



**TELECONFERENCE/VIRTUAL
PHARMACY EXAMINING BOARD**
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
June 28, 2024

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. A quorum of the Board may be present during any committee meetings.

AGENDA

11:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1-5)**
- B. Approval of Minutes of April 25, 2024 (6-10)**
- C. Reminders: Conflicts of Interest, Scheduling Concerns**
- D. Introductions, Announcements, and Recognition**
- E. Administrative Matters – Discussion and Consideration**
 - 1) Department, Staff and Board Updates
 - 2) **Appointments of Liaisons and Alternates, Delegation of Authorities**
 - 3) Board Members – Term Expiration Dates
 - a. Kleppin, Susan – 7/1/2025
 - b. O’Hagan, Tiffany – 7/1/2024
 - c. Peterangelo, Anthony – 7/1/2027
 - d. Walsh, Michael – 7/1/2024
 - e. Weitekamp, John – 7/1/2026
 - f. Wilson, Christa – 7/1/2025
- F. Administrative Rule Matters – Discussion and Consideration (11-31)**
 - 1) Adoption Orders
 - a. Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing **(12-18)**
 - b. Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians **(19-28)**
 - 2) Scope Statement: Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substances Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check **(29-30)**
 - 3) Pending or Possible Rulemaking Projects **(31)**

- G. Legislative and Policy Matters – Discussion and Consideration
- H. Credentialing Matters – Discussion and Consideration
- I. NABP Pulse Regulator Monthly Champions Call – Discussion and Consideration**
- J. Interdisciplinary Advisory Council - Discussion and Consideration**
- K. Liaison Reports – Discussion and Consideration
- L. Speaking Engagements, Travel, or Public Relation Requests, and Reports**
 - 1) Travel Report: NABP 120th Annual Meeting – Fort Worth, TX – May 14-17, 2024 – Tiffany O’Hagan and John Weitekamp
 - 2) Travel Request: NABP District 4 Meeting, September 18-20 – Detroit, MI
 - 3) Travel Request: NABP Executive Officer Forum, September 25-26 – Mount Prospect, IL
- M. Report: PDG-FDA Joint Public Meeting – DSCSA Stabilization Period Midway Checkpoint**
- N. Improving Pharmacist Workplace Satisfaction – Discussion and Consideration**
 - 1) NABP Supporting Just Culture approach
- O. Pilot Program Matters – Discussion and Consideration
- P. 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) Public Health Emergencies
 - 13) Pilot Program Matters
 - 14) Variances
 - 15) Liaison Reports
 - 16) Board Liaison Training and Appointment of Mentors
 - 17) Informational Items
 - 18) Division of Legal Services and Compliance (DLSC) Matters
 - 19) Presentations of Petitions for Summary Suspension
 - 20) Petitions for Designation of Hearing Examiner
 - 21) Presentation of Stipulations, Final Decisions and Orders
 - 22) Presentation of Proposed Final Decisions and Orders
 - 23) Presentation of Interim Orders
 - 24) Pilot Program Matters
 - 25) Petitions for Re-Hearing
 - 26) Petitions for Assessments
 - 27) Petitions to Vacate Orders

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

Q. 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.).

R. Deliberation on Review of Administrative Warning (32-59)

- 1) **12:30 P.M. APPEARANCE:** Julie Zimmer, DLSC Attorney; Michael Ghobrial, Attorney; and A.H.G.I., Respondent: WARN00003717 – 24 PHM 011 – A.H.G.I.

S. Credentialing Matters

- 1) **Application Reviews (60-272)**
 - a. A.F. – Pharmacy Technician **(60-105)**
 - b. C.N.A.L. – Pharmacy (Out-of-State) and Wholesale Distributor **(106-144)**
 - c. J.D. – Pharmacy Technician **(145-202)**
 - d. L.H. – Pharmacy Technician **(203-219)**
 - e. L.S. – Pharmacy Technician **(220-229)**
 - f. M.V.S.I. – Wholesale Distributor **(230-272)**

T. Deliberation on Division of Legal Services and Compliance Matters

- 1) **Administrative Warnings (273-296)**
 - a. 21 PHM 162 – C.N.M. **(273-274)**
 - b. 21 PHM 162 – T.L.S. **(275-276)**
 - c. 22 PHM 041 – A.H.G.I. **(277-279)**
 - d. 22 PHM 116 – W. **(280-281)**
 - e. 23 PHM 009 – F.H. **(282-283)**
 - f. 23 PHM 096 – E.S.P.I. **(284-286)**
 - g. 23 PHM 137 – O.I. **(287-288)**
 - h. 23 PHM 159 – A.A.J. **(289-290)**
 - i. 23 PHM 159 – V.R.A. **(291-292)**
 - j. 23 PHM 189 – E.G. **(293-294)**
 - k. 23 PHM 189 – W.P. **(295-296)**
- 2) **Case Closings (297-363)**
 - a. 20 PHM 064 – W.P. & O.E. **(297-301)**
 - b. 21 PHM 110 – W.P. **(302-310)**
 - c. 22 PHM 139 – D.C. **(311-318)**
 - d. 22 PHM 178 – W. **(319-324)**
 - e. 22 PHM 184 – Q.P.I. **(325-337)**
 - f. 23 PHM 021 – C.P. **(338-341)**
 - g. 23 PHM 036 – C.P. **(342-345)**
 - h. 23 PHM 144 – M.D.I. **(346-349)**
 - i. 23 PHM 156 – W. **(350-355)**
 - j. 23 PHM 159 – W. **(356-360)**
 - k. 24 PHM 0042 – P.I. **(361-363)**

- 3) **Proposed Stipulations, Final Decisions and Orders (364-382)**
 - a. 22 PHM 044 – Mohamed I. Alnahrawi (364-370)
 - b. 23 PHM 114 – Jessica Eicher (371-376)
 - c. 23 PHM 144 – Mark C. Anderson (377-382)

U. Deliberation on Proposed Final Decision and Orders (383-392)

- 1) Complete Pharmacy and Medical Solutions, LLC – (DHA Case Number SPS-24-0013/DLSC Case Number 22 PHM 074)

V. 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

W. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: AUGUST 29, 2024

 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
APRIL 25, 2024**

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

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

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:03 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

Amendments to the Agenda:

- T. 2)
- f. 23 PHM 084 – O.R. (~~295-300~~) (301-304)
- g. 23 PHM 038 – J.R.N. (~~301-304~~) (295-300)

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to adopt the Agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF FEBRUARY 29, 2024

Amendments to the Minutes:

Correct to read:

- **Case Closings**

MOTION: Michael Walsh moved, seconded by John Weitekamp, to close the following DLSC Cases for the reasons outlined below:

- 22 PHM 044 – W. – No Violation (NV)
- 22 PHM 089 – CVS – Insufficient Evidence (IE)
- 22 PHM 101 – CVS – No Violation (NV)
- 22 PHM 101 – M.H. – No Violation (NV)
- 22 PHM 117 – W. Prosecutorial Discretion (P1)
- 22 PHM 127 – W. – Insufficient Evidence (IE)
- 23 PHM 018 – M.M.P. – No Violation (NV)
- 23 PHM 037 – E.S.P. – No Violation (NV)
- 23 PHM 105 – D.J.M. – No Violation (NV)
- 23 PHM 105 – W. – No Violation (NV)
- 23 PHM 125 – W. – Prosecutorial Discretion (P2)
- 23 PHM 142 – W.R.H.P. – No Violation (NV)
- 23 PHM 148 – O.E. – Insufficient Evidence (IE)
- 23 PHM 162 – H.P. – Prosecutorial Discretion (P7)

Motion carried unanimously.

- **RECONVENE TO OPEN SESSION**

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

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to approve the Minutes of February 29, 2024, as amended. Motion carried unanimously.

INTRODUCTIONS, ANNOUNCEMENTS, AND RECOGNITION

MOTION: Anthony Peterangelo moved, seconded by Tiffany O’Hagan, to acknowledge and thank students participating in the 2024 Bring your Child to Work Day for attending the Pharmacy Examining Board meeting. Motion carried unanimously.

PSYCHEDELICS AND MENTAL HEALTH

Presentation – Cody Wenthur, PharmD, PhD

MOTION: Anthony Peterangelo moved, seconded by Tiffany O’Hagan, to acknowledge and thank Cody Wenthur, PharmD, PhD, for his appearance and presentation to the Pharmacy Examining Board. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Adoption Order: Phar 18, Relating to Licensure of Third-Party Logistics Provider

MOTION: John Weitekamp moved, seconded by Susan Kleppin, to approve the Adoption Order for Clearinghouse Rule 23-031 (Phar 18), relating to Licensure of Third-Party Logistics Providers. Motion carried unanimously.

CLOSED SESSION

MOTION: Michael Walsh moved, seconded by Tiffany O’Hagan, 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 1:07 p.m.

DELIBERATION ON REVIEW OF ADMINISTRATIVE WARNING

12:30 P.M. APPEARANCE: Julie Zimmer, DLSC Attorney; Maria Kysely Schneider, Attorney for Respondent; and K.M.L., Respondent: WARN00003678 – 23 PHM 060 – K.M.L.

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to affirm the issuance of the administrative warning in the matter of K.M.L, DLSC Case WARN00003678 – 23 PHM 060 – K.M.L. Motion carried unanimously.

MONITORING

Kyle J. McGilligan, R.Ph. – Requesting Full Licensure

MOTION: John Weitekamp moved, seconded by Susan Kleppin, to grant the request of Kyle J. McGilligan, R.Ph., for Full Licensure. Motion carried unanimously.

Jin Ryu, R.Ph. – Requesting approval to travel to South Korea (June 16–July 6, 2024) (edit to June 6- July 2, 2024) for family matters, reduction in drug screens, discontinuation of mental health wellness therapy (per the treater), and reduction of AA/NA meetings to once per week

MOTION: Tiffany O’Hagan moved, seconded by John Weitekamp, to deny the request Jin Ryu, R.Ph., for reduction in drug screens and reduction of AA/NA meetings, but to grant approval to travel to South Korea (June 6- July 2, 2024) with an alcohol and drug blood test on return, and discontinuation of mental health wellness therapy, per the treater. Reason for Denial: Insufficient time under the Board Order (9/21/2017) to demonstrate adequate compliance. Motion carried unanimously.

CREDENTIALING MATTERS

Application Reviews

Empower Pharmacy - Pharmacy (Out-of-State)

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to deny the Pharmacy (Out-of-State) application of E. P. Reason for Denial: Wis. Stat. § 450.10(1)(a)2., 450.10(1)(b)1., Phar 10.03(17), (1), (2). Motion carried unanimously.

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

Administrative Warnings

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to issue an Administrative Warning in the following DLSC Cases:
23 PHM 109 – J.R.B.
23 PHM 116 – C.A.W.P.

23 PHM 117 – C.A.W.P.
23 PHM 121 – M.H.E.S.
23 PHM 121 – W.C.
23 PHM 123 – S.
23 PHM 142 – B.D.J.
24 PHM 005 – H.A.
24 PHM 011 – A.H.G.
Motion carried unanimously.

Case Closings

MOTION: Tiffany O’Hagan moved, seconded by Anthony Peterangelo, to close the following DLSC Cases for the reasons outlined below:
22 PHM 080 – C. – Prosecutorial Discretion (P1)
22 PHM 090 – H.A.Z. – Insufficient Evidence
22 PHM 131 – P.L. – No Violation
22 PHM 185 – V.C.P. – No Violation
22 PHM 194 – R.A.G. – Insufficient Evidence
23 PHM 084 – O.R. – No Violation
23 PHM 038 – J.R.N. – No Violation
23 PHM 099 – C.O.A. and W.M.P. – Insufficient Evidence
23 PHM 109 – W. – Prosecutorial Discretion (P2)
23 PHM 132 – E.H.P.S.C. – Insufficient Evidence
23 PHM 188 – W. – No Violation
24 PHM 018 – K.C. – Insufficient Evidence
Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

MOTION: John Weitekamp moved, seconded by Susan Kleppin, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of the following cases:
22 PHM 067 – Abdelrahman H. Alarga
22 PHM 067 – Susan O. Coady
22 PHM 067 – Mohammed H. Elghannam
23 PHM 101 – Stephanie L. Nehls
Motion carried unanimously.

RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 2:27 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

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

The meeting adjourned at 2:54 p.m.

DRAFT

**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: 06/17/24 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: 06/28/24	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. Adoption Order: a. Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing b. Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians 2. Scope Statement: Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substances Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check 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, 6, 7, and 8 Adoption Order 2. Phar 1, 4, 7, 10 and 19 Adoption Order 3. Phar 7 Scope Statement 4. 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		06/17/24 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 : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 23-054)

ORDER

An order of the Pharmacy Examining Board to repeal Phar 1.02 (9), 7.43 (1), (3); and (4) (d), and 7.61; amend Phar 7.43 (2), (4) (a) 2. (intro.), (4) (b), (5) (b), and (7) (intro.), and 7.62 (1); create Phar 1.02 (3m), (10m), and (14m), 5.01 (4), 6.025, and 8.01 (5); and repeal and recreate Phar 7.43 (6), relating to remote dispensing.

Analysis prepared by the Department of Safety and Professional Services.

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), and 450.02 (5), Stats.

Explanation of agency authority:

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

Section 450.02 (3) (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.”

Section 450.02 (5), Stats. provides that “the board may promulgate rules governing pharmacies that are operated as remote dispensing sites. Rules promulgated under this subsection may exempt pharmacies operated as remote dispensing sites from requirements governing pharmacies that are not operated as remote dispensing sites.”

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. These changes include the creation of s. Phar 6.025, which are rules that specifically apply to remote dispensing sites, as well as amendments to s. Phar 7.43 to allow for remote dispensing sites to operate without the presence of a pharmacist. Clarification was also added to ss. Phar 5.01 (4) and 8.01 (5) that pharmacies shall include remote dispensing sites. The Board also added a definition of pharmacy graduates to chapter Phar 1, and modified requirements in chapter Phar 7 to allow them to practice pharmacy while waiting for their license to be granted.

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.

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

Comparison with rules in adjacent states:

Illinois: 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].

In Illinois, graduate of a pharmacy program approved by the Illinois Department of Financial and Professional Regulation may be registered as a pharmacy technician with the “student pharmacist” designation, if they have graduated from said program within the last 18 months. Student pharmacists are allowed to practice pharmacy under the supervision of a pharmacist [225 Illinois Compiled Statutes ch. 85 s. 9 (c)].

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)].

In Iowa, graduates of a college of pharmacy approved by the Iowa Board can register as a “pharmacist-intern.” Pharmacist-interns are required to practice under the supervision of a licensed pharmacist. This registration automatically terminates upon the pharmacist-intern receiving “licensure to practice pharmacy in any state, lapse in the pursuit of a degree in pharmacy, or one year following graduation from the college of pharmacy,” whichever happens sooner [657 Iowa Administrative Code sections 4.1 and 4.6 (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. 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].

In Michigan, pharmacy graduates can apply for an educational limited license if they are within 180 days of completing an approved educational program. Pharmacy graduates practicing under an educational limited license may only do so under the “personal charge of a pharmacist” [Michigan Administrative Code R 338.513].

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)].

In Minnesota, pharmacy graduates can apply for a “pharmacist-intern” registration if they are a graduate of a pharmacy college approved by the Minnesota Board. Pharmacist interns must practice under the direct supervision of a licensed pharmacist [Minnesota Administrative Rules Chapter 6800 Parts 5100-5600].

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. While completing this review, the Board also identified a need to create a definition of a Pharmacy Graduate and include them in certain pharmacy practice circumstances.

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

The rule was posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These 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) 266-2112.

Agency contact person:

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

TEXT OF RULE

SECTION 1. Phar 1.02 (3m) is created to read:

Phar 1.02 (3m) “Direct supervision” means immediate, whether in person or real time video conferencing where all parties can communicate by simultaneous means of audio, video, or data communications, availability to continually coordinate, direct and inspect in real time the practice of another.

SECTION 2. Phar 1.02 (9) is repealed.

SECTION 3. Phar 1.02 (10m) and (14m) are created to read:

Phar 1.02 (10m) “Pharmacy graduate” means a graduate of a school of pharmacy approved by the board, who has submitted an application for pharmacist licensure or a qualified applicant awaiting examination for licensure approved by the board.

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

SECTION 4. 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 5. Phar 6.025 is created to read:

Phar 6.025 Licenses; remote dispensing sites. A pharmacy may be subject to rules in this section that apply only to remote dispensing sites, if a pharmacist remotely supervises the location for any period of time. The following conditions shall also be 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 s. 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 may not be responsible for more than 10 remote dispensing sites at any given time without approval from the board.

SECTION 6. Phar 7.43 (1) is repealed.

SECTION 7. Phar 7.43 (2) is 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) or (g), or (i), Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) may dispense at any of the locations under s. ~~450.62 (1) to (4)~~ 450.09 (2) (b) 1. a. to d., Stats.

SECTION 8. Phar 7.43 (3) is repealed.

SECTION 9. Phar 7.43 (4) (a) 2. (intro.) and (4) (b) are amended to read:

Phar 7.43 (4) (a) 2. (intro.) This remote dispensing location is being supervised by a pharmacist employed by ~~located at all of the following:~~

Phar 7.43 (4) (b) Remote dispensing may not occur if ~~the supervising pharmacy is closed~~ a pharmacist is not available remotely.

SECTION 10. Phar 7.43 (4) (d) is repealed.

SECTION 11. Phar 7.43 (5) (b) is amended to read:

Phar 7.43 (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.

SECTION 12. Phar 7.43 (6) is repealed and recreated to read:

Phar 7.43 (6) RESPONSIBILITIES OF MANAGING PHARMACIST. The managing pharmacist responsible for the remote dispensing pharmacy shall do all of the following:

- (a) Have written policies and procedures for system operation, safety, security, accuracy and access.
- (b) Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.
- (c) Visit the remote dispensing location at least monthly to confirm delivery status of all drugs, to ensure written policies and procedures are being followed, and to ensure that remote dispensing personnel comply with all federal and state laws regulating the practice of pharmacy.
- (d) Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.
- (e) Documentation indicating accepting responsibility for compliance with this section, signed and dated by the managing pharmacist.

SECTION 13. Phar 7.43 (7) (intro.) is amended to read:

Phar 7.43 (7) (intro.) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), ~~or (i)~~, Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) shall meet the following requirements to remote dispense:

SECTION 14. Phar 7.61 is repealed.

SECTION 15. Phar 7.62 (1) is amended to read:

Phar 7.62 (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m).

SECTION 16. 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 17. 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)

Dated _____

Agency _____

Chairperson
Pharmacy Examining Board

DRAFT

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 23-072)

ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.68, Stats.

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

Explanation of agency authority:

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

Section 450.02 (3) (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.”

Related statute or rule: 2021 Wisconsin Act 100

Plain language analysis: The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 100. This was achieved by adding a definition of “pharmacy technician” to Phar 1.02, creating Phar 5.07 to clarify where rules for registration of pharmacy technicians can be found, and various amendments to chapter Phar 7 to include that registration as a pharmacy technician is required under certain circumstances. More specifically, the requirements in Phar 7.14 were revised to allow a trained pharmacy technician to do product verification for another pharmacy technician. Additionally, Subchapter V of Chapter Phar 7 was updated to better distinguish between the responsibilities of pharmacy technicians and uncredentialed pharmacy staff. Language clarifying standards of professional conduct was revised in Phar 10.03 (2), (17), and (19) to include pharmacy technicians. Finally, chapter Phar 19 was created to outline rules for pharmacy technician registration and the scope of practice for pharmacy technicians.

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.

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

Comparison with rules in adjacent states:

Illinois: 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 must be at least 16 years old, currently attending or have graduated from high school or have a high school equivalency certificate and have completed the requirements to become a licensed registered certified pharmacy technician. A 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 in the Iowa Administrative Code and 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 338.3651-338.3665].

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 or created Wisconsin Administrative Code Chapters Phar 1, 5, 7, 10 and 19 accordingly.

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

The rule was posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These 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) 266-2112.

Agency contact person:

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

TEXT OF RULE

SECTION 1. Phar 1.01 is amended to read:

Phar 1.01 Authority. Rules in chs. Phar 1 to ~~4719~~ are adopted under authority of ss. 15.08 (5) (b), 227.11 (2), Stats, and ch. 450, Stats.

SECTION 2. Phar1.02 (intro.) and 1.02 (Note) are amended to read:

Phar 1.02 (intro.) As used in ch. Par 1 to ~~4719~~.

Phar 1.02 (Note) The board office is located at ~~1400 East Washington Avenue~~ 4822 Madison Yards Way, Madison, WI ~~53702~~53705.

SECTION 3. Phar 1.02 (2m) and (11m) are created to read:

Phar 1.02 (2m) “Department” means the Wisconsin department of safety and professional services.

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

SECTION 4. Phar 5.07 is created to read:

Phar 5.07 Pharmacy technicians. (1) All requirements for renewal and reinstatement of a pharmacy technician registration are specified in ch. Phar 19.

(2) No pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes is eligible to be registered as a pharmacy technician.

SECTION 5. Phar 7.07 (2)is amended to read:

Phar 7.07 (2) For all prescription drug ~~product~~ products or ~~device dispensing devices~~ dispensed by a pharmacist, 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~~ a pharmacy product verification 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.

SECTION 6. Phar 7.14 (title) is repealed and recreated to read:

Phar 7.14 (title) Pharmacy product verification technician-check-pharmacy technician.

SECTION 7. 7.14 (1) (a), (b) and (d); and 7.14 (2) are amended to read:

Phar 7.14 (1) (a) “~~Delegate~~ Pharmacy product verification technician” means a ~~person~~ registered pharmacy technician to whom the pharmacist has delegated the task of product verification.

(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.

(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 8. Phar 7.14 (2) (a) is repealed.

SECTION 9. Phar 7.14 (2) (b), (2) (c) 3. and 6., (2) (d) 1. and 2., and (2) (e); 7.14 (3) (a) (intro.) and (b) (intro.); 7.14 (4) (a), (b)(intro.), (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.

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

(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:**(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%.

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

(e) Notwithstanding pars. ~~(a)~~ **(b)** to **(d)**, a delegate 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) (intro.) *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:

(b) (intro.) *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.

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

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

(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 verifications including a review of the quality assurance log.

(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~~ product 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 by technicians 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.

(6) (a) 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 10. Chapter Phar 7 subchapter V (title) is repealed and recreated to read:

Subchapter V – Uncredentialed Pharmacy Staff

SECTION 11. Phar 7.60 is repealed and recreated to read:

Phar 7.60 Definition. In this subchapter, “Uncredentialed 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 12. Phar 7.62 (title) is repealed and recreated to read:

Phar 7.62 (title) Uncredentialed pharmacy staff.

SECTION 13. Phar 7.62 (2) is amended to read:

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

SECTION 14. Phar 7.62 (3) (intro.) is renumbered to 7.62 (3) and amended to read:

Phar 7.62 (3) An ~~unlicensed uncredentialed pharmacy staff~~ person may not ~~do any of the following:~~ engage in the practice of pharmacy as defined in s. 450.01 (16), Stats., or the practice of a pharmacy technician as defined in s. Phar 19.02.

SECTION 15. Phar 7.62 (3) (a) to (d) are repealed.

SECTION 16. Phar 7.62 (5), (6), and (7) are amended to read:

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

(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 uncredentialed pharmacy staff~~. This record shall be provided to the board upon request.

(7) A pharmacist may delegate to an ~~unlicensed uncredentialed pharmacy staff~~ person any delegated act approved by the managing pharmacist outside of the restrictions in sub. (3).

SECTION 17. Phar 10.03 (1) to (7), (8) to (17), and (19) are amended to read:

Phar 10.03 (1) Administering, dispensing, supplying or obtaining a drug other than in legitimate practice, or as prohibited by law;

(2) Engaging in any pharmacy 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;

(3) Dispensing a drug which the pharmacist should have known would harm the patient for whom the medication was prescribed;

(4) Dispensing or causing to be dispensed a drug which is outdated or contaminated or known by the pharmacist to be unsafe for consumption;

(5) Falsifying patient records;

(6) Disclosing to the public information concerning a patient without the consent of the patient unless the information is requested by the pharmacy examining board or the department of safety and professional services or unless release is otherwise authorized by law;

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

(8) Providing false information to the pharmacy examining board or its agent;

(9) Refusing to render professional services to a person because of race, color, sex, religion, or age;

(10) Aiding or abetting the unlicensed practice of pharmacy;

(11) Advertising in a manner which is false, deceptive or misleading;

(12) Dispensing sample drug products for any financial consideration;

(13) Exercising undue influence on or taking unfair advantage of a patient in the promotion or sale of services, drugs or other products for the financial gain of the pharmacist or a third party;

(14) Participating in rebate or fee-splitting arrangements with health practitioners or with health care facilities;

(15) Furnishing a prescriber with any prescription order blanks imprinted with the name of a specific pharmacist or pharmacy;

- (16) Using secret formula or code in connection with prescription orders;
- (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 18. Chapter Phar 19 is created to read:

Chapter Phar 19 REGISTRATION OF PHARMACY TECHNICIANS

Phar 19.01 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 19.02 Scope of practice. A pharmacy technician may administer vaccines as authorized under s. 450.035 (2h), Stats., perform technical dispensing functions, compounding, packaging, labeling and storage, pharmacy and inventory management, and other activities involved in the practice of pharmacy delegated by a pharmacist. A pharmacy technician may not perform any of the following:

(1) Except as allowed under s. Phar 7.14, provide the final verification for the accuracy, validity, completeness, or appropriateness of the filled prescription or medication order.

- (2) Complete the drug utilization review under s. Phar 7.03.
- (3) Administer any prescribed drug products, or devices under s. 450.035 (1t), Stats.
- (4) Provide patient specific counseling or consultation.
- (5) Make therapeutic alternate drug selections.
- (6) Provide supervision over the practice of pharmacy to other pharmacy technicians.

Phar 19.03 Renewal and reinstatement. (1) RENEWAL.

- (a) A person with an expired pharmacy technician registration may not reapply for a registration using the initial application process.
- (b) A person renewing their pharmacy technician registration 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 par. (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.

- (2) REINSTATEMENT. A registration holder who has unmet disciplinary requirements and failed to renew the registration 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 s. Phar 19.01 (2).
 - (b) Evidence of completion of any disciplinary requirements.

Phar 19.04 Change of address, employer, or name. Pursuant to ss. 440.11 (1) and 450.068 (3), Stats., each pharmacy technician shall notify the department 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 19. 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)

Dated _____

Agency _____

Chairperson
 Pharmacy Examining Board

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 7

Relating to: Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check.

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 proposed rule is to update requirements in Wisconsin Administrative Code Phar 7 to align with current pharmacy practice in the areas of electronic prescriptions, prescription labelling, CPR for pharmacists, controlled substance prescription transfers, remote dispensing, the definition of a managing pharmacist, initial prescription consultation by a pharmacist, alteration of a prescription, and prescription final check. Additionally, the rule will implement the statutory changes from 2023 Wisconsin Act 27 by updating requirements for epinephrine delivery systems.

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:

Wisconsin Administrative Code Phar 7 includes requirements for the practice of pharmacy. These requirements have the potential to become outdated on a regular basis. If the Board does not make regular updates via the permanent rules process, there will be inconsistencies between current pharmacy practice and what is required in the Wisconsin Administrative Code. This project will ensure that the Wisconsin Administrative Code continues to be current in the practice areas listed above.

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

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.”

450.02 (2), Stats., states that “the Board shall promulgate rules that do all of the following:

(a) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

(b) Define the activities that constitute the practice of a pharmacy technician for purposes if the registration requirement under s. 450.68.”

450.02 (3) (a), Stats., states “[t]he Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

450.02 (3) (b), Stats., states “[t]he Board may promulgate rules establishing security standards for pharmacies.”

450.02 (3) (d), Stats., states “[t]he Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.”

450.02 (3) (e), Stats., states “[t]he Board may promulgate rules establishing minimum standards for the practice of pharmacy.”

450.02 (5), Stats., states “[t]he Board may promulgate rules governing pharmacies that are operated as remote dispensing sites.”

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:

Licensed Pharmacies, Pharmacists, Manufacturers, and Distributors; Registered Pharmacy Technicians

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 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.

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

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, (608) 267-7139

Approved for publication:

Approved for implementation:

Authorized Signature

Authorized Signature

Date Submitted

Date Submitted

**Pharmacy Examining Board
Rule Projects (updated 6/17/24)**

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
23-072 (EmR 2303)	052-22	12/27/2024	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Board Review of Adoption Order at 6/28/24 Meeting; Emergency Rule Effective 02/03/23-05/01/24	Submission for Publication; Anticipated Effective date of 09/01/24
23-054 (EmR 2213)	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Board Review of Adoption Order at 6/28/24 Meeting; Emergency Rule Effective 11/01/22-05/01/24	Submission for Publication; Anticipated Effective date of 09/01/24
Not Assigned Yet	Not Assigned Yet	TBD	Phar 7	Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check	Updated Scope Statement Reviewed at 6/28/24 Meeting	Board Approval of Scope Statement for Publication and Submission to the Governor's Office for Review and Approval
Not Assigned Yet	044-23	01/10/2026	Phar 8	Controlled Substances Requirements	Emergency Rule Pending Fiscal Estimate and Submission to Governor's Office for Approval	Board Review of Preliminary Permanent Rule Anticipated at 8/29/24 Meeting
Not Assigned Yet	007-23	07/23/2025	Phar 15	Compounding Pharmaceuticals	Review of Updated Preliminary Rule Draft at 04/25/24 Meeting	Board Approval of Preliminary Rule Draft for Posting for EIA Comment and Submission to Clearinghouse for Review
23-031	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Effective 7/01/24	N/A