



**VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD**
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
December 1, 2022

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

AGENDA

11:00 A.M.

(OR IMMEDIATELY FOLLOWING THE PHARMACY RULES COMMITTEE)

OPEN SESSION – CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1-4)**
- B. Approval of Minutes of November 3, 2022 (5-7)**
- C. Reminders: Conflicts of Interest, Scheduling Concerns
- D. 11:00 A.M. Public Hearing on EmR 2213 for Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing (8-13)**
 - 1) Review Public Hearing Comments
- E. Administrative Matters – Discussion and Consideration**
 - 1) Department, Staff and Board Updates
 - 2) 2023 Meeting Dates
 - 3) Board Members – Term Expiration Dates
 - a. Kleppin, Susan – 7/1/2025
 - b. O’Hagan, Tiffany – 7/1/2024
 - c. Peterangelo, Anthony – 7/1/2023
 - d. Walsh, Michael – 7/1/2024
 - e. Weiss, Shana – 7/1/2023
 - f. Weitekamp, John – 7/1/2026
 - g. Wilson, Christa – 7/1/2025
- F. Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State Boards of Pharmacy and the U.S. Food and Drug Administration – Discussion and Consideration**
- G. Credentialing Matters – Discussion and Consideration**
 - 1) Review of Pharmacy Forms
 - 2) Remote Dispensing Communication

- H. Legislative and Policy Matters – Discussion and Consideration
- I. Administrative Rule Matters – Discussion and Consideration (14)**
 - 1) Emergency Rule Draft: Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians **(15-24)**
 - 2) Scope Statement: Phar 15, Relating to Compounding Pharmaceuticals **(25-26)**
 - 3) Pending or Possible Rulemaking Projects **(27)**
- J. Implement 2021 Wisconsin Act 9 – 100 Most Prescribed Drugs – Discussion and Consideration**
- K. Education and Examination Matters- Discussion and Consideration**
 - 1) Multistate Pharmacy Jurisprudence Examination (MPJE) Update
- L. Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration**
 - 1) Travel Report: 2022 Annual Meeting: NABP/American Association of Colleges of Pharmacy (AACP) District IV on November 6-8, 2022 in Madison, WI – Tiffany O’Hagan and John Weitekamp
- M. COVID-19 – Discussion and Consideration
- N. Pilot Program Matters – Discussion and Consideration
- O. Discussion and Consideration on Items Added After Preparation of Agenda
 - 1) Introductions, Announcements and Recognition
 - 2) Nominations, Elections, and Appointments
 - 3) Administrative Matters
 - 4) Election of Officers
 - 5) Appointment of Liaisons and Alternates
 - 6) Delegation of Authorities
 - 7) Education and Examination Matters
 - 8) Credentialing Matters
 - 9) Practice Matters
 - 10) Legislative and Policy Matters
 - 11) Administrative Rule Matters
 - 12) Pilot Program Matters
 - 13) Variances
 - 14) Liaison Reports
 - 15) Board Liaison Training and Appointment of Mentors
 - 16) Informational Items
 - 17) Division of Legal Services and Compliance (DLSC) Matters
 - 18) Presentations of Petitions for Summary Suspension
 - 19) Petitions for Designation of Hearing Examiner
 - 20) Presentation of Stipulations, Final Decisions and Orders
 - 21) Presentation of Proposed Final Decisions and Orders
 - 22) Presentation of Interim Orders
 - 23) Pilot Program Matters
 - 24) Petitions for Re-Hearing
 - 25) Petitions for Assessments
 - 26) Petitions to Vacate Orders
 - 27) Requests for Disciplinary Proceeding Presentations

- 28) Motions
- 29) Petitions
- 30) Appearances from Requests Received or Renewed
- 31) Speaking Engagements, Travel, or Public Relation Requests, and Reports

P. 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.).

Q. Deliberation on Division of Legal Services and Compliance Matters

- 1) Administrative Warning**
 - a. 22 PHM 092 – K.A.B. **(28-29)**
- 2) Case Closings**
 - a. 21 PHM 129 – K.S.I. **(30-32)**
 - b. 22 PHM 021 – E.S.P., A.H.G., A.H.G. **(33-37)**
 - c. 22 PHM 055 – M.C.P. **(38-40)**
 - d. 22 PHM 092 – W. **(41-44)**
 - e. 22 PHM 132 – V.H.P. **(45-48)**
- 3) Monitoring Matters**
 - a. Cynthia Hennen, Pharmacist – Requesting Full Licensure **(49-75)**
- 4) Proposed Stipulation and Final Decision and Orders**
 - a. 20 PHM 123 – Oncology Supply, L.L.C. **(76-82)**

R. Deliberation of Items Added After Preparation of the Agenda

- 1) Education and Examination Matters
- 2) Credentialing Matters
- 3) Application Reviews
- 4) DLSC Matters
- 5) Monitoring Matters
- 6) Professional Assistance Procedure (PAP) Matters
- 7) Petitions for Summary Suspensions
- 8) Petitions for Designation of Hearing Examiner
- 9) Proposed Stipulations, Final Decisions and Orders
- 10) Proposed Interim Orders
- 11) Administrative Warnings
- 12) Review of Administrative Warnings
- 13) Proposed Final Decisions and Orders
- 14) Matters Relating to Costs/Orders Fixing Costs
- 15) Case Closings
- 16) Board Liaison Training
- 17) Petitions for Assessments and Evaluations
- 18) Petitions to Vacate Orders
- 19) Remedial Education Cases
- 20) Motions
- 21) Petitions for Re-Hearing
- 22) Appearances from Requests Received or Renewed

S. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

T. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate

U. Open Session Items Noticed Above Not Completed in the Initial Open Session

ADJOURNMENT

NEXT MEETING: JANUARY 19, 2023 (TENTATIVE)

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

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

**HYBRID (IN-PERSON/VIRTUAL)
PHARMACY EXAMINING BOARD
MEETING MINUTES
NOVEMBER 3, 2022**

PRESENT: Susan Kleppin, Tiffany O'Hagan (*via Zoom*), Anthony Peterangelo, John Weitekamp, Michael Walsh (*via Zoom*), Christa Wilson (*via Zoom*)

EXCUSED: Shana Weiss

STAFF: Brad Wojciechowski, Executive Director; Jameson Whitney, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Katlin Schwartz, Bureau Assistant; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:09 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF SEPTEMBER 1, 2022

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to approve the Minutes of September 1, 2022 as published. Motion carried unanimously.

LEGISLATURE AGENDA REQUEST: STATUS OF KRATOM

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to acknowledge that the Pharmacy Examining Board has reviewed the subject of the legal status of Kratom. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Preliminary Rule Draft: Phar 18, Relating to Third Party Logistics Provider Licensure

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to approve the preliminary rule draft of Phar 18, relating to Third Party Logistics Provider Licensure, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Public Agenda Item: USP General Chapter <825>

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to request DSPS staff draft a Scope Statement relating to USP General Chapters 795, 797, and 825. Motion carried unanimously.

CLOSED SESSION

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to 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.). John Weitekamp, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Susan Kleppin-yes; Tiffany O’Hagan-yes; Anthony Peterangelo-yes; Michael Walsh-yes; John Weitekamp-yes; and Christa Wilson-yes. Motion carried unanimously.

The Board convened into Closed Session at 12:40 p.m.

DELIBERATION ON DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Administrative Warnings

21 PHM 115 – O.S.S.

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to issue an Administrative Warning in the matter of O.S.S., DLSC Case Number 21 PHM 115. Motion carried unanimously.

Case Closings

MOTION: Michael Walsh moved, seconded by Tiffany O’Hagan, to close the following DLSC Cases for the reasons outlined below:

1. 21 PHM 013 – C.P., C.C. – Insufficient Evidence
2. 21 PHM 113 – H.F.P.A.S. – No Violation
3. 22 PHM 045 – J.M.R. – Prosecutorial Discretion (P1)
4. 22 PHM 046 – A.P. – Prosecutorial Discretion (P2)
5. 22 PHM 099 – H.D.I. – Prosecutorial Discretion (P1)
6. 22 PHM 111 – F.S.S.P. – No Violation
7. 22 PHM 128 – C. – Prosecutorial Discretion (P7)

Motion carried unanimously.

Proposed Stipulations and Final Decisions and Orders

22 PHM 061 – Brenton M. Severson, R.Ph.

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Brenton M. Severson, R.Ph., DLSC Case Number 22 PHM 061. Motion carried unanimously.

Monitoring Matters

Peter Dickman, Pharmacist Requesting Full Licensure

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to grant the request of Peter Dickman, Pharmacist for full licensure. Motion carried unanimously.

Andrew Seidlitz, Pharmacist Requesting the Addition of Four (4) Hours Per Month as Pharmacist in Charge and/or Reduction in Drug and Alcohol Screens

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to deny the request of Andrew Seidlitz, Pharmacist, for reduction in drug and alcohol screens, but to grant the addition of four (4) hours per month as a Pharmacist in Charge. **Reason for Denial:** Failure to demonstrate continuous and successful compliance (i.e., Missed check ins). Respondent needs to fully comply with the complete terms and conditions of the original Board Order (1/28/2021). Motion carried unanimously.

Brad Spross, Pharmacist Requesting Full Licensure

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to grant the request of Brad Spross, Pharmacist for full licensure. Motion carried unanimously.

RECONVENE TO OPEN SESSION

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 1:41 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

(Be advised that any recusals or abstentions reflected in the Closed Session motions stand for the purposes of the affirmation vote.)

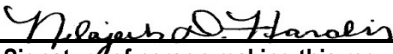
ADJOURNMENT

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 1:43 p.m.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Nilajah Hardin Administrative Rules Coordinator		2) Date when request submitted: 11/18/22 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 12/01/22	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? 11:00 A.M. Public Hearing on EmR 2213 for Phar 1, 5, 6, 7, and 8 Relating to Remote Dispensing 1. Review Public Hearing Comments	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <i>(If yes, please complete Appearance Request for Non-DSPS Staff)</i> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: The Board will hold a public hearing on this Emergency Rule as required by the rulemaking process.			
11) Authorization			
 Signature of person making this request		11/18/22 Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING EMERGENCY RULES

The statement of scope for this rule, SS 053-22, was approved by the Governor on June 13, 2022, published in Register 798B on June 27, 2022, and approved by the Pharmacy Examining Board on July 8, 2022. This emergency rule as approved by the Governor on October 6, 2022.

ORDER

An order of the Pharmacy Examining Board to amend Phar 7.43 (2), (5) (b), (6) (title), (6) (a), and (6) (a) 5; to create Phar 1.02 (14m), 5.01 (4), 6.025, and 8.01 (5); and to repeal Phar 1.02 (9) and 7.43 (1) relating to remote dispensing.

Analysis prepared by the Department of Safety and Professional Services.

EXEMPTION FROM FINDING OF EMERGENCY

The Legislature by section 14 (1) of 2021 Wisconsin Act 101 provides an exemption from a finding of emergency for the adoption of the rule.

ANALYSIS

Statutes interpreted: ss. 450.02 (5) and 450.09 (1) and (2) (b) 2, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), (d), and (e). Stats, and 2021 Wisconsin Action 101 s. 14 (1)

Explanation of agency authority:

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

Section 450.02 (3) (a), Stats. allows the board to “promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

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

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

2021 Wisconsin Act 101, Section 14 (1) provides: “The pharmacy examining board may promulgate emergency rules under s. 227.24 necessary to implement this act. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until May 1, 2024, or the date on which permanent rules take effect, whichever is sooner.”

Related statute or rule: s. 961.31, Stats.

Plain language analysis: The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 101.

Summary of, and comparison with, existing or proposed federal regulation: The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains requirements for pharmacy licensure and dispensing. There is a provision that allows a pharmacy that is not in the same location as its home pharmacy, and services are being provided during an emergency situation, to operate as an emergency remote pharmacy. The Illinois Department of Financial and Professional Regulation may also waive the requirement for a pharmacist to be on duty at all times for state facilities that are not treating human ailments. Additionally, automated pharmacy systems operated from a remote site must be under continuous supervision of a pharmacist however, that pharmacist is not required to be physically present if they can monitor the system electronically. [225 Illinois Compiled Statutes ch. 85 s. 15 and 22b]. The Illinois Department of Financial and Professional Regulation is also responsible for the promulgation of rules to implement certain sections of the Illinois Pharmacy Practice Act. These rules in the Illinois Administrative Code include definitions for “emergency situation” and what is required in order to operate an emergency remote temporary pharmacy [Illinois Administrative Code s. 1330.420].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and include requirements for remote dispensing in hospital pharmacies. Additionally, a pharmacist is required to be onsite at a telepharmacy site for at least 16 hours per month and can otherwise monitor the site remotely. The

telepharmacy site is a separate licensure category from a correctional, hospital, nuclear, or general pharmacy site. If the average number of prescriptions dispensed per day exceeds 150 at a telepharmacy site, the pharmacist is required to be on site 100 percent of the time and the site must apply for licensure as a general pharmacy. [657 Iowa Administrative Code sections 7.7 and 13.9 (6)].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for pharmacy in Michigan, among several other occupations. Unless at a mental health facility or hospital, remote pharmacies cannot be located within 10 miles of another pharmacy, unless a waiver is granted by the Michigan Board. A pharmacist is required to oversee a remote pharmacy; however, a qualified pharmacy technician must be on site at all times that the pharmacy is open if the pharmacist in charge is not physically present. A Pharmacist may not be responsible for more than three remote pharmacy sites at any one time [Michigan Compiled Laws s. 333.17742a and b].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Part 6800 of the Minnesota Administrative Code includes the regulations for pharmacy in Minnesota. [Minnesota Administrative Rules part 6800]. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes pharmacy regulations. According to Section 34 (10) of this chapter, it is unlawful to run a pharmacy without a pharmacist in charge. Operation of a pharmacy without a pharmacist present and on duty is only allowed under an approved variance by the Board. [Minnesota Statutes 151.34 (10), 151.071 (2) (13)].

Summary of factual data and analytical methodologies: The Board reviewed the statutory changes from 2021 Wisconsin Act 101 and updated Wisconsin Administrative Code Chapters Phar 1, 5, 6, 7, and 8 accordingly.

Fiscal Estimate: The Fiscal Estimate will be attached upon completion.

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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-26-7139; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1 Phar 1.02 (9) is repealed.

SECTION 2 Phar 1.02 (14m) is created to read:

Phar 1.02 (14m) “Remote dispensing site” has the meaning given in s. 450.01 (21c), Stats.

SECTION 3 Phar 5.01 (4) is created to read:

Phar 5.01 (4) For the purposes of this chapter and pursuant to s. 450.09 (1) (a), Stats., pharmacies shall include remote dispensing sites.

SECTION 4 Phar 6.025 is created to read:

Phar 6.025 Licenses; remote dispensing sites. A pharmacy may be subject to rules that apply only to remote dispensing sites if no pharmaceutical services is provided at that pharmacy by a pharmacist who is present in the pharmacy, and the following conditions have been met:

- (1) The Licensee provides notice to the Board of all of the information outlined in s. 450.06, Stats.
- (2) The site meets all of the requirements listed in Phar 7.43.
- (3) The site is any of the location types listed under s. 450.09 (2) (b) 1., Stats.
- (4) A managing pharmacist shall report to the Board if they are responsible for 5 or more remote dispensing sites. A managing pharmacist shall not be responsible for more than 10 remote dispensing sites at any given time without approval from the Board.

SECTION 5 Phar 7.43 (1) is repealed.

SECTION 6 Phar 7.43 (2); (4) (b); (5) (b); (6) (title), (6) (a), (6) (a) 5, and (6) (b) are amended to read:

Phar 7.43 (2) LOCATION. A pharmacist or a person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i), Stats., may dispense at any of the locations under s. ~~450.062 (1) to (4)~~ 450.09 (2) (b) 1. a. to d., Stats.

(4) (b) Remote dispensing may not occur if ~~the supervising pharmacy is closed a~~ pharmacist is not available remotely.

(5) (b) Labeling requirements under s. Phar 7.05. The prescription label shall contain the name and address of the ~~supervising pharmacy~~ remote dispensing site as the licensed facility from which the prescribed drug or device was dispensed.

(6) (title) RESPONSIBILITIES OF MANAGING PHARMACIST ~~OR SUPERVISING PHARMACIST.~~

(6) (a) The managing pharmacist of the supervising pharmacy ~~or the supervising pharmacist~~ shall do all of the following:

(6) (a) 5. Documentation indicating accepting responsibility for compliance with this section, signed and dated by ~~both the managing pharmacist and supervising pharmacist,~~ indicating the name of the supervising pharmacist, and the dates the supervision responsibilities ~~begin and end.~~

(6) (b) The managing pharmacist at the supervising pharmacy ~~or supervising pharmacist~~ is responsible for all remote dispensing connected to the supervising pharmacy.

SECTION 7 Phar 8.01 (5) is created to read:

Phar 8.01 (5) REMOTE DISPENSING SITES. For the purposes of this chapter and pursuant to s. 450.09 (1) (a), stats., pharmacies shall include remote dispensing sites.

SECTION 8 Pursuant to 2021 Wisconsin Act 101 section 14 (1), this emergency rule shall take effect upon publication in the official state newspaper and remain in effect until May 1, 2024 or until the date on which permanent rules take effect, whichever is sooner.

(END OF TEXT OF RULE)

Dated 9/16/2022

Agency 

Chairperson
Pharmacy Examining Board

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Nilajah Hardin Administrative Rules Coordinator		2) Date when request submitted: 11/18/22 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 12/01/22	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Administrative Rule Matters – Discussion and Consideration 1. Emergency Rule Draft: Phar 1, 5, 7, 10 and 19 Relating to Registration of Pharmacy Technicians 2. Scope Statement: Phar 15, Relating to Compounding Pharmaceuticals 3. Pending or Possible Rulemaking Projects	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <i>(If yes, please complete Appearance Request for Non-DSPS Staff)</i> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Attachments: 1. Phar 1, 5, 7, 10 and 19 Emergency Rule Draft 2. Phar 15 Scope Statement 3. Rule Projects Chart Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx			
11) Authorization			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING EMERGENCY RULES

The statement of scope for this rule, SS 052-22, was approved by the Governor on June 13, 2022, published in Register 798B on June 27, 2022, and approved by the Pharmacy Examining Board on July 8, 2022. This emergency rule as approved by the Governor on (date)

ORDER

An order of the Pharmacy Examining Board to amend Phar 1.01, 1.02 (intro), 1.02 (Note), 7.07 (2), 7.14 (2), (2) (b), (2) (c) 3. and 6., (2) (d) 1. and 2., (2) (e), (3) (a) and (b), (4) (a), (b), (c), and (d), (5), (6) (a) 1. and 2, 7.43 (7), ch. Phar 7 subch. V (title), 7.62 (title), (1), (2), (3), (3) (a), (5), (6), and (7), 10.03 (2), (7), (17), and (19); create Phar 1.01 (11m), 5.07, 7.60 (intro.) and (3), and ch. Phar 19; and repeal Phar 7.14 (2) relating to registration of pharmacy technicians.

Analysis prepared by the Department of Safety and Professional Services.

EXEMPTION FROM FINDING OF EMERGENCY

The Legislature by section 40 (1) of 2021 Wisconsin Act 100 provides an exemption from a finding of emergency for the adoption of the rule.

ANALYSIS

Statutes interpreted: s. 450.68, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), (d), and (e). Stats, and 2021 Wisconsin Action 100 s. 40 (1)

Explanation of agency authority:

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

Section 450.02 (3) (a), Stats. allows the board to “promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

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

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

2021 Wisconsin Act 100, Section 40 (1) provides: “The pharmacy examining board may promulgate emergency rules under s. 227.24 necessary to implement this act. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until May 1, 2024, or the date on which permanent rules take effect, whichever is sooner.”

Related statute or rule: s. 961.31, Stats.

Plain language analysis: The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 100.

Summary of, and comparison with, existing or proposed federal regulation: The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains requirements for licensure of registered pharmacy technicians, as well as for pharmacists and pharmacies. Registered pharmacy technicians in Illinois have to be at least 16 years old, is attending or has graduated from high school or has a high school equivalency certificate and must complete the requirements to become a licensed registered certified pharmacy technician. A licensed registered certified pharmacy technician must be at least 18 and as of January 1, 2024, have graduated from a pharmacy technician training program or obtained documentation from the pharmacist-in-charge at the pharmacy where they are employed that they have successfully completed a nationally accredited training program. [225 Illinois Compiled Statutes ch. 85 s. 9 and 9.5]. The Illinois Department of Financial and Professional Regulation is also responsible for the promulgation of rules to implement certain sections of the Illinois Pharmacy Practice Act. These rules in the Illinois Administrative Code include application requirements for both registered and registered certified pharmacy technicians, as well as rules for their training and education [Illinois Administrative Code s. 1330.200-1330.220].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. Title IV Chapter 155A of the Iowa Code includes the statutory requirements for pharmacy technician registration, licensure of pharmacists and pharmacies, and prescription drug orders, among other requirements. In Iowa pharmacy technicians must register with the Iowa Board and the responsibility for their actions is with the licensed pharmacist who is supervising them [Iowa Code ch.155A s.6A]. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and also include requirements for pharmacy technicians. Among those requirements, the chapter includes registration procedures, training, delegation and practice, national certification, as well as unethical conduct and discipline [657 Iowa Administrative Code ch. 3].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for pharmacy in Michigan, among several other occupations. Also included in those regulations are the statutory requirements for licensure and practice of pharmacy technicians. [Michigan Compiled Laws s. 333.17739]. The Michigan Administrative Rules also include requirements for pharmacy technicians administered by the Michigan Department of Licensing and Regulatory Affairs in conjunction with the Michigan Board. These rules include licensure, examination, training, and approved education program requirements for pharmacy technicians [Michigan Administrative Rules R 338.3561-338.3665].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Part 6800 of the Minnesota Administrative Code includes the regulations for pharmacy in Minnesota. These rules include requirements for pharmacy technician registration, education, training, and supervision [Minnesota Administrative Rules part 6800.3850]. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes pharmacy regulations and requirements for pharmacy technicians. This statute specifically clarifies the nature of the supervisory relationship of the pharmacist to the technician, as well as how many technicians each individual pharmacist may supervise. [Minnesota Statutes 151.102].

Summary of factual data and analytical methodologies: The Board reviewed the statutory changes from 2021 Wisconsin Act 100 and updated Wisconsin Administrative Code Chapters Phar 1, 5, 7, 10 and 19 accordingly.

Fiscal Estimate: The Fiscal Estimate will be attached upon completion.

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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-26-7139; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 1.01, 1.02 (intro.), and 1.02 (Note) are amended to read:

Phar 1.01 Authority. Rules in chs. Phar 1 to ~~1719~~ are adopted under authority of ss. 15.08 (5) (b), 227.11 (2), Stats, and ch. 450, Stats.

Phar 1.02 (intro.) As used in ch. Par 1 to ~~1719~~.

Phar 1.02 (Note) The board office is located at ~~1400 East Washington Avenue~~ 4822 Madison Yards Way Madison, WI ~~5370253705~~.

SECTION 2. Phar 1.01 (11e) is created to read:

Phar 1.01 (11m) “Pharmacy technician” means a person registered by the board under s. 450.068, Stats.

SECTION 3. Phar 5.07 is created to read:

Phar 5.07 Pharmacy Technicians. All requirements for renewal and reinstatement of a pharmacy technician registration are specified in chapter Phar 19.

SECTION 4. Phar 7.07 (2); 7.14 (title); 7.14 (1) (a), (b) and (d); and 7.14 (2) are amended to read:

Phar 7.07 (2) For all prescription drug product or device dispensing, the prescription record shall identify the pharmacist responsible for each part of the final check. If sub. (1) (a) or (b) is completed by ~~delegate-check-delegate~~ pharmacy product verification technician-check-pharmacy technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the ~~delegate-pharmacy product verification technician~~ performing the check.

Phar 7.14 (title) ~~Delegate-check-Delegate~~ Pharmacy Product Verification Technician-check-Pharmacy Technician.

(1) (a) “~~Delegate~~ Pharmacy product verification technician” means a ~~person~~ registered pharmacy technician to whom the pharmacist has delegated the task of product verification.

(1) (b) “~~Delegate-check-delegate~~ Pharmacy product verification technician-check-pharmacy technician” means the process in which ~~one delegate~~ a pharmacy product verification technician conducts the task of product verification of technical dispensing functions completed by an ~~unlicensed individual~~ a pharmacy technician. A delegate pharmacy product verification technician may not conduct product verification as part of the final check of their own product preparation.

(1) (d) ““Supervising pharmacist” means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a delegate pharmacy product verification technician and ensuring for direct supervision of the delegate pharmacy product verification technician.”

(2) ~~DELEGATE PHARMACY PRODUCT VERIFICATION TECHNICIAN QUALIFICATIONS.~~ A pharmacist may delegate the product verification of a prescription or chart order to a delegate pharmacy technician who meets all of the following:

SECTION 5. Phar 7.14 (2) (a) is repealed.

SECTION 6. Phar 7.14 (2) (b), (2) (c) 3. and 6., (2) (d) 1. and 2., and (2) (e); 7.14 (3) (a) and (b); 7.14 (4) (a), (b), (b) 1., (c), and (d); 7.14 (5); and 7.14 (6) (a) 1. and 2. are amended to read:

Phar 7.14 (2) (b) Completed an accredited pharmacy technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(2) (c) 3. Eligible ~~medications~~ product for ~~delegate-check-delegate~~ pharmacy product verification technician-check-pharmacy technician.

(2) (c) 6. A practical training designed to assess the competency of the delegate pharmacy technician prior to starting the validation process. The practical training shall include simulation of at least 2 occurrences of each of the following:

(2) (d) 1. The delegate pharmacy technician being validated shall make a product verification on the work of a pharmacist or ~~unlicensed person~~ another pharmacy technician for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.

(2) (d) 2. A pharmacist shall audit 100% of the product verifications made by the delegate pharmacy technician during the validation process.

(2) (e) Notwithstanding pars. (a) (b) to (d), a delegate an individual who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the delegation pharmacy product verification technician qualifications unless the delegate individual fails to meet the quality assurance standards under sub. (4).

(3) (a) *Institutional pharmacies.* The delegate pharmacy product verification technician may do the product verification in an institutional pharmacy if all of the following requirements are met:

(3) (b) *Community pharmacies.* The delegate pharmacy product verification technician may do the product verification in a community pharmacy if all of the following requirements are met:

(4) (a) A minimum of 5% of each delegate's pharmacy product verification technician's verifications shall be audited by a licensed pharmacist. The accuracy of each delegate pharmacy product verification technician shall be tracked individually.

(4) (b) A record of each delegate-check-delegate pharmacy product verification technician-check-pharmacy technician audit shall include all of the following:

(4) (b) 1. Name of the pharmacy product verification delegate technician.

(4) (c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each delegate's pharmacy product verification technician's previous 12 months accuracy and correctness of delegate-check-delegate pharmacy product verification technician-check-pharmacy technician verifications including a review of the quality assurance log.

(4) (d) A delegate pharmacy product verification technician shall be revalidated if the delegate individual fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed delegate-check-delegate pharmacy product verification technician-check-pharmacy technician verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate pharmacy product verification technician-check-pharmacy technician which shall be made available to the board upon request.

(6) (a) 1. All validation records of each delegate pharmacy product verification technician that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising ~~delegate-check-~~~~delegate~~ pharmacist, indicating the name of the supervising ~~delegate-check-~~~~delegate~~ pharmacist, and the dates the supervision responsibilities begin and end.

SECTION 7. Phar 7.43 (7) is amended to read:

Phar 7.43 (7) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), (gm), or (i), Stats., shall meet the following requirements to remote dispense:

SECTION 8. chapter Phar 7 subchapter V (title) is amended to read:

Subchapter V – ~~Unlicensed Persons~~ Pharmacy Staff

SECTION 9. Phar 7.60 (intro) and (3) are created to read:

Phar 7.60 Definitions. In this subchapter:

Phar 7.60 (3) “Pharmacy staff” means any staff practicing in the pharmacy who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats.

SECTION 10. Phar 7.62 (title), (1), (2), (3), (3) (a), (5), (6), and (7) are amended to read:

Phar 7.62 (title) ~~Unlicensed persons~~ Pharmacy staff.

Phar 7.62 (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f), (g) or (gm), Stats.

Phar 7.62 (2) A pharmacist shall provide general supervision of ~~unlicensed personnel~~ pharmacy staff. A pharmacist shall be available to the ~~unlicensed-pharmacy staff~~ pharmacy staff person for consultation either in person or contact by telecommunication means.

Phar 7.62 (3) ~~An unlicensed~~ A pharmacy staff person may not do any of the following:

Phar 7.62 (3) (a) Provide the final check on the accuracy and correctness of drug product or device dispensing under s. Phar 7.07 (1) (a) or (b), ~~unless the person is validated for delegate-check- delegate~~ under s. Phar 7.14.

Phar 7.62 (5) A managing pharmacist shall provide training to or verify competency of ~~an unlicensed~~ a pharmacy staff person prior to the ~~unlicensed~~ pharmacy staff person performing a delegated act.

Phar 7.62 (6) The managing pharmacist shall determine which acts may be delegated in a pharmacy. The managing pharmacist has a duty to notify all pharmacists practicing in that pharmacy which acts may be delegated to specific ~~unlicensed persons~~ pharmacy staff. This record shall be provided to the board upon request.

Phar 7.62 (7) A pharmacist may delegate to ~~an unlicensed~~ a pharmacy staff person any delegated act approved by the managing pharmacist.

SECTION 11. Phar 10.03 (2), (7), (17), and (19) are amended to read:

Phar 10.03 (2) Engaging in any pharmacy or pharmacy technician practice which constitutes a danger to the health, welfare, or safety of patient or public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist or pharmacy technician which harmed or could have harmed a patient;

(7) Failing to report to the pharmacy examining board any pharmacy or pharmacy technician practice which constitutes a danger to the health, safety or welfare of patient or public;

(17) Having a pharmacist license or pharmacy technician registration revoked or suspended in another state or United States jurisdiction or having been subject to other disciplinary action by the licensing authority thereof;

(19) Practicing without a current license or registration.

SECTION 12. Chapter Phar 19 is created to read:

Chapter Phar 19

REGISTRATION OF PHARMACY TECHNICIANS

Phar 19.01 Effective Date. The rules in this chapter are effective on June 1, 2023.

Phar 19.02 Registration. (1) No person may engage in the practice of a pharmacy technician or use the title “pharmacy technician” or “pharmacy tech” unless the person is registered as a pharmacy technician by the Board.

(2) A person applying for a pharmacy technician registration shall satisfy all of the following:

(a) Submit a completed application form.

Note: Instructions for applications are available on the department of safety and professional services’ website at <http://dsps.wi.gov>.

(b) Pay the fee determined by the Department under s. 440.05 (1), Stats.

(c) Subject to ss. 111.321, 111.322, and 111.335, stats., the applicant does not have an arrest or conviction record.

(d) The applicant satisfies one of the following:

1. Is at least 18 years of age and has graduated from high school or has attained high school graduation equivalency as determined by the department of public instruction.
2. Is enrolled in a youth apprenticeship program for pharmacy technicians that is on the list of youth apprenticeship programs approved by the department of workforce development under s. 106.13 (2m), Stats.

(3) A person who has applied for a registration as a pharmacy technician and whose practice as a pharmacy technician is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board and during the period before which the board takes final action on the persons application may practice as a pharmacy technician.

Phar 19.03 Scope of Practice. Each pharmacy technician shall practice under their registration as determined under chapter Phar 7.14.

Phar 19.04 Renewal and Reinstatement. (1) RENEWAL.

(a) A person with an expired pharmacy technician registration may not reapply for a license using the initial application process.

(b) A person renewing their pharmacy technician registration within 5 years shall do all of the following:

1. Submit a completed renewal application.

Note: Instructions for renewal applications are available on the department of safety and professional services' website at <http://dsps.wi.gov>.

2. Pay the renewal fee as determined by the department under s. 440.03 (9) (a), Stats. and any applicable late renewal fee.

(c) Notwithstanding sub. (b), if a pharmacy technician fails to obtain renewal on or before the applicable renewal date, the board may suspend the pharmacy technician's registration.

(d) This subsection does not apply to registration holders who have unmet disciplinary requirements. A person renewing the license after 5 years shall do all of the following:

1. Submit a completed renewal application.

Note: Instructions for renewal applications are available on the department of safety and professional services' website at <http://dsps.wi.gov>.

2. Pay the renewal fee as determined by the department under s. 440.03 (9) (a), Stats. and any applicable late renewal fee.

3. XXXX

(2) REINSTATEMENT. A registration holder who has unmet disciplinary requirements and failed to renew the license within 5 years or whose registration has been surrendered or revoked may apply to have the registration reinstated in accordance with all of the following:

- (a) Evidence of completion of the requirements under sub (1) (d).
- (b) XXXX

Phar 19.05 Change of Address, Employer, or Name. Pursuant to ss. 440.11 (1) and 450.068 (3), each pharmacy technician shall notify the department in writing of an address change or change of employer within 10 days of the change, and a name change within 30 days of the change.

Note: Instructions for providing notification of address change, change of employer, or a name change are available on the department of safety and professional services' website at <http://dsps.wi.gov>.

SECTION 13. Pursuant to 2021 Wisconsin Act 100 section 40 (1), this emergency rule shall take effect upon publication in the official state newspaper and remain in effect until May 1, 2024 or until the date on which permanent rules take effect, whichever is sooner.

(END OF TEXT OF RULE)

Dated _____ Agency _____
Chairperson
Pharmacy Examining Board

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 15

Relating to: Compounding Pharmaceuticals

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The objective of the rule is to update Wisconsin Administrative Code Chapter Phar 15 to incorporate by reference United States Pharmacopeia (USP) General Chapters 795 and 797 that are effective on November 1, 2023. The Board will also be incorporating USP General Chapter 825 by reference, which has been available since December 1, 2020.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

The Pharmacy Examining Board recently completed a revision to Phar 15 which became effective on August 1, 2022. The new updated USP standards for chapters 795 and 797 were recently released and will be effective in late 2023. The Board would like to update Phar 15 to align with the current standards as soon as possible.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

15.08 (5) (b) 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.

450.02 (3) (e) The board may promulgate rules establishing minimum standards for the practice of pharmacy.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

120 hours

6. List with description of all entities that may be affected by the proposed rule:

Pharmacies, including pharmacies located within hospitals, and pharmacists.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, and labeling requirements. Outsourcing facilities may also distribute compounded drugs in response to an order that is not patient specific.

The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

Moderate economic impact. It may have an economic impact on small businesses.

Contact Person: Nilajah Hardin, (608) 267-7139, DSPSAdminRules@wisconsin.gov

Approved for publication:

Approved for implementation:

Authorized Signature

Authorized Signature

Date Submitted

Date Submitted

**Pharmacy Examining Board
Rule Projects (updated 12/01/22)**

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	052-22	12/27/2024	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Drafting of Emergency Rules	Board Approval of Emergency Rules for Submission to the Governor's Office and Publication
Not Assigned Yet	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Emergency Rule Effective on 11/01/22; Public Hearing for Emergency Rule at 12/01/22 Meeting	Permanent Rule Drafting
Not Assigned Yet	137-20	4/19/2023	Phar 1, 6, 7, 8, 12, 13	Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors	Project Will be Allowed to Expire	New Scope Statement if Needed after Updates to Drug Supply Chain Security Act in 2023
21-074	079-20	12/22/2022	Phar 5, 6, 7, 11, 12	Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction	Incorporation of Standards Letter Pending Attorney General Approval	Submission of Final Rule Draft and Legislative Report to the Governor's Office for Approval
Not Assigned Yet	102-21	05/01/2024	Phar 7 and 10	Consumer Disclosures	Ready for EIA Comment Posting and Fiscal Estimate	Submission to Clearinghouse
Not Assigned Yet	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Ready for EIA Comment Posting and Fiscal Estimate	Submission to Clearinghouse