveness and inappropriate or toxic residues. The selection and use of disinfectants shall be guided by microbicidal activities, inactivation by organic matter, residue, and shelf life. Disinfectants shall have antifungal, antibacterial and antiviral activity. Sporicidal agents shall be used at least weekly to clean compounding areas.

(6) Storage sites for compounding ingredients and supplies shall remain free from dust and debris.

(7) Floors, walls, ceiling and shelving in the classified and segregated compounding areas are cleaned when no aseptic operations are in progress. Cleaning shall be performed in the direction from cleanest to dirtiest areas.

(8) All cleaning tools and materials shall be low-lint and dedicated for use in the buffer room, ante room and segregated compounding areas. If cleaning tools and materials are reused, procedures shall be developed based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned.

(9) Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent delivered from a spray bottle or other suitable delivery method. After the disinfectant is wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.

(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. 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.

(11) When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 primary engineering control without the need to disinfect the individual sterile supply items.

15.34 Urgent use compounded sterile preparations.

(1) The compounding process shall be a continuous process that does not exceed one hour, unless required for the preparation.

(2) Administration shall begin within one hour of the completion of the preparation.

(3) Aseptic technique shall be followed during preparation, and procedures shall be used to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other compounded sterile products.

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

15.35 Sterilization methods.

(1) Sterilization methods employed shall sterilize while maintaining its physical and chemical stability and the packaging integrity of the compounding sterile preparations. The efficacy of sterilization and depyrogenation of container closure systems performed in the pharmacy shall be established, documented, and reproducible.

(2) Pre-sterilization requirements shall meet all of the following:

(a) During all compounding activities that precede terminal sterilization, including weighing and mixing, compounding personnel shall be garbed and gloved in the same manner as when performing compounding in an ISO Class 5 environment. All pre-sterilization procedures shall be completed in an ISO Class 8 or better environment.

(b) Immediately before use, all nonsterile measuring, mixing, and purifying devices used in the compounding process shall be thoroughly rinsed with sterile, pyrogen-free water and then thoroughly drained or dried.

(3) Sterilization shall be performed utilizing one of the following methods:

(a) *Sterilization by filtration.* Sterilization by filtration involves the passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent. Filtration may not be used when compounding a suspension when the suspended particles are removed by the filter being used. This method shall meet all of the following:

1. Sterile filters used to sterile filter preparations shall meet all of the following requirements:

a. Be pyrogen-free and have a nominal pore size of 0.22 microns.

b. Be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the compounded sterile preparations will be filtered.

c. Be chemically and physically stable at the compounding pressure and temperature conditions.

d. Have sufficient capacity to filter the required volumes.

e. Yield a sterile filtrate while maintaining pre-filtration pharmaceutical quality, including strength of ingredients of the specific compounded sterile preparations.

2. The filter dimensions and liquid material to be sterile filtered shall permit the sterilization process to be completed rapidly without the replacement of the filter during the filtering process.

3. When compounded sterile preparations are known to contain excessive particulate matter, one of the following shall occur:

a. A pre-filtration step using a filter of larger nominal pore size.

b. A separate filter of larger nominal pore size placed upstream of the sterilizing filter to remove gross particulate contaminants before the

compounding sterile compound is passed through the sterilizing grade filter.

4. Sterilization by filtration shall be performed entirely within an ISO Class 5 or better air quality environment.

5. Filter units used to sterilize compounded sterile preparations shall be subjected to the manufacturers' recommended post-use integrity test.

(b) *Sterilization by steam heat*. The process of thermal sterilization using saturated steam under pressure shall be the method for terminal sterilization of aqueous preparations in their final, sealed container closure system. The effectiveness of steam sterilization shall be established and verified with each sterilization run or load by using biological indicators, physicochemical indicators and integrators. This method shall meet all of the following:

1. All materials shall be directly exposed to steam under adequate pressure for the length of time necessary, as determined by use of appropriate biological indicators, to render the items sterile. The duration of the exposure period shall include sufficient time for the compounded sterile preparation to reach the sterilizing temperature.

2. The compounded sterile preparation and other items shall remain at the sterilizing temperature for the duration of the sterilization period. The sterilization cycle shall be designed to achieve a sterility assurance level of 10^{-6}.

3. Compounded sterile preparations shall be placed in trays which allow steam to reach the compounded sterile preparations without entrapment of air. Paper, glass and metal devices or items shall be wrapped in low lint protective fabric, paper or sealed in envelopes that will permit steam penetration and prevent post sterilization microbial contamination.

4. Immediately before filling ampules and vials, solutions shall be passed through a filter having a nominal pore size of not larger than 1.2 microns for removal of particulate matter.

5. Sealed containers shall be able to generate steam internally. Stoppered and crimped empty vials shall contain a small amount of moisture to generate steam. Deep containers, including beakers and graduated cylinders, shall be placed on their sides to prevent air entrapment or have a small amount of water placed in them.

6. Porous materials and items with occluded pathways shall only be sterilized by steam if the autoclave chamber has cycles for dry goods.

7. The steam supplied shall be free of contaminants and generated using clean water.

8. The seals on the doors of autoclave chambers shall be examined visually every day they are used for cracks or damage and the seal surfaces shall be kept clean.

9. A data recorder or chart shall be used to monitor each cycle and the data shall be reviewed to identify cycle irregularities in temperature or exposure time.

10. Materials in direct contact with the compounded sterile preparation shall undergo a depyrogenation process before being sterilized using steam heat unless the materials used are certified to be pyrogen-free.

(c) *Sterilization by dry heat.* Dry heat sterilization shall be used only for those materials that cannot be sterilized by steam or filtration. The effectiveness of dry heat sterilization

shall be verified using appropriate biological indicators and temperature sensing devices. This method shall meet all of the following:

1. The duration of the exposure period shall include sufficient time for the compounding sterile preparation or items to reach the sterilizing temperature. The compounded sterile preparation and items shall remain at the sterilizing temperature for the duration of the sterilization period.
2. Heated air shall be evenly distributed throughout the chamber.
3. Sufficient space shall be left between materials to allow for good circulation of the hot air.
4. The oven shall be equipped with temperature controls and a timer.
5. A data recorder or chart shall be used to monitor each cycle and the data shall be reviewed to identify cycle irregularities in temperature or exposure time.
6. Materials shall first undergo a depyrogenation process before being sterilized using dry heat, unless the materials used are certified to be pyrogen-free.

(4) Dry heat depyrogenation shall be used to render glassware and other thermostable containers pyrogen free. The duration of the exposure period shall include sufficient time for the items to reach the depyrogenation temperature. The items shall remain at the depyrogenation temperature for the duration of the depyrogenation period. The effectiveness of the dry heat depyrogenation cycle shall be established and verified annually using endotoxin challenge vials to demonstrate that the cycle is capable of achieving at least a 3-log reduction in endotoxins.

15.36 Inspection, sterility testing and antimicrobial effectiveness.

(1) PHYSICAL INSPECTION. (a) At the completion of compounding, the compounded sterile preparation shall be inspected by performing all of the following:

1. Visually inspect the container closure for leakage, cracks in the container or improper seals.
2. Visually check the compounded sterile preparation for phase separation.
3. Each individual injectable unit shall be inspected against a lighted white background and a black background for evidence of visible particulates or other foreign matter or discoloration.

(b) For compounded sterile preparations which will not be dispensed promptly after preparation, an inspection shall be conducted immediately before it is dispensed for any defects, including precipitation, cloudiness or leakage, which may develop during storage.

(c) Compounded sterile preparations with any observed defects shall be immediately discarded or marked and segregated from acceptable units in a manner that prevents them from being dispensed.

(2) STERILITY TESTING.

(a) The membrane filtration method shall be used for sterility testing unless it is not possible due to the compounded sterile preparation formulation. The direct inoculation of the culture method shall be used when the membrane filtration method is not possible.

(b) If a preparation may be needed before the results of sterility testing have been received, the pharmacy shall daily observe the incubating test specimens and immediately recall the dispensed preparations when there is any evidence of microbial growth in the test specimens. The patient and the prescriber to whom a potentially contaminated

compounded sterile preparation was administered shall be notified immediately of the potential risk.

(c) Positive sterility test results shall prompt a rapid and systematic investigation into the causes of the sterility failure, including identification of the contaminating organism and any aspects of the facility, process or personnel that may have contributed to the sterility failure. The investigation and resulting corrective actions shall be documented.

(d) All Category 2 compounded sterile preparations made from one or more nonsterile ingredients, except those for inhalation and ophthalmic administration, shall be tested to ensure that they do not contain excessive bacterial endotoxins.

(e) Notwithstanding par. (d), a compounded sterile preparation does not need to be tested for bacterial endotoxins if the material is stored under cool and dry conditions and one of the following:

1. The certificate of analysis for the nonsterile ingredient lists the endotoxins burden, and that burden is found acceptable.
2. The pharmacy has predetermined the endotoxins burden of the nonsterile ingredient and that burden is found acceptable.

(3) ANTIMICROBIAL EFFECTIVENESS. Compounded sterile preparations containing a preservative added by the compounder shall pass an antimicrobial effectiveness testing with the results obtained on the specific formulation before any of the compounded sterile preparation is dispensed. The test may be conducted only once on each formulation in the particular container-closure system in which it will be stored or dispensed. The antimicrobial effectiveness test shall occur at one of the following times:

(a) At the completion of the sterility test.

(b) At the time of preparation for compounded sterile preparations which have not undergone a sterility testing.

15.37 Beyond Use Dating.

(1) Sterility and stability considerations shall be taken into account when establishing a BUD. 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 prepared Category 2 compounded sterile preparations, one of the following:

1. Prepared with one or more nonsterile ingredients, 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 4 days when the preparation is stored at controlled room temperature.

b. Within 7 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 sterility testing performed, one of the following:
   a. Within 6 days when the preparation is stored at controlled room temperature.
   b. Within 9 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 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 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 with only 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 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 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 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.

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.

(2) The BUD established in sub. (1) may not be exceeded or extended for compounded sterile preparations without verifiable supporting valid scientific sterility and stability information that is directly applicable to the specific preparation or compound.

(3) For compounded sterile preparations which have been assigned a BUD based upon storage in a freezer, the integrity of the container-closure system with the specific compounded sterile preparation in it shall have been demonstrated for 45 days at frozen storage. The container-closure integrity test may be conducted only once on each formulation in the specific container closure-system in which it will be stored or dispensed.

(4) When a preservative is added, the compounded sterile formulation shall pass antimicrobial effectiveness testing that shall include inoculation of standardized microorganisms, incubation serial sampling, and calculation of the changes in colony forming unit concentrations in terms of log reduction. The results of antimicrobial effectiveness testing shall be obtained before any of the compounded sterile preparation is dispensed. Preservatives shall not be used as a substitute for good compounding practices.

15.38 Training and evaluation. (1) GENERAL. The managing pharmacist, pharmacists, pharmacy technicians, pharmacy interns and pharmacy externs compounding sterile preparations shall successfully complete didactic or practical training. The didactic or practical training shall be done before any compounding personnel initially prepares compounded sterile preparations and annually thereafter and shall include all of the following:

(a) Hand hygiene and garbing.

(b) Cleaning and disinfection.

(c) Measuring and mixing.

(d) Aseptic manipulation.

(e) Cleanroom behavior.

(f) Sterilization and depyrogenation.

(g) Use of equipment.

(h) Documentation.

(i) Use of primary engineering controls.

(2) EVALUATION. Compounding personnel shall successfully complete an initial and annual evaluation which includes all of the following:

(a) Visual observation of hand hygiene and garbing.

(b) Visual observation of aseptic technique.

(c) Gloved fingertip and thumb sampling.

(d) Media-fill tests.

(3) GLOVED FINGERTIP. Successfully gloved and thumb sampling is measured by samplings resulting in zero colony-forming units no fewer than three times. Sampling shall be performed on sterile gloves inside of an ISO Class 5 primary engineering control. Gloved fingertip and thumb sampling in a RABS or an isolator shall be taken from the sterile gloves placed over the gauntlet gloves. When gloved fingertip sample results exceed action levels defined by the

pharmacy, a review of hand hygiene and garbing procedures, glove and surface disinfection procedures and work practices shall be performed and documented.
(5) RECORDS. The pharmacy shall maintain written policies and procedures for the initial and ongoing training and evaluation of persons involved in compounding sterile preparations. Documentation of all training, assessments, gloved fingertip tests and media-fill simulations shall be maintained by the pharmacy for 5 years and made available to the Board upon request.

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

(END OF TEXT OF RULE)

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

Dated May 26, 2017 Agency

Chair of the Pharmacy Examining Board

-

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

2. Administrative Rule Chapter, Title and Number
Phar 15

3. Subject
Compounding Pharmaceuticals

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

5. Chapter 20, Stats. Appropriations Affected
20.165(1)(g)

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

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

8. Would Implementation and Compliance Costs Be Greater Than $20 million?
☐ Yes ☒ No

9. Policy Problem Addressed by the Rule
This rule repeals and recreates the requirements for compounding pharmaceuticals.

10. 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.
This rule was posted for economic comments for 30 days and none were received.

11. Identify the local governmental units that participated in the development of this EIA.
None.

12. 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)
This rule will not have an economic impact on public utility rate payers, local governmental units or the State's economy. The Board does not know how many or which pharmacies are compounding sterile pharmaceuticals, therefore, is unable to determine whether this rule will have an economic impact on specific businesses.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit to the rule is to update the standards of compounding in the state of Wisconsin. The Board primarily utilized the United States Pharmaceopeia chapters 795 and 797 which are the recognized pharmacopeial standards. The Board also reviewed several other states which have updated their compounding rules since the New England Compounding Center meningitis outbreak in 2012.
The alternative to the rule is to maintain the current rules which do not adequately protect the public from harm.

14. Long Range Implications of Implementing the Rule
The long range benefit is the safe compounded pharmaceutical products.

15. Compare With Approaches Being Used by Federal Government
None. The federal government does regulate outsourcing facilities.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Illinois: Illinois requires a specific area for compounding; records to be kept of each compounded prescription and the

components; reference books; and a pharmacy operations manual with policies and procedures pertinent to the complexity and size of the compounding operations. The pharmacy may compound drug products to be sued by practitioners in their office for administration to patients. Sterile compounding requires: a designated area of sufficient size to accommodate a laminar airflow hood, barrier isolation chamber and proper storage of drugs and supplies; the laminar airflow hood shall be certified annually; sink with hot and cold water; refrigerator and/or freezer with a thermometer or temperature recording device; current resource materials and texts; patient profile or medication system; specific labeling requirements including beyond use date and time; and compounding records are to be maintained for 5 years.

Iowa: Iowa requires compliance with United States Pharmacopeia, Chapters 795 and 797. In addition, an FDA registered outsourcing facility must be licensed as a pharmacy in Iowa.

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 by the Pharmacy Compounding Accreditation Board and be in compliance with United States Pharmacopeia standards. In addition, any outsourcing facility must be licensed as a pharmacy in Michigan.

Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow United States Pharmacopeia, chapter 795 standards and pharmacies compounding sterile drug preparations to follow United States Pharmacopeia, chapter 797 standards.

17. Contact Name	18. Contact Phone Number
Sharon Henes	(608) 261-2377

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

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

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.

Philip J. Trapskin, PharmD, RPh
2861 Crinkle Root Drive
Fitchburg, WI 53711

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

(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,

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JOINT COMMITTEE FOR THE REVIEW OF ADMINISTRATIVE RULES

COMMITTEE CO-CHAIRS: SENATOR STEVE NASS AND REPRESENTATIVE JOAN BALLWEG

December 13, 2017

Laura Gutierrez, Secretary
Department of Safety & Professional Services
P.O. Box 8935
Madison, WI 53708-8935

Dear Secretary Gutierrez,

We are writing to notify you that on December 12, 2017 the Joint Committee for Review of Administrative Rules (JCRAR) held a public hearing on CR 16-085, relating to compounding pharmaceuticals. Pursuant to s. 227.19 (5) (b) 2., Stats., JCRAR approved a motion requesting the Pharmacy Examining Board (PEB) consider modifications to the rule. The motion requesting modifications was passed by 10-0 vote.

In the motion, JCRAR requested the PEB consider changes including, but not limited to the following:

1. Include a purpose statement section at the beginning of this rule clearly stating the purpose of this regulation, Phar 15, is to create a state regulatory standard that aligns with the United States Pharmacopeia Chapters 795 and 797 and that 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.

We request that the PEB or DSPS notify the JCRAR co-chairs in writing whether the Board plans to consider reviewing CR 16-085 for modifications, pursuant to s. 227.19 (5) (b) 2., Stats.

Sincerely,

Senator Steve Nass
Co-Chair, JCRAR

Rep. Joan Ballweg
Co-Chair, JCRAR

SEN.NASS@LEGIS.WISCONSIN.GOV
608-266-2635
P.O. BOX 7882, STATE CAPITOL
MADISON, WI 53707-7882

REP.BALLWEG@LEGIS.WISCONSIN.GOV
608-266-8077
P.O. BOX 8953, STATE CAPITOL
MADISON, WI 53708-8953

Chapter Phar 17

PHARMACY INTERNSHIP

Phar 17.01 Authority. The rules in this chapter are adopted pursuant to the authority in ss. 15.08 (5) (b), 227.11 (2), and 450.03 (1) (g) and (2) (b), Stats.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02; **correction made under s. 13.92 (4) (b) 7., Stats., Register June 2015 No. 714.**

Phar 17.02 Definitions. In this chapter:

(1) "Academic internship" means a practical experience program consisting of the practice of pharmacy sponsored by a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(2) "Direct supervision" means immediate on premises availability to continually coordinate, direct and inspect at first hand the practice of another.

(3) "Foreign graduate internship" means the practice of pharmacy by a person who has first filed an application with the board for original licensure under s. Phar 2.02 and has not graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(4) "Intern" means a person engaged in the practice of pharmacy pursuant to subs. (1), (3), (6) and (8) or s. 450.03 (1) (g), Stats.

(5) "Internship in the practice of pharmacy" means the completion of a minimum of 1500 hours in aggregate in the practice of pharmacy under subs. (1), (3), (6), (7) or (8).

(6) "Postgraduate internship" means the practice of pharmacy by a person who has first filed an application with the board for original licensure under s. Phar 2.02 and has graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(7) "Practical experience internship" means practical experience acquired in another state which is comparable to an internship as described in subs. (1), (3), (6) and (8).

(8) "Student non−academic internship" means the practice of pharmacy by a person which is not acquired in an academic internship.

(9) "Supervising pharmacist" means a pharmacist who supervises and is responsible for the actions of an intern in the practice of pharmacy.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02.

Phar 17.03 Academic internship. A person participating in an academic internship is not required to register as an intern with the board. There is no restriction in the number of hours earned in an academic internship.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02.

Phar 17.04 Foreign graduate internship. (1) Prior to performing duties as an intern or to receiving credit for hours participating in a foreign graduate internship the person must file an application with the board for original licensure under s. Phar 2.02, and submit evidence satisfactory to the board of having obtained certification by the foreign pharmacy graduate examination committee.

(2) A foreign graduate internship is limited to performing duties constituting the practice of pharmacy under the supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location worked by an intern under his or her supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request. Prior to performing duties as an intern or to receiving credit for hours in an internship in the practice of pharmacy under this section the supervising pharmacist shall be disclosed in the initial application and any change of a supervising pharmacist shall be disclosed to the board prior to further performing duties constituting the practice of pharmacy as an intern.

(4) Upon completing a maximum of 2000 hours of the practice of pharmacy in a foreign graduate internship, the internship is terminated and the person shall not further engage in the practice of pharmacy until obtaining licensure from the board.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02; CR 06−050: am. (1), (2) and (4), r. (3) and (5) Register October 2006 No. 610, eff. 11−1−06.

Phar 17.05 Postgraduate internship. (1) Prior to performing duties as an intern or to receiving credit for hours participating in a postgraduate internship, the person must file an application with the board for original licensure under s. Phar 2.02 and submit to the board evidence of having been graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(2) A postgraduate internship is limited to performing duties constituting the practice of pharmacy under the supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location worked by an intern under his or her supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request.

(3) Upon completing a maximum of 2000 hours of the practice of pharmacy in a postgraduate internship, the internship is terminated and the person shall not further engage in the practice of pharmacy until obtaining licensure from the board.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02; CR 06−050: am. (2) Register October 2006 No. 610, eff. 11−1−06.

Phar 17.06 Practical experience internship. There is no restriction in the number of hours earned in a practical experience internship. In determining comparable practical experience the board shall consider the duties performed constituting the practice of pharmacy as described in s. 450.01 (16), Stats.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02.

Phar 17.07 Student non−academic internship. (1) Prior to performing duties as an intern or to receiving credit for hours participating in a student non−academic internship the person must successfully complete his or her second year in and be enrolled at a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(2) A student non−academic internship is limited to performing duties constituting the practice of pharmacy under the direct supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location

worked by an intern under his or her direct supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02.

PHARMACY RULES LIST

Current Rule Projects

In Process

Phar 15 (Compounding) –Legislative Review (Scope expires Feb 4, 2020)
Phar 1 (add definitions apply to chapter 17) – Public Hearing 1/9/18 (Scope Expires March 18, 2020)
Phar 7 (Practice of Pharmacy) – Currently Drafting (Scope expires Feb 4, 2020)

Projects identified on previous Goals Lists which fall under this chapter

7.015 Technicians
7.09 (1) (b) Automated Dispensing Systems
7.02 Prescription Labels
Pharmacists working from home
Patient consultation
Collaborative Practice Agreements
Delivery (security of drugs shipped through the mail)

Phar 7 (Institution TCT) – Scope published 9/18/17 (Pilot ends 9/30/19; Scope expires 3/18/20)
Phar 7 (Community TCT) – Scope published 9/18/17 (Pilot ends 10/31/19; Scope expires 3/18/20)
Phar 7 (Pharmacist Tech Ratio) – Scope published 9/18/17 (Pilot ends 9/30/19; Scope expires 3/18/20)
Phar 7 (Automated Final Check) – Scope published 9/18/17 (Pilot ends 9/30/19; Scope expires 3/18/20)
Phar 17 (Intern) – Scope published 9/18/17 (Scope Expires March 18, 2020)

Future Rule Projects

Required rules pursuant to 450.073 (3), Wis. Stats. (Electronic track and trace)
Compliance with Drug Supply Chain Security Act

- Third Party Logistics Providers
- Wholesale Distributor Requirements
- Product Tracing Requirements

Phar 8 – Partial fill of controlled substances, security of controlled substances
Phar 12 Update (including security requirements)
Phar 13 Clean-Up
Out of state pharmacies
Phar 6.07 (3) – Storage of controlled substances (specifically schedule 3-5)
Par 2 – Foreign educated applicants

DBA REMOTE SITE	ADDRESS	CITY-ST-ZIP	RECEIVED	PHARMACY #
Marshfield Clinic Dispensing	900 West Clairemont Ave	Eau Claire, WI 54701-612	04-21-10	7858-42
St Clare Memorial Hospital Suring Health Center	913 East Main Street	Suring, WI 54174	05-10-10	5339-42
HFM Meds to Go	3310 Calument Avenue	Manitowoc, WI 54220	02-14-11	8556-42
Muscoda Hometown Precription Services	125 W Nebraska Street	Muscoda, WI 53573	05-03-11	5538-42
Marshfield Clinic Dispensing-Lake Hallie Center	12961 27th Ave	Chippewa Falls WI 54729	06-24-11	7858-42
Marshfield Clinic Dispensing-Lmercer Center	5110 North Highway 51	Mercer, WI 54547	06-24-11	7174-42
Aurora Two Rivers Clinic Dispensary	2219 Garfield Street	Two Rivers, WI 54241	06-27-11	8104-42
Langlade Hospital Hotel Dieu of St Joseph of Antigo WI	501 Aurora Street	Antigo, Wi 54409	08-24-11	7099-42
Bellin Health Meds	555 Quality Court	Wrightstown, WI 54180	08-29-11	8904-42
Aurora Waterford Clinic Dispensary	818 Forrest Lane Suite 101	Waterword WI 53185	09-20-11	8104-42
Aurora Green Bay Clinic Dispensary	2253 West Mason Street	Green Bay WI 54303	09-20-11	8104-42
Aurora Mayfair Clinic Dispensary	1055 North Mayfair Road	Wauwatosa, Wi 53226	12-19-11	8104-42
Aurora Kenosha Dispensary	7540 2nd Ave	Kenosha WI 53143	01-25-12	9107-42
Aurora Hartland Clinic Dispensary	600 Walnut Ridge Dr	Hartland, WI 53029	04-11-12	9107-42
Aurora Kaukauna Clinic Dispensary	2700 Crooks Ave	Kaukauna, WI 54130	03-22-12	9107-42
Aurora Kenosha Dispensary	7540 2nd Ave	Kenosha WI 53143	02-27-12	9107-42
Aurora Prescription Dispensing Site	375 East Ave Suite 1	Lomira, WI 53048	05-01-12	9107-42
Aurora Prescription Dispensing Center	W3985 County Rd NN	Elkhorn, WI 53121	05-08-12	9107-42
Aurora Prescription Dispensing Center	180 W Grange Ave	Milwwaukee, WI 53207	07/18/12	9107-42
Tri-County Memorial	8601 Lincoln Street	Whitehall, WI 54773	07-05-12	4750-42

DBA REMOTE SITE	ADDRESS	CITY-ST-ZIP	RECEIVED	PHARMACY #
Musoda Hometown Prescription Services	1075 North Wisconsin Ave	Muscoda, WI 53573	07-31-12	5538-42
Aurora Precription Dispensing Center	600Walnut Ridge Dr	Hartland, WI 53029	08-13-12	9035-42
Aurora Prescription Dispensing Center	313 South Main Stret	Cedar Grove, WI 53013	08-13-12	9035-42
Aurora Prescription Dispensing Center	525 Kenosha Street Suite C	Walworth, WI 53184	08-15-12	9035-42
Bellin Health Meds Remote Dispensing Site	555 Quality Court	Wrightstown, WI 54180	08-23-12	7816-42
St. Elizabeth Hospital Pharmacy	1550 Midway Place	Menasha, WI 54952	11-5-2012	4990-42
Bellin Health Meds Remote Dispensing Site Green Bay	3263 Eaton Rd	Green Bay, WI 54180	9-6-2012	7816-42
Aurora Prescription Dispensing Center	W231 N1440 Corporate Ct	Waukesha, WI 53186	10-1-2012	9035-42
Aurora Prescription Dispensing Center	W3985 County Rd NN	Elkhorn, WI 53121	9-19-2012	9035-42
Aurora Prescription Dispensing Center	S68 W15500 Janesville Rd	Muskego, WI 53150	9-19-2012	9035-42
St Clare Memorial Hospital Lena Health Center	200 S Rosera St, PO Box 1	Lena, WI 54139	12-6-2012	5339-42
CMH Oconto Medical Center	103 First St	Oconto, WI 54153	12-6-2012	5339-42
St Clare Memorial Oconto Health Center	103 First St	Oconto, WI 54153	03-04-13	9179-42
St Clare Memorial Hospital Mountain Health Center	14353 Hwy 32/64	Mountain, WI 54149	03-04-13	9179-42
Genoa Healthcare of Wisconsin LLC	229 E Wisconsin Ave, Ste 6	Milwaukee, WI 53202	4-30-13	9163-42
St Clare Memorial Hospital Pulaski RDS	940 S St Augustine Dr	Pulaski, WI 54162	5-24-13	5339-42
Northlakes Clinic Pharmacy	600 Shell Creek Rd	Minong, WI 54859	6-5-13	9206-42
Aurora Prescription Dispensing Center #1810	S68 W15500 Janesville Rd	Muskego, WI 53150	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1145	W3985 County Rd NN	Elkhorn, WI 53121	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1222	313 S Main St	Cedar Grove, WI 53013	8-16-2013	9395-42

DBA REMOTE SITE	ADDRESS	CITY-ST-ZIP	RECEIVED	PHARMACY #
Aurora Prescription Dispensing Center #1174	525 Kenosha Street Suite C	Walworth, WI 53184	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1160	W231 N1440 Corporate Ct	Waukesha, WI 53186	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1067	600 Walnut Ridge Dr	Hartland, WI 53029	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1312	2700 Crooks Ave	Kaukauna, WI 54130	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1260	1055 N. Mayfair Rd	Wauwatosa, WI 53226	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1250	2219 Garfield St	Two Rivers, WI 54241	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1179	7540 22nd Ave	Kenosha, WI 53143	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1141	2253 W. Mason St	Green Bay, WI 54303	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1108	375 East Ave Suite 1	Lomira, WI 53048	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1068	818 Forrest Ln, Suite 101	Waterford, WI 53185	8-16-2013	9395-42
Aurora Prescription Dispensing Center #1005	180 W Grange Ave	Milwaukee, WI 53207	8-16-2013	9395-42
Phillips Drug Store Corporation	1515 Academy St	Elroy, WI 53929	11-7-2013	5621-42
Gundersen Tri-County Hospital Remote Dispensing Site	18601 Lincoln St	Whitehall, WI 54773	11-7-2013	4750-42
Aurora Prescription Dispensing Center	201 E. Morrissey Dr	Elkhorn, WI 53121	12-4-2013	9395-42
Agnesian Prescription Center - Mayville	360 S. Mountin Dr	Mayville, WI 53050	12-10-2013	8107-42
Agnesian Prescription Center - Brownville	900 Main Street	Brownville, WI 53006	1-14-2014	8107-42
Phillips Drug Store Corporation - Necedah	1408 Wheelihan Ave	Necedah, WI 54646	2-11-2014	5621-42
Aurora Prescription Dispensing Center	16985 W Bluemound Rd St	Brookfield, WI 53005	2-24-2014	9395-42
Aspirus Clinic Pharmacy	2720 Plaza Dr, Ste 1125	Wausau, WI 54401	3-11-2014	8072-42
Memorial Health Center, Inc	135 S. Gibson St	Medford, WI 54451	3-20-2014	4917-42

DBA REMOTE SITE	ADDRESS	CITY-ST-ZIP	RECEIVED	PHARMACY #
Phillips Drug Store Corp Mauston	1040 Division St	Mauston, WI 53948	7-9-2014	5621-42
Marshfield Clinic Dispensing Riverview Center	1000 Starr Ave	Eau Claire, WI 54703	8-11-2014	8125-42
Marshfield Clinic Dispensing Oakwood Center	3501 Golf Rd	Eau Claire, WI 54701	8-11-2014	7858-42
Marshfield Clinic Dispensing Merrill Center	1205 O'day St	Merrill, WI 54452	8-11-2014	7174-42
Skywalk Delafield	3195 Hillside Dr	Delafield, WI 53018	11-4-2014	9271-42
Omni Pharmacy	7810 W Good Hope Rd	Milwaukee, WI 53233	11-14-2014	9121-42
UW Health Remote Dispensing Services	2202 S Park St	Madison, WI 53713	3-2-2015	9239-42
Phillips Total Care Northwest	256 N Willson Dr	Altoona, WI 54720	10-7-2015	9001-42
HSHS RDS Oostburg	11 S 10th St	Oostburg, WI 53070	12-2-2015	5339-42
Aurora Prescription Dispensing Center	700 N Lake Ave Ste 101	Twin Lakes, WI 53181	3-30-2016	9395-42
St Vincent De Paul Community Outreach Dispensary	1301 Cheri Blvd	Marinette WI 54143	05-04-2016	9183-42
Skywalk Mequon	1655 W MEQUON RD	MEQUON WI 53092	05-23-16	9271-42
Beaver Dam Hometown Pharmacy	609 N Spring St	Beaver Dam WI 53916	6-16-16	9356-42
Corner Drug Hometown Pharmacy	206 N Iowa St	Dodgeville WI 53533	6-16-16	5538-42
Muscoda Hometown Prescription Services	1075 N Wisconsin Ave	Muscoda WI 53573	7-21-16	8528-42
Highland Hometown Prescription Services	723 Main St	Highland WI 53543	7-21-16	5538-42
Aurora Prescription Dispensing Center	7878 N 76th St Suite 101	Milwaukee WI 53223	7-13-16	9395-42
Whole Health Prescription Pickup	1225 W Mitchell St	Milwaukee WI 53204	7/11/2016	9246-42
Whole Health Prescription Pickup	2020 W Wells St	Milwaukee WI 53233	7/11/16	9246
Philips Pharmacy-Mauston	1040 Division St	Mauston, WI 53948	9/23/16	5621-42

DBA REMOTE SITE	ADDRESS	CITY-ST-ZIP	RECEIVED	PHARMACY #
Philips Pharmacy-Elroy	1515 Academy St	Elroy, WI 53929	9/23/16	5621-42
SSM HEALTH PRESCRIPTION CENTER	10 TOWER DR SUITE 300	SUN PRAIRIE 53590	11/08/16	8338-42
AURORA PRESCRIPTION DISPENSING CENTER	620 S WISCONSIN DR	HOWARDS WI 53083	11/18/16	9395-42
AURORA PRESCRIPTION DISPENSING CENTER	1001 SERVICE RD SUITE	KIEL WI 53042	11/18/16	9395-42
Florence Prescription Services	1010 Olive Ave	Florence WI 54121	12/07/16	8527-42
SSM HEALTH PRESCRIPTION CENTER	700 S PARK STREET	Madison, WI 53713	12/09/16	8338-42
UW Health Remote Dispensing Services	2880 University Ave	Madison, WI 53713	12/14/16	9435-42
UW HEALTH REMOTE DISPENSING SERVICES	6041 Brasswood Dr.	Fitchburg WI 53719	12/27/16	9435-42
GENOA A QOL HEALTHCARE COMPANY LLC	1501 AIRPORT RD SUITE	WAUKESHA WI 53188-24	02/22/17	9439-42
NORTHLAKES CLINIC PHARMACY REMOTE DISPENSING	300 MAIN ST W	ASHLAND WI 54806	03/01/17	9206-42
Young's - Greenheck Health/Wellness Center	734 Ross Ave	Schofield, WI 54476	03/24/17	8993-42
ALL SAINTS PRESCRIPTION SERVICES	511 COMMERCE DR SUIT	MADISON WI 53719	04/11/17	7704-42
MBMC PHILLIPS NECEDAH PRESCRIPTION SERVICES	1408 WHEELIHAN AVE	NECEDAH WI 54646	4/11/17	9434-42
VILLAGE PHARMACY	1100 BERGSLIEN ST	BALDWIN	4/26/17	9210-42
AURORA PRESCRIPTION DISPENSIN CENTER	2707 15TH PL SUITE 101	KENOSHA WI 53140	4/28/17	9395-42
AURORA PRESCRIPTION DISPENSING CENTER	709 SPRING VALLEY RD S	BURLINGTON WI 53105	5/18/18/	9395-42
ANNA JOHN PHARMACY	2901 S OVERLAND RD	ONEIDA WI 54155	5/18/18	8243-42
LAKESHORE PRESCRIPTION SERVICES	2719 CALUMET AVE	MANITOWOC WI 54220	7/21/17	9472-42
AURORA PRESCRIPTION DISPENSING CENTER	200 E RYAN RD SUITE 101	OAK CREEK WI 53154	7/20/17	9395-42
BELLIN HEALTH OCONTO HOSPITAL	2820 ROOSEVELT RD	MARINETTE WI 54143	7/5/17	9130-42

DBA REMOTE SITE	ADDRESS	CITY-ST-ZIP	RECEIVED	PHARMACY #
MTH LLC	1001 CECELIA DR SUITE 2	PEWAUKEE WI 53072	8/22/17	9058-42
FROEDTERT AND MCW MEQUON HEALTH CENTER REMO	11402 N PORT WASHINGT	MEQUON WI 53092-3454	10/11/17	9162-42

PHARMACY NAME	Reason for Change	Date of Change
Marshfield Clinic Pharmacy		
St Clare Memorial Hospital Pharmacy	Old name: CMH Primary Care Clinic	9/5/2014
Lakeshore Pharmacy		
Corner Drug Hometown Pharmacy		
Marshfield Clinic Pharmacy	**CLOSED**	5/19/2014
Marshfield Clinic Pharmacy		
Aurora Pharmacy #1024		
Langlade Hospital Hotel Dieu of St Joseph of Antigo WI		
Bellin Health Pharmacy		
Aurora Pharmacy 1024		
Aurora Pharmacy 1024		
Aurora Pharmacy 1024		
Aurora Pharmacy 1024	Withdrawn 02-15-12	
Aurora Pharmacy 1024		
Aurora Pharmacy 1024		
Aurora Pharmacy 1024		
Aurora Pharmacy 1024		
Aurora Pharmacy 1024		
Aurora Pharmacy 1024		
Gundersen Lutheran Medical Center		

PHARMACY NAME	Reason for Change	Date of Change
Corner Drug Hometown Pharmacy		
Aurora Pharmacy		
Aurora Pharmacy		
Aurora Pharmacy		
Bellin Health Pharmacy		
St. Elizabeth Hospital Pharmacy		
Bellin Health Pharmacy		
Aurora Pharmacy		
Aurora Pharmacy #1119		
Aurora Pharmacy #1119		
St Clare Memorial Hospital Pharmacy	Old name: CMH Primary Care Clinic Lena	9/5/2014
Community Memorial Hospital Pharmacy	Switched Supervising Pharmacy to 9179-42	3/4/2013
St Clare Memorial Hospital Pharmacy Gillett	Old name: CMH Oconto Medical Center	9/5/2014
St Clare Memorial Hospital Pharmacy Gillett	Old name: CMH Primary Care Clinic Mountain	9/5/2014
Genoa Healthcare		
St Clare Memorial Hospital Pharmacy	Old name: CMH RDS Pulaski Remote Dispens	9/5/2014
Northlakes Clinic Pharmacy		
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016

PHARMACY NAME	Reason for Change	Date of Change
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Phillips Drug Store Corporation		
Gundersen Lutheran Medical Center		
Aurora Pharmacy #1424	Old Lic #9208-42.	2/11/2016
Pharmacy Plus	closed on 4/14/17	4/14/2017
Pharmacy Plus	closed on 4/14/17	4/14/2017
Phillips Drug Store Corporation		
Aurora Pharmacy #1424	closed on 5/11/17- Old Lic #9208-42.	2/11/2016
Aspirus Clinic Pharmacy		
Memorial Health Center		

remote sites

PHARMACY NAME	Reason for Change	Date of Change
Phillips Drug Store Corporation		
Marshfield Clinic Pharmacy		
Marshfield Clinic Pharmacy		
Marshfield Clinic Pharmacy		
Skywalk Pharmacy New Berlin	Closed on 2/24/2017	
Omni Pharmacy		
UW Health Pharmacy Services		
Phillips Total Care Pharmacy		
HSHS Pharmacy #101		
Aurora Pharmacy		
St Vincent De Paul Charitable Pharmacy		
Skywalk pharmacy new berlin		
Muscoda Hometown Prescription Services		
Highland Hometown Prescription Services		
New Glarus Hometown Pharmacy		
Corner Drug Inc		
Aurora Pharmacy		
Whole Health Pharmacy		
Whole Health Pharmacy		
Philips Pharmacy		

PHARMACY NAME	Reason for Change	Date of Change
Philips Pharmacy		
SSM HEALTH PHARMACY		
AURORA PHARMACY		
AURORA PHARMACY		
Crivitz Pharmacy		
SSM HEALTH PHARMACY		
UW Health Pharmacy Services		
UW Health Pharmacy Services		
GENOA A QOL HEALTHCARE COMPANY LLC		
NORTHLAKES CLINIC PHARMACY		
Young's - Greenheck Health/Wellness Center		
FRITSCH'S CORNER DRUG STORE		
MBMC MAUSTON PHILLIPS LLC		
VILLAGE PHARMACY		
AURORA PHARMACY		
AURORA PHARMACY		
ONEIDA COMMUNITY HEALTH CENTER PHARMACY		
LAKESHORE PHARMACY		
AURORA PHARMACY		
BELLIN HEALTH OCONTO HOSPITAL		

PHARMACY NAME	Reason for Change	Date of Change
HAYAT PHARMACY		
FROEDTERT HEALTH MENOMONEE FALLS CLINIC PHARMACY		

Pharmacy Society of Wisconsin

November 1, 2017

Thaddeus Schumacher, Chair
Wisconsin Pharmacy Examining Board
Department of Safety and Professional Services
1400 E. Washington Avenue
Madison, Wisconsin 53708

RE: Speaking Invitation: PSW Legislative Day – February 8, 2018

Dear Dr. Schumacher,

The Pharmacy Society of Wisconsin (PSW) is hosting its annual Legislative Day on Thursday, February 8, 2018 in Madison, Wisconsin. We anticipate an attendance of over 300 pharmacists, pharmacy technicians, and pharmacy students. The agenda will include a discussion of several pharmacy-related legislative and regulatory priorities.

On behalf of the Board of Directors and staff of the Pharmacy Society of Wisconsin, I would like to invite you and other members of the Pharmacy Examining Board to attend our Legislative Day and address our members. They would appreciate hearing a regulatory update from Pharmacy Examining Board members and, if you agree, would appreciate having time to ask questions of PEB members.

The details of the day are as follows:

Date: Thursday, February 8, 2018
Location: Monona Terrace Convention Center, 1 John Nolen Drive, Madison, WI
Requested Speaking Time: 11:15 a.m. to 12:15 p.m.

Please let me know at your convenience if you will be able to join us, and please do no not hesitate to contact me at dlaurent@pswi.org or 608-827-9200 with any questions. Thank you for your consideration of this request.

Sincerely,

dmlaurent

Danielle M. Laurent, MPH
Director, Public Affairs
Pharmacy Society of Wisconsin

701 Heartland Trail
Madison, WI 53717
t: 608.827.9200 f: 608.827.9292
info@pswi.org www.pswi.org

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:
Meena Balasubramanian on behalf of Gretchen Mrozinski Division of Legal Services and Compliance	December 15, 2017 Items will be considered late if submitted after 4:30 p.m. and less than: ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others

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?
January 9, 2018	☐ Yes ☒ No	Pharmacy Case Forfeitures

7) Place item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☒ Yes ☐ No	

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

DLSC would like guidance from the Pharmacy Examining Board on using forfeitures in discipline cases.

11) Authorization

Signature of person making this request	Date
	December 15, 2017
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.

Revised 10/12

State of Wisconsin
Department of Safety and Professional Services

AGENDA REQUEST FORM

Name and Title of Person Submitting the Request:	Date When Request Submitted:
Meena Balasubramanian on behalf of Attorney Gretchen Mrozinski Division of Legal Services and Compliance	January 2, 2018 **Items will be considered late if submitted after 4:30 p.m. and less than:** ▪ 8 work days before the meeting for Medical Board ▪ 8 work days before meeting for all other boards

Name of Board, Committee, Council:

Pharmacy Examining Board

Board Meeting Date:	Attachments:	How should the item be titled on the agenda page?
January 9, 2018	☐ Yes ☐ No	Wis. Admin. Code § Phar 6.07 - Storage

Place Item in:	Is an appearance before the Board being scheduled? If yes, by whom?	Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes by (name) ☐ No	

Describe the issue and action the Board should address:

DLSC would like to explain the application of Wis. Admin. Code § Phar 6.07 pertaining to inspections and discuss the need for a possible rule change.

Authorization:

Signature of person making this request — Date: 1/2/18

Supervisor signature (if required) — Date: 1/2/18

Bureau Director signature (indicates approval to add late items 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 Board's 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
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Sharon Henes **Administrative Rules Coordinator**	19 December 2017 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 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?
9 January 2018	☒ Yes ☐ No	**Public Hearing on Clearinghouse Rule 17-090 relating to authority and definitions** **Review and respond to Clearinghouse Report and Public Hearing comments**

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes (Fill out Board Appearance Request) ☐ No	

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

Hold Public Hearing at 11:00 a.m.

Discuss any public hearing comments. Review, discuss and respond to any Clearinghouse comments.

11) Authorization

Sharon Henes

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.
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Revised 8/13

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to amend Phar 1.01 and Phar 1.02 (intro.) relating to authority and definitions.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.03 (2) (b), Stats.

Statutory authority: s. 15.08 (5) (b), Stats.

Explanation of agency authority:

The examining board shall promulgate rules for its own guidance and for the guidance of the profession to which it pertains and define an enforce professional conduct and unethical practices not inconsistent with the law relating to the particular profession. {s. 15.08 (5) (b), Stats.]

Related statute or rule: n/a

Plain language analysis:

Currently the authority and definition sections indicate the authority and definitions apply to chapters Phar 1 to 16. Chapter Phar 17 Pharmacy Internship was created in 2002 and that rulemaking order inadvertently did not expand the authority and definitions to include ch. Phar 17. This rule clarifies the authority and definition extend to ch. 17.

Summary of, and comparison with, existing or proposed federal regulation: None

Comparison with rules in adjacent states:

Illinois: Illinois requires approved educational programs to contain an externship and clerkship experience.

Iowa: Iowa has administrative rules governing pharmacist internships.

Michigan: Michigan has administrative rules governing pharmacist internships.

Minnesota: Minnesota has administrative rules governing pharmacist internships.

Summary of factual data and analytical methodologies:

This rule is for clarification that the authority and definitions apply to all of the Pharmacy Code chapters.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule revises the authority and definition chapter to apply to all of the pharmacy code chapters and does not have an economic impact.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed 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 Kirsten.Reader@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on January 9, 2018 at 11:00 a.m. to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 1.10 and 1.02 (intro.) are amended to read:

Phar 1.01 Authority. Rules in chs. Phar 1 to ~~16~~ 17 are adopted under authority of ss. 15.08 (5) (b), 227.11 (2), Stats, and ch. 450, Stats.

Phar 1.02 Definitions. As used in chs. Phar 1 to ~~16~~ 17:

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.

(END OF TEXT OF RULE)

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

2. Administrative Rule Chapter, Title and Number
Phar 1

3. Subject
Authority and Definitions

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

5. Chapter 20, Stats. Appropriations Affected

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

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

8. Would Implementation and Compliance Costs Be Greater Than $20 million?
☐ Yes ☒ No

9. Policy Problem Addressed by the Rule
Currently the authority and definition sections indicate the authority and definitions apply to chapters Phar 1 to 16. Chapter Phar 17 Pharmacy Internship was created in 2002 and that rulemaking order inadvertently did not expand the authority and definitions to include ch. Phar 17. This rule clarifies the authority and definition extend to ch. 17.

10. 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.
This rule was posted for economic comments and none were received.

11. Identify the local governmental units that participated in the development of this EIA.
None

12. 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)
This rule will not have a fiscal or economic impact.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is clarifying the authority and definitions apply to all Phar chapters.

14. Long Range Implications of Implementing the Rule
The long range implication is the authority and definitions will apply to all Phar chapters.

15. Compare With Approaches Being Used by Federal Government
None.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
The comparison was based upon the subject matter of Phar 17.
Illinois: Illinois requires approved educational programs to contain an externship and clerkship experience.
Iowa: Iowa has administrative rules governing pharmacist internships.
Michigan: Michigan has administrative rules governing pharmacist internships.
Minnesota: Minnesota has administrative rules governing pharmacist internships.

17. Contact Name	18. Contact Phone Number
Sharon Henes	(608) 261-2377

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

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 Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Dan Williams	Items will be considered late if submitted after 4:30 p.m. and less than: ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others

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

Wisconsin Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
January 9, 2018	☐ Yes ☐ No	**NABP appearance re: Programs and Services – Discussion and Consideration**

7) Place Item in:	8) Is an appearance before the Board being scheduled? If yes, who is appearing?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes by ☐ No	N/A

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

Bill Cover, R.Ph.
Member Relations and Government Affairs Director
National Association of Boards of Pharmacy | **www.nabp.pharmacy**
1600 Feehanville Dr | Mount Prospect, IL 60056 | **Phone: 224/565-5694**

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:
Laura Smith, Bureau Assistant on behalf of Dan Williams, Executive Director	11/22/17 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?
1/9/2018	☒ Yes ☐ No	Administrative Matters/Updates 1) Election of Officers 2) Appointment of Liaisons and Alternates 3) Delegation of Authorities

7) Place Item in:	8) Is an appearance before the Board being scheduled?	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:

1) The Board should conduct Election of its Officers for 2018
2) The new Chairperson should review and appoint/reappoint Liaisons and Alternates as appropriate
3) The Board should review and then consider continuation or modification of previously delegated authorities

11) Authorization

Laura Smith — 11/22/2017

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:

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3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

Pharmacy Examining Board

2017 ELECTION RESULTS	
Board Chair	Thaddeus Schumacher
Vice Chair	Philip Trapskin
Secretary	Franklin LaDien
2017 LIAISON APPOINTMENTS	
Continuing Education (CE) Liaison and Office of Education and Examinations Liaison(s)	Terry Maves
Credentialing Liaison(s)	Terry Maves, Cathy Winters
Digest Liaison(s)	Philip Trapskin
Legislative Liaison(s)	Terry Maves, Thaddeus Schumacher, Philip Trapskin
DLSC Liaison(s)	Thaddeus Schumacher, Cathy Winters
Professional Assistance Procedure (PAP) Liaison(s)	Franklin LaDien
Monitoring Liaison(s)	Franklin LaDien, Cathy Winters
Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g)	Philip Trapskin
Pilot Program Liaison(s)	Philip Trapskin, Cathy Winters
PHARM Rep to SCAODA	Kristi Sullivan
2017-2018 SCREENING PANEL APPOINTMENTS	
March 2017 - January 2018	Cathy Winters, Kristi Sullivan, Franklin LaDien
2017 COMMITTEE MEMBER APPOINTMENTS	
Pharmacy Rules Committee	Franklin LaDien, Thaddeus Schumacher, Philip Trapskin

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to affirm the Chair's appointment of liaisons for 2017. Motion carried unanimously.

Delegated Authority for Urgent Matters

MOTION: Philip Trapskin moved, seconded by Terry Maves, that, in order to facilitate the completion of assignments between meetings, the Board delegates its authority by order of succession to the Chair, highest ranking officer, or longest serving member of the Board, to appoint liaisons to the Department to act in urgent matters, make appointments to vacant liaison, panel and committee positions, and to act when knowledge or experience in the profession is required to carry out the duties of the Board in accordance with the law. Motion carried unanimously.

Delegated Authority for Application Denial Reviews

MOTION: Philip Trapskin moved, seconded by Terry Maves, that the Board counsel or another department attorney is formally authorized to serve as the Board's designee for purposes of Wis. Admin Code § SPS 1.08(1). Motion carried unanimously.

Document Signature Delegation

MOTION: Philip Trapskin moved, seconded by Terry Maves, to delegate authority to the Chair or chief presiding officer, or longest serving member of the Board, by order of succession, to sign documents on behalf of the Board. In order to carry out duties of the Board, the Chair, chief presiding officer, or longest serving member of the Board, has the ability to delegate this signature authority for purposes of facilitating the completion of assignments during or between meetings. The Chair, chief presiding officer, or longest serving member of the Board delegates the authority to Executive Director or designee to sigh the name of any Board member on documents as necessary and appropriate. Motion carried unanimously.

Credentialing Authority Delegations

MOTION: Philip Trapskin moved, seconded by Terry Maves, to delegate authority to the Credentialing Liaisons to address all issues related to credentialing matters. Motion carried unanimously.

MOTION: Philip Trapskin moved, seconded by Terry Maves, to delegate credentialing authority to DSPS for those submitted applications that meet criteria of Rule and Statute and thereby would not require further Board or Board liaison review. Motion carried unanimously.

Education Delegations

MOTION: Philip Trapskin moved, seconded by Terry Maves, to delegate authority to the Continuing Education (CE) and Office of Education and Examination Liaison(s) to address all issues related to CE, education and examinations. Motion carried unanimously.

Variance Report Delegation

MOTION: Philip Trapskin moved, seconded by Terry Maves, to delegate authority to the Variance Report Liaison to address all issues related to variance report matters. Motion carried unanimously.

Rules Committee

MOTION: Philip Trapskin moved, seconded by Terry Maves, to grant the Rules Committee the ability to address all rule making. Motion carried unanimously.

Screening Panel Authority Expansion to DLSC

MOTION: Terry Maves moved, seconded by Kristi Sullivan, to delegate to DLSC the discretion to prescreen cases in order to: request additional information if needed; open any case that demonstrates a clear violation of the law, and; close cases that clearly do not allege a provable violation of law. Motion carried unanimously.

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Ashley Ayres Monitoring and Intake Supervisor Division of Legal Services and Compliance	December 18, 2017 Items will be considered late if submitted after 4:30 p.m. and less than: ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others

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?
January 9, 2018	☒ Yes ☐ No	Appointment of Monitoring Liaison and Delegated Authority Motion

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes (Fill out Board Appearance Request) ☒ No	

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

Adopt or reject the Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor document as presented in today's agenda packet.

11) Authorization

A Ashley Ayres — December 18, 2017

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:
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Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor

The Monitoring Liaison ("Liaison") is a Board/Section designee who works with department monitors to enforce Board/Section orders as explained below.

Current Authorities Delegated to the Monitoring Liaison

The Liaison may take the following actions on behalf of the Board/Section:

1. Grant a temporary reduction in random drug screen frequency upon Respondent's request if he/she is unemployed and is otherwise compliant with Board/Section order. The temporary reduction will be in effect until Respondent secures employment in the profession. The Department Monitor ("Monitor") will draft an order and sign on behalf of the Liaison.

2. Grant a stay of suspension if Respondent is eligible per the Board/Section order. The Monitor will draft an order and sign on behalf of the Liaison.

3. Remove the stay of suspension if there are repeated violations or a substantial violation of the Board/Section order. In conjunction with removal of any stay of suspension, the Liaison may prohibit Respondent from seeking reinstatement of the stay for a specified period of time. The Monitor will draft an order and sign on behalf of the Liaison.

4. Grant or deny approval when Respondent proposes continuing/remedial education courses, treatment providers, mentors, supervisors, change of employment, etc. unless the order specifically requires full-Board/Section approval.

5. Grant a maximum of one 90-day extension, if warranted and requested in writing by Respondent, to complete Board/Section-ordered continuing education.

6. Grant a maximum of one extension or payment plan for proceeding costs and/or forfeitures if warranted and requested in writing by Respondent.

7. Grant full reinstatement of licensure if Respondent has fully complied with all terms of the order without deviation. The Monitor will draft an order and obtain the signature or written authorization from the Liaison.

8. Grant or deny a request to appear before the Board/Section in closed session.

9. *(Except Pharmacy)* Accept Respondent's written request to surrender credential. If accepted by the Liaison, Monitor will consult with Board Counsel to determine if a stipulation is necessary. If a stipulation is not necessary, Monitor will draft an order and sign on behalf of the Liaison. If denied by the Liaison, the request to surrender credential will go to the full Board for review.

10. *(Except Pharmacy)* Grant Respondent's petition for a reduction in drug screens per the standard schedule, below. If approved, Monitor will draft an order and sign on behalf of the Liaison.

    a. Year 1: 49 screens (including 1 hair test, if required by original order)
    b. Year 2: 36 screens (plus 1 hair test, if required by original order)
    c. Year 3: 28 screens plus 1 hair test
    d. Year 4: 28 screens plus 1 hair test
    e. Year 5: 14 screens plus 1 hair test

11. *(Dentistry only)* – Ability to approve or deny all requests from a respondent.

Current Authorities Delegated to the Department Monitor

The Monitor may take the following actions on behalf of the Board/Section, draft an order and sign:

1. Grant full reinstatement of licensure if CE is the sole condition of the limitation and Respondent has submitted the required proof of completion for approved courses.

2. Suspend the license if Respondent has not completed Board/Section-ordered CE and/or paid costs and forfeitures within the time specified by the Board/Section order. The Monitor may remove the suspension and issue an order when proof completion and/or payment have been received.

3. Suspend the license (or remove stay of suspension) if Respondent fails to enroll and participate in an Approved Program for drug and alcohol testing within 30 days of the order, or if Respondent ceases participation in the Approved Program without Board approval. This delegated authority only pertains to respondents who must comply with drug and/or alcohol testing requirements.

Proposed (New) Delegations to the Monitoring Liaison

The Monitoring Unit is proposing the following additions to the Monitoring Liaison's authority:

1. Board Monitoring Liaison may determine whether Respondent's petition is eligible for consideration by the full Board/Section.

2. Board Monitoring Liaison may approve or deny Respondent's request to be excused from drug and alcohol testing for work, travel, etc.