



**TELECONFERENCE/VIRTUAL
PHARMACY EXAMINING BOARD**
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
January 18, 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. Be advised that board members may attend meetings designated as “Hybrid” in-person or virtually.

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 December 7, 2023 (5-8)**
- C. Reminders: Conflicts of Interest, Scheduling Concerns**
- D. Introductions, Announcements, and Recognition**
- E. 11:00 A.M. Public Hearing for Clearinghouse Rule 23-072 on Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians (9-28)**
 - 1) Review Public Hearing Comments and Respond to Clearinghouse Report
- F. Administrative Matters – Discussion and Consideration**
 - 1) Department, Staff and Board Updates
 - 2) 2024 Meeting Dates **(29)**
 - 3) Annual Policy Review **(30-32)**
 - 4) Election of Officers, Appointments of Liaisons and Alternates, Delegation of Authorities **(33-51)**
 - 5) 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
- G. Administrative Rule Matters – Discussion and Consideration (52-72)**
 - 1) Final Rule Draft: Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing **(53-66)**
 - 2) Emergency Rule Draft: Phar 8, Relating to Controlled Substances Requirements **(67-71)**
 - 3) Pending or Possible Rulemaking Projects **(72)**

- H. Legislative and Policy Matters – Discussion and Consideration (73-81)**
 - 1) 2023 Senate Bill 705/2023 Assembly Bill 626
- I. Credentialing Matters – Discussion and Consideration
- J. Improving Pharmacist Workplace Satisfaction – Discussion and Consideration (82)**
- K. Liaison Reports – Discussion and Consideration
- L. Speaking Engagements, Travel, or Public Relation Requests, and Reports**
 - 1) MPJE Item Development Workshop, March 13-15, 2024, Mount Prospect, IL
 - 2) MPJE State-Specific Review, September 11-13, 2024, TBA
- M. NABP Pulse Regulator Monthly Champions Call – 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) 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
- 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. 23 PHM 118 – S.S.P., Inc. **(83-84)**
 - b. 23 PHM 119 – E.P., LLC **(85-86)**
 - c. 23 PHM 120 – A.S.P. **(87-88)**
- 2) **Case Closings**
 - a. 22 PHM 063 – P.M.S. **(89-92)**
 - b. 23 PHM 024 – K.M.O. **(93-101)**
 - c. 23 PHM 025 – W. **(102-107)**
 - d. 23 PHM 053 – W. **(108-113)**
 - e. 23 PHM 087 – S.A.F. **(114-118)**
- 3) **Proposed Stipulations, Final Decisions and Orders**
 - a. 22 PHM 101, Jason D. Crawford, R.Ph. **(119-124)**
 - b. 23 PHM 139, Paul A. Blazkovec **(125-131)**

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: FEBRUARY 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://dps.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.

**VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
MEETING MINUTES
DECEMBER 7, 2023**

PRESENT: Susan Kleppin, Tiffany O’Hagan, Anthony Peterangelo, Michael Walsh, John Weitekamp, Christa Wilson

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 11:07 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES OF OCTOBER 26, 2023

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to approve the Minutes of October 26, 2023, as published. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Scope Statement

Phar 7, Relating to Comprehensive Review

MOTION: Tiffany O’Hagan moved, seconded by Michael Walsh, to approve the Scope Statement revising Phar 7, relating to Comprehensive Review, for submission to the Department of Administration and Governor’s Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion failed.

MOTION: Michael Walsh moved, seconded by Tony Peterangelo, to request DSPS staff draft a Scope Statement revising Phar 7 relating to electronic prescriptions, prescription labeling, CPR for pharmacists, Epinephrine Delivery Systems, and controlled substance prescription transfers. Motion carried.

IMPLEMENT 2021 WISCONSIN ACT 9 – 100 MOST PRESCRIBED DRUGS

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to approve the Top 100 Most Prescribed Drug List as required by s. 450.13(5m) (b) for publication on the DSPS website. Motion carried unanimously.

SPEAKING ENGAGEMENTS, TRAVEL, OR PUBLIC RELATION REQUESTS, AND REPORTS

120th NABP Annual Meeting, May 14 – 17, 2024, Fort Worth, TX

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to designate Tiffany O’Hagan as the Board’s delegate and John Weitekamp, as the Board’s alternate delegate, and Executive Director Brad Wojciechowski to attend the 120th NABP Annual Meeting on May 14 – 17, 2024, in Fort Worth, TX. 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 1:44 p.m.

CREDENTIALING MATTERS

Empower Pharmacy – Out of State Pharmacy Applicant

MOTION: John Weitekamp moved, seconded by Christa Wilson, to table the Out of State Pharmacy application of Empower Pharmacy, and request two additional consultant reports required by the Stipulated Settlement and disciplinary order issued by California. Motion carried unanimously.

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

Administrative Warnings

MOTION: Michael Walsh moved, seconded by Tiffany O’Hagan, to issue an Administrative Warning in the following DLSC Cases:

22 PHM 035 – H.P. 20
22 PHM 149 – H.P.
22 PHM 154 – C.V.S.
22 PHM 154 – T.T.T., R.Ph.
23 PHM 057 – R.P.C., R.Ph.
23 PHM 094 – P.A.A., R.Ph.
Motion carried unanimously.

Case Closings

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

22 PHM 035 – H.P. 9 – No Violation (NV)
22 PHM 035 – H.P. 12 – No Violation (NV)
22 PHM 035 – H.P. 19 – No Violation (NV)
22 PHM 035 – H.P. 2 – Insufficient Evidence (IE)
22 PHM 035 – H.P. 7 – Insufficient Evidence (IE)
22 PHM 035 – H.P. 16 – Insufficient Evidence (IE)
22 PHM 084 – W – No Violation
22 PHM 126 – R.U.P. – Lack of Jurisdiction (L2)
22 PHM 164 – W.P.I. & W.V.P. – No Violation
22 PHM 179 – CVS – Prosecutorial Discretion (P1)
23 PHM 010 – W.P. & C.P.K. – Insufficient Evidence (IE)
23 PHM 057 – W. – No Violation
23 PHM 094 – P.N.S. – Prosecutorial Discretion (P7)
23 PHM 098 – G.Z. – Insufficient Evidence (IE)
23 PHM 108 – L.C.P. – Insufficient Evidence (IE)
Motion carried unanimously.

21 PHM 162 – W.P.

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to refer back to DLSC, DLSC Case Number 21 PHM 162, against W.P., for further investigation. Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

21 PHM 157 – McGuff Compounding Pharmacy Services, Inc.

MOTION: John Weitekamp moved, seconded by Michael Walsh, to adopt the Proposed Decision and Order in the matter of disciplinary proceedings against McGuff Compounding Pharmacy Services, Inc., DLSC Case Number 21 PHM 157. Motion carried unanimously.

RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 2:53 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.

ADJOURNMENT

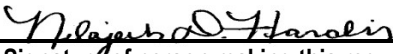
MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 2:55p.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: 01/05/24 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: 01/18/24	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 for Clearinghouse Rule 23-072 on Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians 1. Review Public Hearing Comments and Respond to Clearinghouse Report	
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 rule as required by the rulemaking process.			
11) Authorization			
 Signature of person making this request		01/04/24 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)

PROPOSED 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), (2), (3) (intro.), (5), (6), and (7), 10.03 (2), (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) and 7.62 (3) (a) to (d), 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.

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.

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, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on January 18, 2024, 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 ~~53702~~53705.

SECTION 2. Phar 1.01 (11m) 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. (1) All requirements for renewal and reinstatement of a pharmacy technician registration are specified in chapter 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 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~~ 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.

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

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.

Phar 7.14 (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.

Phar 7.14 (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.

Phar 7.14 (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.

Phar 7.14 (2) (c) 3. Eligible ~~medications~~ products for ~~delegate-check-~~delegate~~ pharmacy product verification technician-check-pharmacy technician~~.

Phar 7.14 (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:

Phar 7.14 (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%.

Phar 7.14 (2) (d) 2. A pharmacist shall audit 100% of the product verifications made by the ~~delegate~~ pharmacy technician during the validation process.

Phar 7.14 (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).

Phar 7.14 (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:

Phar 7.14 (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:

Phar 7.14 (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.

Phar 7.14 (4) (b) A record of each ~~delegate-check-delegate~~ pharmacy product verification technician-check-pharmacy technician audit shall include all of the following:

Phar 7.14 (4) (b) 1. Name of the pharmacy product verification ~~delegate~~ technician.

Phar 7.14 (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 verifications including a review of the quality assurance log.

Phar7.14 (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~~ product verifications within the last 6 months.

Phar 7.14 (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.

Phar 7.14 (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.

Phar 7.14 (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 7. chapter Phar 7 subchapter V (title) is amended to read:

Subchapter V – ~~Unlicensed Persons~~ Uncredentialed Pharmacy Staff

SECTION 8. Phar 7.60 (intro) is created to read:

Phar 7.60 Definitions. In this subchapter:

SECTION 9. Phar 7.60 (2) is repealed.

SECTION 10. Phar 7.60 (3) is created to read:

Phar 7.60 (3) “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 11. Phar 7.62 (title), (2), and (3) (intro.) are amended to read:

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

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.

Phar 7.62 (3) (intro.) 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 12. Phar 7.62 (3) (a) to (d) are repealed.

SECTION 13. 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.

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

Phar 7.62 (7) A pharmacist may delegate to an ~~unlicensed~~ uncredentialed pharmacy staff person any delegated act approved by the managing pharmacist pursuant to sub. (3).

SECTION 14. Phar 10.03 (2), (17), and (19) are amended to read:

Phar 10.03 (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;

Phar 10.03 (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;

Phar 10.03 (19) Practicing without a current license or registration.

SECTION 15. 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 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 or uncredentialed pharmacy staff.

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 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.

(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. 19.02 (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), 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 16. 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)

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	2. Date December 20, 2023
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) Phar 1, 5, 7, 10 and 19 (Permanent Rule)	
4. Subject Registration of Pharmacy Technicians	
5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	6. Chapter 20, Stats. Appropriations Affected s. 20.165 (1) (hg)
7. Fiscal Effect of Implementing the Rule <input type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input checked="" type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input checked="" type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget	
8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0	
10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Policy Problem Addressed by the Rule This rule implements the statutory changes from 2021 Wisconsin Act 100 by creating requirements for registration of pharmacy technicians.	
12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments. The rule will be posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.	
13. Identify the Local Governmental Units that Participated in the Development of this EIA. N/A	
14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred) The Department of Safety and Professional Services estimates a total of \$19,200 in one-time costs to the agency. Ongoing costs to credential and regulate the new profession are estimated at \$248,900 annually and will be recovered through a fee determined under Wis. Stat. § 440.03(9), which requires the Department to recalculate biennially the administrative and enforcement costs of the department that are attributable to the regulation of each professional occupation or business under chapters 440 to 480. The estimated costs may not be absorbed in the agency budget. Additional appropriation authority is needed to expend collected fees to support estimated expenditures for administration of the new profession.	
15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefits of implementing this rule are that the Pharmacy Examining Board's sections of the Administrative Code will be aligned with Wisconsin State Statutes.	
16. Long Range Implications of Implementing the Rule The long range implications of implementing this rule are clear rules for registration of Pharmacy Technicians.	

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

17. Compare With Approaches Being Used by Federal Government

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.

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

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].

19. Contact Name

20. Contact Phone Number

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Nilajah Hardin, Administrative Rules Coordinator

608-267-7139

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

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

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
-



Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **23-072**

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

Submitted by **PHARMACY EXAMINING BOARD**

12-20-2023 RECEIVED BY LEGISLATIVE COUNCIL.

01-05-2024 REPORT SENT TO AGENCY.

MSK:SM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]
Comment Attached YES NO
2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]
Comment Attached YES NO
3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]
Comment Attached YES NO
4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]
Comment Attached YES NO
5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]
Comment Attached YES NO
6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]
Comment Attached YES NO
7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]
Comment Attached YES NO



Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Margit Kelley
Clearinghouse Assistant Director

Anne Sappenfield
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CLEARINGHOUSE RULE 23-072

Comments

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

2. Form, Style and Placement in Administrative Code

a. The rule caption’s listing of treated provisions should be grouped in the following order: to repeal; to renumber and amend; to amend; and to create. [s. 1.01 (1) (b), Manual.]

b. The board’s plain language analysis for the proposed rule should be revised to provide a brief summary of the proposed rule that provides an understandable and objective description of the effect of the proposed rule. The summary should contain sufficient detail to enable the reader to understand the content of the proposed rule and the changes made to existing rules. [s. 1.01 (2) (b), Manual.]

c. SECTION 1 of the proposed rule should be reorganized into separate SECTIONS. Subunits of different rule sections should not be combined in a single treatment SECTION. [s. 1.03 (1) and (2) (b) 1. and (c) 2., Manual.] Accordingly, the separate SECTIONS should be organized as follows:

(1) To amend s. Phar 1.01.

(2) To amend s. Phar 1.02 (intro.) and (Note).

d. In SECTION 2 of the proposed rule, the treatment clause and rule caption should be corrected to cite “1.02”, rather than “1.01”.

e. In SECTION 3 of the proposed rule, creating s. Phar 5.07, the format of the cross-reference in sub. (1) to “chapter Phar 19” should be revised to “ch. Phar 19”.

f. SECTION 4 of the proposed rule should be reorganized into separate SECTIONS. The treatment of the subunit under s. Phar 7.07 should be in a separate SECTION from the treatment of the subunits under s. Phar 7.14.

g. In the treatment clause for SECTION 6 of the proposed rule, each of the affected subunits that is an introduction should be identified as “(intro.)”. This should also be revised in the rule caption’s listing of affected provisions.

h. In SECTION 7 of the proposed rule, the title for subch. V of ch. Phar 7 is amended in its entirety. Accordingly, the treatment could be identified as repealing and recreating the title, rather than amending the title. If revised to that treatment, the new material would be shown without underscoring. [s. 1.04 (5), Manual.] This comment also applies in SECTION 4 of the proposed rule, amending s. Phar 7.14 (title), and SECTION 11 of the proposed rule, amending s. Phar 7.62 (title).

i. In SECTION 8 of the proposed rule, the text of the created s. Phar 7.60 (intro.) should be shown without underscoring.

j. In SECTION 10, the proposed rule creates a definition for “Uncredentialed Pharmacy staff” within subch. V of ch. Phar 7, but that term is also used in the material created in ch. Phar 19 within the proposed rule. Should that definition, and other definitions within subch. V of ch. Phar 7, be moved to ch. Phar 1 to make clear they apply to all chapters of the board’s rules?

k. In SECTION 11 of the proposed rule, the treatment of s. Phar 7.62 (3) (intro.) should be moved to a separate SECTION, in order to renumber the provision as s. Phar 7.62 (3), since all of the subunits under sub. (3) are repealed by SECTION 12 of the proposed rule. Alternatively, the board could consider renumbering the material as something like s. Phar 7.62 (3m), if it may help to reduce confusion on whether the current or previous provision is being referred to and to reduce erroneous cross-references.

l. In SECTION 14 of the proposed rule, consider expanding the amended provisions to include all of the subsections in s. Phar 10.03 that currently end in a semicolon. Under current drafting conventions, a series of subunits should each end in a period. The proposed rule could be revised to include the current subunits that end in a semicolon, to amend each semicolon to a period. [s. 1.11 (3), Manual.]

m. In s. Phar 19.01 (2) (c), the abbreviation “stats.” should be revised to “Stats.”.

n. In s. Phar 19.02 (1), the abbreviation “s.” should be inserted before the cross-reference to s. Phar 7.14.

o. In s. Phar 19.03 (1) (c), the reference to “sub. (b)” should be revised to “par. (b)”, if par. (b) is the intended cross-reference.

p. In s. Phar 19.04, the abbreviation “Stats.,” should be inserted after the statutory cross-references.

q. If a treatment clause identifies multiple subunits of a rule section, it is not necessary to repeat the rule section number or previously identified higher subunits. See, for example, the treatment clauses for SECTIONS 4 and 6 of the proposed rule. [s. 1.03 (2) (c) 2. (Example), Manual.]

r. The rule caption’s listing of treated provisions should be updated to reflect any changes made in response to these comments.

3. Conflict With or Duplication of Existing Rules

SECTIONS 11 and 12 of the proposed rule modify provisions that identify certain acts that may not be done by an unlicensed person, but those acts are incorporated by cross-reference within the proposed rule’s treatment to s. Phar 7.62 (7). It is not clear if the intent of the proposed rule is to allow a pharmacist to delegate any acts within the practice of pharmacy or the practice of a pharmacy technician under s. 7.62 (3), or if the intent is to only allow delegation of acts not

mentioned in s. 450.01 (16) or s. Phar 19.02. The proposed rule should be modified for clarification.

4. Adequacy of References to Related Statutes, Rules and Forms

The material created in s. Phar 19.03 (2) (a) makes reference to “s. 19.02 (2)”, but it is not clear how the material in s. Phar 19.02 (2) is a requirement that could be completed for reinstatement. Section Phar 19.02 (2) simply lists an act that may not be performed by a pharmacy technician. Is this the correct cross-reference? Additionally, the cross-reference in sub. (2) (a) should include the identifier “Phar”.

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In s. Phar 1.02 (1) (Note), the comma that appears in the current text after the street address and before the city name should be shown.

b. In s. Phar 5.07 (title), the word “Technicians” should not be capitalized. [s. 1.10 (2) (b) 2., Manual.]

c. The word “Pharmacy” should not be capitalized within the definition of “Uncredentialed Pharmacy staff” in s. Phar 7.60 (3), or as used in s. Phar 7.62 (title).

d. In s. Phar 7.14 (title), only the initial word should be capitalized.

e. In ch. Phar 19, review the section titles and revise the format so that only the first word of each section title is capitalized.

f. In s. Phar 19.01 (2) (b), the word “Department” should not be capitalized. Also, “department” is not a defined term in ch. Phar 1 or in proposed ch. Phar 19. The term could be spelled out, but as it is used in two other locations in ch. Phar 19, it may be preferable to define the term with the definitions in ch. Phar 1.

**PHARMACY EXAMINING BOARD
2024 Meeting Dates**

Meeting Date		Start time	Agenda item deadline
Thursday, January 18, 2024	Virtual	11:00 AM	1/5/2024
Thursday, February 29, 2024	Virtual	11:00 AM	2/19/2024
Thursday, April 25, 2024	in person	11:00 AM	4/15/2024
Thursday, June 20, 2024	Virtual	11:00 AM	6/10/2024
Thursday, August 29, 2024	Virtual	11:00 AM	8/19/2024
Thursday, October 24, 2024	in person	11:00 AM	10/14/2024
Thursday, December 5, 2024	Virtual	11:00 AM	11/22/2024

**PHARMACY RULES COMMITTEE
2024 Meeting Dates**

Meeting Date		Start time	Agenda item deadline
Thursday, January 18, 2024	Virtual	9:00 AM	1/5/2024
Thursday, February 29, 2024	Virtual	9:00 AM	2/19/2024
Thursday, April 25, 2024	in person	9:00 AM	4/15/2024
Thursday, June 20, 2024	Virtual	9:00 AM	6/10/2024
Thursday, August 29, 2024	Virtual	9:00 AM	8/19/2024
Thursday, October 24, 2024	in person	9:00 AM	10/14/2024
Thursday, December 5, 2024	Virtual	9:00 AM	11/22/2024

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

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brenda Taylor, Board Services Supervisor		2) Date when request submitted: 12/14/2023	
3) Name of Board, Committee, Council, Sections: All Boards			
4) Meeting Date: First Meeting of 2024	5) Attachments: <input checked="" type="checkbox"/> Yes	6) How should the item be titled on the agenda page? Annual Policy Review	
7) Place Item in: <input checked="" type="checkbox"/> Open Session	8) Is an appearance before the Board being scheduled? <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if applicable: N/A	
10) Describe the issue and action that should be addressed: Board SharePoint Site: https://dsps.boards.wisconsin.gov/			
<p>Please be advised of the following Policy Items:</p> <ol style="list-style-type: none"> 1. In-Person Meeting Policy: Depending on the frequency of Board meetings, a Board may be allowed a certain number of in-person meetings. <ul style="list-style-type: none"> • 4-5 Meetings per year = 1 in-person opportunity • 6-8 Meetings per year = 2 in-person opportunities • 12 Meetings per year = 4 in-person opportunities 2. Attendance/Quorum: Thank you for your service and commitment to meeting attendance. If you cannot attend a meeting or have scheduling conflicts impacting your attendance, please let us know as soon as possible. Timely notification is appreciated as a quorum is required for Boards, Sections, and Councils to meet pursuant to Open Meetings Law. 3. Walking Quorum: Board/Section/Council members must not collectively discuss the body's business outside a properly noticed meeting. Should several members of a body do so, the members could be violating the open meetings law. 4. Mandatory Training: All Board Members must complete Public Records and Ethics Training, annually. Register to set up an account in the Cornerstone LearnCenter online portal or Log in to an existing account. 5. Agenda Deadlines: Please communicate agenda topics to your Executive Director before the agenda submission deadline at 12:00 pm, 8 business days prior to a meeting. (Attachment: Timeline of a Meeting) 6. Per Diem and Reimbursement Claims: Please submit all Per Diem and Reimbursement claims to DSPTS within 30 days of the close of each month in which expenses are incurred. (Attachment: Per Diem Example) 7. Lodging Accommodations/Hotel Cancellation Policy: Lodging accommodations are available to eligible members. Standard eligibility: the member must leave home before 6:00 am to attend a meeting by the scheduled start time. <ol style="list-style-type: none"> a. If a member cannot attend a meeting it is their responsibility to cancel their reservation within the applicable cancellation timeframe. b. If a meeting is changed to occur remotely, is canceled, or rescheduled, DSPTS staff will cancel or modify reservations as appropriate. 8. Inclement Weather Policy: In the event of inclement weather, the DSPTS may change a meeting from an in-person venue to hosted as virtual/teleconference only. 			
11)		Authorization	
<i>Brenda Taylor</i>		<i>12/14/2023</i>	
<p>Directions for including supporting documents:</p> <ol style="list-style-type: none"> 1. This form should be saved with any other documents submitted to the Agenda Items folders. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director 			

Timeline of a Meeting

8 business days prior to the meeting: All agenda materials are due to the Department by 12:00 pm, 8 business days prior to the meeting date.

7 business days prior to the meeting: The draft agenda page is due to the Executive Director. The Executive Director transmits to the Chair for review and approval.

5 business days prior to the meeting: The approved agenda is returned to the Board Administration Specialist for agenda packet production and compilation.

4 business days prior to the meeting: Agenda packets are posted on the DSPS Board SharePoint site and on the Department website.

Agenda Item Examples:

- Approval of the Agenda and previous meeting Minutes
- Open Session Items
 - Public Hearings (relating to Administrative Rules)
 - Administrative Matters
 - Legislation and Policy Matters
 - Administrative Rules Matters
 - Credentialing Matters
 - Education and Exam Issues
 - Public Agenda Requests
 - Current Issues Affecting the Profession
 - Public Comments
- Closed Session items
 - Deliberations on Proposed Disciplinary Actions
 - Stipulations
 - Administrative Warnings
 - Case Closings
 - Monitoring Matters
 - Professional Assistance Procedure (PAP) Issues
 - Proposed Final Decisions and Orders
 - Orders Fixing Costs/Matters Relating to Costs
 - Credentialing Matters
 - Education and Exam Issues

Thursday of the Week Prior to the Meeting: Agendas are published for public notice on the Public Notices and Meeting Minutes website: publicmeetings.wi.gov.

1 business day after the Meeting: "Action" lists are distributed by staff detailing board actions on closed session business.

5 business days after the Meeting: "To Do" lists are distributed to staff to ensure that board decisions are acted on and/or implemented within the appropriate divisions in the Department. Minutes approved by the board are published on the the Public Notices and Meeting Minutes website: publicmeetings.wi.gov.

Department of Safety and Professional Services

PER DIEM REPORT

INSTRUCTIONS: Claimant records board-related activities by entering the date of an activity, the duration of time spent in that activity, the relevant purpose code (see purpose code descriptions below), where the activity is conducted, and the type of activity performed. Only one (1) \$25.00 per diem payment can be issued on any given calendar day.

Purpose Codes:

- A. Official meetings including video/teleconference calls** (automatic day of per diem): i.e., board, committee, board training or screening panels; **Hearings**, i.e., Senate Confirmation, legislative, disciplinary or informal settlement conferences; **Examinations and Test Development Sessions**, i.e., test administration, test review or analysis events, national testing events, tour of test facilities, etc.)
- B. Other** (One (1) per diem will be issued for every five (5) hours spent in category B, per calendar month): i.e., review of disciplinary cases, consultation on cases, review of meeting materials, board liaison work e.g., contacts regarding Monitoring, Professional Assistance Procedure, Credentialing, Education and Examinations

NAME OF EXAMINING BOARD OR COUNCIL EXAMPLE EXAMINING BOARD			BOARD OR COUNCIL MEMBER'S NAME MARY SUNSHINE	
Activity Date MM/DD/YY	Duration of Activity Hours/Minutes	Purpose Code A or B	Where Performed City/Location (Home, Work, DSPS)	Activity Describe Activity Performed (see purpose codes)
12/2/20	2 hrs	B	Pleasant Prairie/Home	Review of screening panel materials
12/3/20	2 hr / 30 mins	B	Pleasant Prairie/Home	Review of screening panel materials
12/10/20	1 hr	A	Pleasant Prairie/Home	Screening Panel Meeting - Teleconference
12/12/20	1 hr / 30 mins	B	Pleasant Prairie/Home	Case consultation
12/13/20	1 hr	B	Pleasant Prairie/Home	Liaison: Application Review
12/16/20	6 hrs	A	Madison/DSPS	Board Member Training
				<p>The 5-hour rule applies to "B" code activities. Add the 'B' codes within the calendar month and then divide by five (5) hours to calculate your per diem payment. In this case the total is seven (7) hours which equals one (1) day of per diem.</p> <p>Each 'A' code is an automatic day of per diem regardless of time spent in that activity. Ms. Sunshine is eligible for two (2) additional days of payment.</p> <p>Department staff completes the fields titled "Total Days Claimed".</p>
CLAIMANT'S CERTIFICATION			Comments:	
The undersigned certifies, in accordance with § 16.53, Wis. Stats., that this account for per diem, is just and correct; and that this claim is for service necessarily incurred in the performance of duties required by the State, as authorized by law.				
<i>Mary Sunshine</i>		1/4/2021		
Claimant's Signature	Date	Supervisor	Date	

EMPL ID: 100012345-0

To be completed by Department staff: TOTAL DAYS CLAIMED: 3 @ \$25.00 = 75.00

PHARMACY EXAMINING BOARD

OFFICERS as of 12/31/2023	
Chairperson	John Weitekamp
Vice Chairperson	Tiffany O’Hagan
Secretary	Susan Kleppin

LIAISON APPOINTMENTS as of 12/31/2023	
Credentialing Liaison(s)	Anthony Peterangelo, Tiffany O’Hagan, Christa Wilson
Education and Examinations Liaison(s)	Susan Kleppin <i>Alternate:</i> John Weitekamp
Monitoring Liaison(s)	Michael Walsh, Christa Wilson <i>Alternate:</i> Anthony Peterangelo
Professional Assistance Procedure (PAP) Liaison(s)	Anthony Peterangelo <i>Alternate:</i> Susan Kleppin
Travel Authorization Liaison(s)	John Weitekamp <i>Alternate:</i> Tiffany O’Hagan
Legislative Liaison(s)	Anthony Peterangelo, Tiffany O’Hagan, John Weitekamp
Pilot Program Liaison(s)	Tiffany O’Hagan, Anthony Peterangelo
Newsletter Liaison(s)	Christa Wilson <i>Alternate:</i> John Weitekamp
Website Liaison(s)	Michael Walsh
Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g)	John Weitekamp
PHARM Rep to SCAODA	Susan Kleppin <i>Alternate:</i> John Weitekamp
Variance Liaison(s)	Tiffany O’Hagan <i>Alternate:</i> Anthony Peterangelo

SCREENING PANEL APPOINTMENTS	
Screening Panel	John Weitekamp, Tiffany O'Hagan, Michael Walsh <i>Alternate: Anthony Peterangelo</i>
COMMITTEE MEMBER APPOINTMENTS	
Pharmacy Rules Committee	Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp



State of Wisconsin

DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

CORRESPONDENCE / MEMORANDUM

DATE: January 9, 2024

TO: Board, Council, and Committee Members

FROM: Legal Counsel

SUBJECT: Liaison Definitions and Delegations Explanations

Overall Purpose of Liaison Appointments

Each Board/Section (Board) has inherent authority that is established in our Wisconsin Statutes. This authority may change from Board to Board. For further information on your Board's authority review Wis. Stat. ch. 15. Generally, each Board has authority to grant credentials, discipline credential holders, and set standards for education and examinations. Additionally, Liaisons assist with the operations of the Boards purpose by weighing in on legislative matters, traveling to national conferences, or communicating with stakeholders.

The Department asks that each year the Boards make liaison appointments to assist the Board and Department to accomplish these tasks in an efficient manner. Your practical knowledge and experience, as an appointed member of a professional board, are essential in making determinations regularly. The Liaison positions below assist the Department to complete operations between Board meetings. In most cases, Liaisons can make decisions for the full Board in their designated area. These are determined through the delegation process. However, a Liaison may also decide to send the delegated issue to the full Board for consideration as appropriate. Delegations assist the Board in defining the roles and authorities of each Liaison.

Liaison Definitions

Credentialing Liaison: The Credentialing Liaison is empowered by the Board to review and make determinations regarding certain applications for credentials. The Credentialing Liaison may be called on by Department staff to answer questions that pertain to qualifications for licensure, which may include whether a particular degree is suitable for the application requirements, whether an applicant's specific work experience satisfies the requirements in statute or rule for licensure, or whether an applicant's criminal or disciplinary history is substantially related to the practice of the profession in such a way that granting the applicant a credential would create a risk of harm to the public. Questions will likely be sent by Department

staff to the Credentialing Liaison via email and may include application materials. The Credentialing Liaison serves a very important role in the credentialing process.

Monitoring Liaison: The Monitoring Liaison is empowered by the Board to make decisions on any credential that is limited either through a disciplinary order or initial licensure. The Department Monitors will send requests from credential holders to the Monitoring Liaison. These requests vary wildly. A common request could be to remove a limitation that has been placed on a credential or to petition for full licensure. The Monitoring Liaison can review these requests and make decisions on behalf of the Board. The Board has the authority to grant decision making latitude to their liaison to any degree. The specific monitoring delegations are found in the Monitoring Document attached to the agenda. If the Monitoring Liaison has a question on a request, it is advisable for the Liaison to consult further with Department staff or bring the matter to the full Board for consideration.

Professional Assistance Procedure (PAP) Liaison: PAP is a voluntary program open to credential holders with substance abuse issues who wish to seek help by being held accountable through treatment and monitoring by the Department and Board. As part of PAP, the credential holder enters into an agreement with the Department to undergo testing, counseling, or other rehabilitation. The PAP Liaison's role includes responding to credential holders' requests for modifications and terminations of provisions of the agreement. Similar to the Monitoring Liaison, the Department Monitors will send requests from credential holders to the PAP Liaison for further review.

Education and Examination Liaison: Some Boards are required by statute or rule to approve qualifying education and examinations. The Education and Examination Liaison provides guidance to Department staff to exercise authority of the Board to approve or decline examinations and educational programs. This determination requires a level of professional expertise and should be performed by a professional member of the Board. For some Boards, the Education and Examination Liaison will also be tasked with approving continuing education programs and courses.

Legislative Liaison: The Legislative Liaison is permitted to act and speak on the Board's behalf regarding pending and enacted legislation or actions being considered by the legislature outside of Board meetings. The Legislative Liaison is not the Board's designated lobbyist and should exercise their delegated authority carefully.

Travel Authorization Liaison: The Travel Authorization Liaison is authorized to approve a Board member to travel to events and speak or act on the Board's behalf between Board meetings. The Travel Authorization Liaison is called upon to make decisions when sufficient notice was not received, and the full Board could not determine a representative to travel. The Travel Authorization Liaison is tasked with making determinations if the Board appointed representative is not able to attend or if the Board becomes authorized to send additional members. As scholarship and funding streams can be unpredictable.

Communication Liaison: The Communication Liaison responds on behalf of the Board when questions arise that require a response from the Board. The Communication Liaison works with

the Department to cultivate an appropriate response. The Communication Liaison can be responsible for all types of communication on behalf of the Board. However, the Board can appoint a separate **Website Liaison** to work with DSPS staff to make changes and ensure the Board webpage contains updated and accurate information. Additionally, for the Boards that are required by statute to produce a newsletter or digest. The Board can appoint a separate **Newsletter/Digest Liaison** to assemble and approve content for those communications.

Screening Panel Members: The duties of the Screening panel are to review incoming complaints against credential holders and determine which complaints should be opened for investigation and which complaints should be closed without further action. The complexity and amount of work in this role depends substantially on your particular Board. As a member of the Screening panel you are asked to apply your professional expertise to determine if a complaint alleges unprofessional conduct.

Delegations Explanations

Credentialing Delegations

The overall purpose of credentialing delegations is to allow the credentialing process to proceed as efficiently and effectively as possible.

Delegation of Authority to Credentialing Liaison (Generic)

MOTION EXAMPLE: to delegate authority to the Credentialing Liaison(s) to serve as a liaison between the Department and the Board and to act on behalf of the Board in regard to credentialing applications or questions presented to them, including the signing of documents related to applications.

PURPOSE: To permit one representative of the Board to assist Department staff with credentialing applications and eliminate the need for the entire Board to convene to consider credential application content or questions. Additionally, it is most efficient to have the designated liaison who has assisted with the credentialing process to be able to effectuate decisions which require a signature.

Delegation of Authority to DSPS When Credentialing Criteria is Met

MOTION EXAMPLE: to delegate credentialing authority to the Department to act upon applications that meet all credentialing statutory and regulatory requirements without Board or Board liaison review.

PURPOSE: To permit Department staff to efficiently issue credentials and eliminate the need for Board/Section/Liaison review when all credentialing legal requirements are met in an application.

Delegation of Authority for Predetermination Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to make decisions regarding predetermination applications pursuant to Wis. Stat. § 111.335(4)(f).

PURPOSE: In general, the Wisconsin Fair Employment Act (codified in Wis. Stat. Ch. 111) prohibits licensing agencies from discriminating against applicants because of their arrest and/or conviction record. However, there are exceptions which permit denial of a license in certain circumstances. Individuals who do not possess a license have a legal right to apply for a determination of whether they are disqualified from obtaining a license due to their conviction record. This process is called “Predetermination”. Predeterminations must be completed within 30 days. This delegation allows Department Attorneys to conduct predetermination reviews and efficiently make these legal determinations without need for Board/Section/Liaison review.

Delegation of Authority for Conviction Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to review and approve applications with convictions which are not substantially related to the practice.

PURPOSE: As used here, “substantially related” is a legal standard that is used in the Wisconsin Fair Employment Act. The concept of what is “substantially related” is informed by case law. This delegation permits Department Attorneys to independently conduct conviction reviews and efficiently approve applications if convictions are not substantially related to the practice of the profession. Applications that contain conviction records that may be substantially related to the practice of a profession will still be submitted to the Credentialing Liaison for input.

Delegation to DSPS When Applicant’s History Has Been Previously Reviewed

MOTION EXAMPLE: to delegate authority to Department staff to approve applications where Applicant’s prior discipline has been approved for a previous credential and there is no new discipline.

PURPOSE: Some Boards offer progressive levels of credentials. This delegation eliminates the need for a re-review of discipline that has already been considered and approved by the Board/Section/Liaison for a lower-level credential.

Delegation to DSPS When Applicant’s Conviction History Has Been Previously Reviewed

MOTION EXAMPLE: to delegate authority to Department staff to approve applications where criminal background checks have been approved for a previous credential and there is no new conviction record.

PURPOSE: Some Boards offer progressive levels of credentials. This delegation eliminates the need for a re-review of conviction history that has already been reviewed and approved for a lower-level credential.

Delegation of Authority for Reciprocity Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to review and approve reciprocity applications in which the out of state license requirements meet Wisconsin license requirements. (specific legal standards are referenced in the motion depending on credential/profession type).

PURPOSE: Applications via reciprocity or endorsement require comparison of Wisconsin licensing requirements to the licensing requirements of another jurisdiction. These reviews consider the legal standard for reciprocity, which varies by profession, as well as the specified legal requirements to obtain licensure in the profession. This delegation permits Department Attorneys to independently conduct reciprocity reviews and efficiently approve applications if legal standards and requirements are met for licensure. Applications for which reciprocity may not be available will still be submitted to the Credentialing Liaison for input.

Delegation of Authority for Military Reciprocity Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to review and approve military reciprocity applications in which the individual meets the requirements of Wis. Stat. § 440.09.

PURPOSE: The law permits service members, former service members, and their spouses to be licensed if they hold licensure in other jurisdictions that qualify them to perform acts authorized by the credential they are seeking in Wisconsin. This is a shortened path to licensure that does not require meeting the specific requirements/standards for licensure/reciprocity in a profession. By law, the Department/Board must expedite the issuance of a reciprocal license via military reciprocity. This delegation permits Department Attorneys to independently conduct military reciprocity reviews and efficiently approve applications if legal standards and requirements are met for licensure. Applications for which reciprocity may not be available will still be submitted to the Credentialing Liaison for input.

Delegation of Authority for Application Denial Reviews

MOTION EXAMPLE: to delegate authority to the Department's Attorney Supervisors to serve as the Board designee for purposes of reviewing and acting on requests for hearing as a result of a denial of a credential.

PURPOSE: When an application is denied, the applicant has a legal right to appeal the denial determination. Applicants must meet a specified legal standard in order to have an appeal granted. Additionally, Wisconsin law sets specific time frames for appeal decisions. This delegation permits Department Attorney Supervisors to independently review and efficiently act on requests for hearing as a result of a denial of a credential.

Delegation to Department Attorneys to Approve Duplicate Legal Issue

MOTION EXAMPLE: to delegate authority to Department Attorneys to approve a legal matter in connection with a renewal application when that same/similar matter was already addressed

by the Board and there are no new legal issues for that credential holder. Motion carried unanimously.

PURPOSE: The intent of this delegation is to be able to approve prior discipline by the Board for the renewal applicant. This delegation eliminates the need for a re-review of discipline that has already been considered and approved by the Board/Section/Liaison.

Monitoring Delegations

The overall purpose of monitoring delegations is to be able to enforce the Boards orders and limited licenses as efficiently and effectively as possible. Monitoring delegations have two categories: delegations to the monitoring liaison and delegations to the Department Monitor.

Delegation of Authority to Department Monitor

MOTION EXAMPLE: to delegate authority to the Department Monitor

- a. to grant full reinstatement of licensure if education is the only limitation and credential holder has submitted the required proof of course completion.
- b. to suspend the credential if the credential holder has not completed Board ordered education, paid costs, paid forfeitures, within the time specified by the Board Order.
- c. to lift a suspension when compliance with education and costs provisions have been met.

PURPOSE: These delegations allow for the Department Monitor to automatically act on requests when certain criteria are met or not met without needing to burden the Board Monitoring Liaison. The Board can set their own criteria for what actions they would like to be handled by the Department, the Monitoring Liaison and the full Board.

Delegation of Authority to Monitoring Liaison

MOTION EXAMPLE: to delegate authority to the Monitoring Liaison to approve or deny all requests received by the credential holder.

PURPOSE: These delegations allow the Board to set criteria for what decisions can be made by the Board member(s) serving as the Monitoring Liaison and what matters should be decided by the full Board. The Board has the authority to set specific criteria or to permit the liaison to make all determinations at their discretion.

Education and Exam Delegations

MOTION EXAMPLE: to delegate authority to the Education and Examination Liaison(s) to address all issues related to continuing education and examinations. Motion carried unanimously. (Differs by Board)

PURPOSE: Some Boards are responsible for approving qualifying educational programs or continuing education courses. A delegation is executed in order for a Board member to make

these determinations on behalf of the Boards and with assistance of the Department. Additionally, some Boards review examinations and individual scores to qualify for a credential.

Miscellaneous Delegations

Document Signature

MOTION EXAMPLE: to delegate authority to the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to sign documents on behalf of the Board in order to carry out its duties. Motion carried unanimously.

MOTION EXAMPLE: in order to carry out duties of the Board, the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) has the ability to delegate signature authority for purposes of facilitating the completion of assignments during or between meetings. The members of the Board hereby delegate to the Executive Director, Board Counsel or DPD Division Administrator, the authority to sign on behalf of a Board member as necessary. Motion carried unanimously.

PURPOSE: In order to take the action approved at Board meetings, the Department may need to draft correspondence and/or Orders after the meetings have adjourned. These actions then need to be signed by a Board Member. This interaction usually takes place over email and a Board member can authorize the use of his/her signature that is kept on file.

Urgent Matters

MOTION EXAMPLE: in order to facilitate the completion of urgent matters between meetings, the Board delegates its authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving Board member in that succession), to appoint liaisons to the Department to act in urgent matters. Motion carried unanimously.

PURPOSE: Allows for quick responses to urgent matters that may need Board approval or for which the Department requires guidance from the Board.

Delegation to Chief Legal Counsel

Due to Loss of Quorum

MOTION EXAMPLE: to delegate the review and authority to act on disciplinary cases to the Department's Chief Legal Counsel due to lack of/loss of quorum after two consecutive meetings. Motion carried unanimously.

PURPOSE: Sometimes Boards can struggle to meet quorum necessary to conduct business. This happens for a multitude of reasons but this delegation allows for the Boards to have disciplinary cases decided by Chief Legal Counsel if the Board fails to meet quorum for two consecutive meetings.

Stipulated Resolutions

MOTION EXAMPLE: to delegate to the Department's Chief Legal Counsel (CLC) the authority to act on behalf of the Board concerning stipulated resolutions providing for a surrender, suspension, or revocation of a credential, where the underlying merits involve serious and dangerous behavior, and where the signed stipulation is received between Board meetings. The Board further requests that CLC only act on such matters when the best interests of the Board, Department and the Public are best served by acting upon the stipulated resolution at the time the signed stipulation is received versus waiting for the next Board meeting. Motion carried unanimously.

PURPOSE: For matters of public safety, it may be necessary to take immediate action on a stipulated agreement rather than allowing a credential holder to continue practicing unencumbered until the next scheduled meeting. This delegation allows CLC to act on behalf of the Board when there is a stipulated agreement. A stipulated agreement is an agreement to which all relevant parties have consented to the terms.

Voluntary Surrenders

MOTION: to delegate authority to the assigned case advisor to accept or refuse a request for voluntary surrender pursuant to Wis. Stat. § 440.19 for a credential holder who has a pending complaint or disciplinary matter.

MOTION: to delegate authority to the Department to accept the voluntary surrender of a credential when there is no pending complaint or disciplinary matter with the Department pursuant to Wis. Stat. § 440.19.

PURPOSE: Credential holders can ask the Boards to surrender their credentials at any time. These delegations are in place for the different situations that arise from those requests. If a credential holder is seeking to surrender their credential because they wish to leave the profession that can be processed with this delegation by the Department if they have no pending disciplinary complaints. If the credential holder wishes to surrender while they have a pending disciplinary complaint that request is reviewed by the individual Board member assigned to the case.

DLSC Pre-screening

MOTION EXAMPLE: to delegate pre-screening decision making authority to the DSPS screening attorney for opening cases where the credential holder has failed to respond to allegations contained in the complaint when requested by intake (Case will be opened on failure to respond and the merits of the complaint).

PURPOSE: Pre-Screening delegations exist so the Board can define specific parameters where the Department can review disciplinary complaints and open those cases if they meet certain criteria. Boards also have the authority to set certain criteria that would allow the Department to review and close a case if the criteria is met.

Roles and Authorities Delegated for Monitoring

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

Authorities Delegated to the Monitoring Liaison

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

1. Grant a temporary reduction in random drug screen frequency upon Respondent’s request if he/she is unemployed and is otherwise compliant with Board/Section order. The temporary reduction will be in effect until Respondent secures employment in the profession. The Department Monitor (“Monitor”) will draft an order and sign on behalf of the Liaison.
2. Grant a stay of suspension if Respondent is eligible per the Board/Section order. The Monitor will draft an order and sign on behalf of the Liaison.
3. Remove the stay of suspension if there are repeated violations or a substantial violation of the Board/Section order. In conjunction with removal of any stay of suspension, the Liaison may prohibit Respondent from seeking reinstatement of the stay for a specified period of time. The Monitor will draft an order and sign on behalf of the Liaison.
4. Grant or deny approval when Respondent proposes continuing/disciplinary/remedial education courses, treatment providers, mentors, supervisors, change of employment, etc. unless the order specifically requires full-Board/Section approval.
5. Grant full reinstatement of licensure if Respondent has fully complied with all terms of the order without deviation. The Monitor will draft an order and obtain written authorization from the Liaison to sign on their behalf.
6. Grant or deny a request to appear before the Board/Section in closed session.
7. The Liaison may determine whether Respondent’s petition is eligible for consideration by the full Board/Section.
8. Accept Respondent’s written request to surrender credential. If accepted by the Liaison, Monitor will consult with Board Counsel to determine if a stipulation is necessary. If a stipulation is not necessary, Monitor will draft an order and sign on behalf of the Liaison. If denied by the Liaison, the request to surrender credential will go to the full Board for review. (Except PHM, MED)

9. Grant Respondent's petition for a reduction in drug screens per the standard schedule, below. If approved, Monitor will draft an order and sign on behalf of the Liaison. Orders that do not start at 49 screens will still follow the same standard schedule.
 - a. Initial: 49 screens (including 1 hair test, if required by original order)
 - b. 1st Reduction: 36 screens (plus 1 hair test, if required by original order)
 - c. 2nd Reduction: 28 screens plus 1 hair test
 - d. 3rd Reduction: 14 screens plus 1 hair test
10. (*Dentistry only*) Ability to approve or deny all requests from a respondent.
11. The Liaison may approve or deny Respondent's request to be excused from drug and alcohol testing for work, travel, etc. (Applies only to these Boards: Dietitians, Massage/Bodywork Therapy Board, DEN, PAB, CHI, MED, RAD)
12. **The Liaison may have full authority to approve or deny a request from a Respondent that otherwise would require the approval of the full Board if the request cannot be heard and voted on due to lack of/loss of quorum.**
13. **The Liaison may have full authority to terminate any treatment ONLY upon written request from Respondent and written recommendation from Respondents treater.**

Authorities Delegated to the Department Monitor

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

1. Grant full reinstatement of licensure if education is the sole condition of the limitation and Respondent has submitted the required proof of completion for approved courses.
2. Suspend the license if Respondent has not completed Board/Section-ordered education and/or paid costs and forfeitures within the time specified by the Board/Section order. The Monitor may remove the suspension and issue an order when proof of completion and/or payment have been received.
3. Suspend the license (or remove stay of suspension) if Respondent fails to enroll and participate in an Approved Program for drug and alcohol testing within 30 days of the order, or if Respondent ceases participation in the Approved Program without Board approval. This delegated authority only pertains to respondents who must comply with drug and/or alcohol testing requirements.
4. Grant or deny approval when Respondent proposes treatment providers [, mentors, supervisors, etc.] unless the Order specifically requires full-Board/Section or Board designee approval. (Except for MED)
5. Grant a maximum of one 90-day extension, if warranted and requested in writing by Respondent, to complete Board/Section-ordered continuing/disciplinary/remedial education.
6. Grant a maximum of one 90-day extension or payment plan for proceeding costs and/or forfeitures if warranted and requested in writing by Respondent.
7. Grant a maximum of one 90-day extension, if warranted and requested in writing by Respondent, to complete a Board/Section-ordered evaluation or exam.

Authorities Delegated to Board Legal Counsel

Board Legal Counsel may take the following actions on behalf of the Board/Section:

1. Sign Monitoring orders that result from Board/Section meetings on behalf of the Board/Section Chair.
-

Updated 03/13/2023

2022 Roles & Authorities

**PHARMACY EXAMINING BOARD
2023 DELEGATION of AUTHORITIES**

Document Signature Delegations

MOTION: Michael Walsh moved, seconded by Tiffany O’Hagan, to delegate authority to the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to sign documents on behalf of the Board in order to carry out its duties. Motion carried unanimously.

MOTION: Tiffany O’Hagan moved, seconded by Michael Walsh, in order to carry out duties of the Board, the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) has the ability to delegate signature authority for purposes of facilitating the completion of assignments during or between meetings. The members of the Board hereby delegate to the Executive Director or DPD Division Administrator, the authority to sign on behalf of a board member as necessary. Motion carried unanimously.

Delegated Authority for Urgent Matters

MOTION: Anthony Peterangelo moved, seconded by Tiffany O’Hagan, that in order to facilitate the completion of urgent matters between meetings, the Board delegates its authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession), to appoint liaisons to the Department to act in urgent matters. Motion carried unanimously.

Delegation to Chief Legal Counsel Due to Loss of Quorum

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to delegate the review and authority to act on disciplinary cases to the Department’s Chief Legal Counsel due to lack of/loss of quorum after two consecutive meetings. Motion carried unanimously.

Delegation to Chief Legal Counsel for Stipulated Resolutions

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to delegate to DSPS Chief Legal Counsel the authority to act on behalf of the Board concerning stipulated resolutions providing for a surrender, suspension, or revocation of a credential, where the underlying merits involve serious and dangerous behavior, and where the signed stipulation is received between Board meetings. The Board further requests that CLC only act on such matters when the best interests of the Board, Department and the Public are best served by acting upon the stipulated resolution at the time the signed stipulation is received versus waiting for the next Board meeting. Motion carried unanimously.

Monitoring Delegations

Delegation of Authorities for Monitoring

MOTION: Michael Walsh moved, seconded by Christa Wilson, to adopt the “Roles and Authorities Delegated for Monitoring” document as presented in the January 19, 2023 agenda materials on pages 22-24. Motion carried unanimously.

Delegation of Authorities for Legal Counsel to Sign Monitoring Orders

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to delegate to Legal Counsel the authority to sign Monitoring orders that result from Board meetings on behalf of the Board Chairperson. Motion carried unanimously.

Credentialing Authority Delegations

Delegation of Authority to Credentialing Liaison

MOTION: Michael Walsh moved, seconded by Tiffany O’Hagan, to delegate authority to the Credentialing Liaison(s) to serve as a liaison between the Department and the Board and to act on behalf of the Board in regard to credentialing applications or questions presented to them, including the signing of documents related to applications. Motion carried unanimously.

Delegation of Authority to DSPS When Credentialing Criteria is Met

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to delegate credentialing authority to the Department to act upon applications that meet all credentialing statutory and regulatory requirements without Board or Board liaison review. Motion carried unanimously.

Delegation of Authority for Predetermination Reviews

MOTION: Michael Walsh moved, seconded by Christa Wilson, to delegate authority to the Department Attorneys to make decisions regarding predetermination applications pursuant to Wis. Stat. § 111.335(4)(f). Motion carried unanimously.

Delegation of Authority for Conviction Reviews

MOTION: Christa Wilson moved, seconded by Anthony Peterangelo, to delegate authority to Department Attorneys to review and approve applications with municipal/ordinance violations and misdemeanors which are not substantially related to the practice of pharmacy. Motion carried unanimously.

Delegation to DSPS When Applicant’s Discipline History Has Been Previously Reviewed

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to delegate authority to Department staff to approve applications where Applicant's prior discipline has been approved for a previous pharmacy credential and there is no new discipline. Motion carried unanimously.

Delegation to DSPS When Applicant's Conviction History Has Been Previously Reviewed

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to delegate authority to Department staff to approve applications where criminal background checks have been approved for a previous pharmacy credential and there is no new conviction record. Motion carried unanimously.

Delegation of Authority for Reciprocity/Endorsement Reviews

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to delegate authority to the Department Attorneys to review and approve reciprocity/endorsement applications in which the applicant met requirements comparable to those that existed in this state at the time the person became licensed in the other state. Motion carried unanimously.

Delegation of Authority for Military Reciprocity Reviews

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to delegate authority to the Department Attorneys to review and approve military reciprocity applications in which the individual meets the requirements of Wis. Stat. § 440.09. Motion carried unanimously.

Delegated Authority for Application Denial Reviews

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to delegate authority to the Department's Attorney Supervisors to serve as the Board's designee for purposes of reviewing and acting on requests for hearing as a result of a denial of a credential. Motion carried unanimously.

Pre-Screening Delegation to Open Cases

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to delegate pre-screening decision making authority to the Department screening attorney for opening cases as outlined below:

1. OWIs of 3 or more that occurred in the last 5 years.
2. Reciprocal discipline cases.
3. Impairment and/or diversion at work that includes a positive drug/alcohol test or admission by respondent.
4. Conviction of a misdemeanor or felony that the attorney believes is substantially related and is not otherwise excluded from consideration via Wis. Stat. ch. 111.

5. No response from the respondent after intake requested a response (case would be opened for the failure to respond issue as well as the merits).

Motion carried unanimously.

Pre-Screening Delegation to Close Cases

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to delegate pre-screening decision making authority to the Department screening attorney for closing cases as outlined below:

1. One OWI that is non-work related and if AODA assessment completed, assessment does not indicate dependency.
2. Complaints that even if allegations are true, do not amount to a violation of law or rules.
3. To close at prescreening complaints that the Board has already reviewed and acted upon that are the result of multiple-state discipline based on original violations.

Motion carried unanimously.

Voluntary Surrenders

MOTION: Michael Walsh moved, seconded by Christa Wilson, to delegate authority to the assigned case advisor to accept or refuse a request for voluntary surrender pursuant to Wis. Stat. § 440.19 for a credential holder who has a pending complaint or disciplinary matter. Motion carried unanimously.

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to delegate authority to the Department to accept the voluntary surrender of a credential when there is no pending complaint or disciplinary matter with the Department pursuant to Wis. Stat. § 440.19. Motion carried unanimously.

Education and Examination Liaison(s) Delegation

MOTION: Christa Wilson moved, seconded by Michael Walsh, to delegate authority to the Education and Examination Liaison(s) to address all issues related to continuing education, and examinations. Motion carried unanimously.

Pilot Program Liaison(s) Delegation

MOTION: Christa Wilson moved, seconded by Anthony Peterangelo, to delegate authority to the Pilot Program Liaison(s) to address all issues related to pilot program matters. Motion carried unanimously.

Authorization for DSPS to Provide Board Member Contact Information to National Regulatory Related Bodies

MOTION: Michael Walsh moved, seconded by Christa Wilson, to authorize the Department staff to provide national regulatory related bodies with all board member contact information that the Department retains on file. Motion carried unanimously.

Optional Renewal Notice Insert Delegation

MOTION: Christa Wilson moved, seconded by Michael Walsh, to designate the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to provide a brief statement or link relating to board-related business within the license renewal notice at the Board's or Board designee's request. Motion carried unanimously.

Rules Committee Delegation

MOTION: Susan Kleppin moved, seconded by Christa Wilson, to grant the Rules Committee the ability to address all rulemaking as related to drafting and making recommendations to the full Board. Motion carried unanimously.

Committee Membership Delegation

MOTION: Tiffany O'Hagan moved, seconded by Christa Wilson, that in order to facilitate the completion of its duties between meetings, the Board delegates authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to appoint members to its committees between meetings as necessary. Motion carried unanimously.

Legislative Liaison Delegation

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to delegate authority to the Legislative Liaisons to speak on behalf of the Board regarding legislative matters. Motion carried unanimously.

Travel Authorization Liaison Delegation

MOTION: Christa Wilson moved, seconded by Tiffany O'Hagan, to delegate authority to the Travel Authorization Liaison to approve any board member travel to and/or participation in events germane to the board, and to designate representatives from the Board to speak and/or act on the Board's behalf at such events. Motion carried unanimously.

Newsletter Liaison(s) Delegation

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to delegate authority to the newsletter liaison(s) to handle all matters relating to newsletters. Motion carried unanimously.

Website Liaison(s) Delegation

MOTION: Susan Kleppin moved, seconded by Christa Wilson, to authorize to the Website Liaison(s) to act on behalf of the Board in working with Department staff to identify and execute website updates. Motion carried unanimously.

SCAODA Representative Delegation


MOTION: Anthony Peterangelo moved, seconded by Christa Wilson, to authorize the SCAODA representative to vote on behalf of the Board at the State Council on Alcohol and Other Drug Abuse meetings. Motion carried unanimously.

Variance Liaison(s) Delegation

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to delegate to the Variance Liaison(s) the Board's authority to approve, rescind, and modify variances under §450.02(3m). Motion carried unanimously.

**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: 1/05/24 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: 01/18/24	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. Final Rule Draft: Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing 2. Emergency Rule Draft: Phar 8, Relating to Controlled Substances Requirements 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 – Legislative Report, Final Rule Draft, EIA 2. Phar 8 – Emergency Rule Draft 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		01/05/24 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 :
PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE
PHARMACY EXAMINING BOARD : CR 23-054**

I. THE PROPOSED RULE:

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

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

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

The 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.

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

The Pharmacy Examining Board held a public hearing on October 26, 2023. The following people either testified at the hearing, or submitted written comments:

- Richelle Andrae, Government Relations Specialist, Wisconsin Primary Health Care Association (WCHA)
- Xin Rippel, Director of Pharmacy, Family Health Center Pharmacy – Marshfield
- Michael DeBisschop, Pharm.D.
- Danielle Womack, Vice President – Public Affairs, Pharmacy Society of Wisconsin (PSW)

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

- The WCHA expressed their support of the proposed rule project and requested expedited implementation be prioritized by the Board. The WCHA also requested that the Board address an issue with labelling prescriptions from remote dispensing sites. Specifically, whether a separate label is allowed with the remote dispensing site's location listed.

- Xin Rippel provided background information on Family Health Center of Marshfield as it relates to pharmacy services to a rural population. They also requested clarification on the process for registering as a remote dispensing site and how that works with licensure, DEA registration and other regulatory requirements.
- Michael DeBisschop provided suggestions for changes in the following areas of the rule project:
 - Pharmacy graduates should also be included in s. Phar 7.61.
 - Clarify whether pharmacists who supervise a remote dispensing site also have to be located at a pharmacy or if they can be supervising a remote dispensing site from a non-pharmacy location.
 - In s. Phar 7.43 (7) (c), clarify whether the 1500 hour work requirement includes internship or rotation time, or if it only applies to paid work time. Also, clarify the term “pharmacist delegate” with a definition or replace it with a more descriptive term.
- The PSW provided suggestions for changes to ss. Phar 7.43 (6) (a) and (b). They recommended removing the term “supervising pharmacy,” as the term does not accurately describe what is happening with remote dispensing sites.

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

- Phar 7.43 (4) (b) was amended to read “remote dispensing may not occur if a pharmacist is not available remotely. A pharmacist shall provide direct supervision of pharmacist delegates at remote dispensing pharmacies. A pharmacist shall be available to the pharmacist delegate either in person or contact by telecommunication means.”
- Phar 7.43 (6) (intro.) was amended to read: “RESPONSIBILITIES OF MANAGING PHARMACIST. The managing pharmacist responsible for the remote dispensing pharmacist shall do all of the following:”
- Phar 7.43 (b) (b) was repealed.
- Phar 7.43 (7) (d) was created to read: “A pharmacist shall provide direct supervision of pharmacist delegates. A pharmacist shall be available to the pharmacist delegate either in person or contact via telecommunication means.”
- Phar 7.60 and 7.61 were repealed.
- Phar 1.02 (3m) was created to read: “‘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.”

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment: 5c. In s. Phar 6.025 (intro.), consider revising the introductory statements to use the active voice. [s. 1.05 (1) (d), Manual] Also, consider revising the first sentence of the introduction, is it intended that any time a pharmacist remotely supervises a location, that it is a sufficient condition to apply the specific rules for remote dispensing?

Response: The Board has accepted this comment and would like to note that any time a pharmacist remotely supervises a location, the rules for remote dispensing apply.

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

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

DRAFT

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)

PROPOSED 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) (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) repeal Phar 1.02 (9), 7.43 (1), (3); and (4) (d); and amend Phar 7.43 (2), (4) (b), (5) (b), (6) (title), (6) (a), (6) (a) 5, (6) (b), and (7), and 7.62 (1), 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); ~~and 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) 266-6795.

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.

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, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on October 26, 2023, 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 ~~(3m)~~, (10m), and (14m) are 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.

Phar 1.02 (10m) “Pharmacy graduate” means a graduate of a school of pharmacy approved by the ~~pharmacy examining~~ 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 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 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 ~~l~~icensee 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 ~~b~~Board if they are responsible for 5 or more remote dispensing sites. A managing pharmacist ~~may shall~~ not be responsible for more than 10 remote dispensing sites at any given time without approval from the ~~b~~Board.

SECTION 5 Phar 7.43 (1) is repealed.

SECTION 6 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 7 Phar 7.43 (3) is repealed.

SECTION 8. Phar 7.43 (4) (b) is amended to read:

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

SECTION 9. Phar 7.43 (4) (d) is repealed.

SECTION 10. Phar 7.43 (5) (b); ~~(6) (title), (6) (a), (6) (a) 5, and (6) (b); and (7) are~~ 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.

~~(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 11. 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 12. 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 ~~151~~. 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 ~~162~~. 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), ~~s~~Stats., pharmacies shall include remote dispensing sites.

SECTION ~~173~~. 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)

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

Dated _____

Agency _____

Chairperson
Pharmacy Examining Board

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	2. Date September 29, 2023
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) Phar 1, 5, 6, 7, and 8 - Permanent Rule	
4. Subject Remote Dispensing	
5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	6. Chapter 20, Stats. Appropriations Affected s. 20.165 (1) (g)
7. Fiscal Effect of Implementing the Rule <input type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input checked="" type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input checked="" type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget	
8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input checked="" type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0	
10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Policy Problem Addressed by the Rule These rules implement the statute changes from 2021 Wisconsin Act 101. The Board also added a definition of pharmacy graduates, and modified requirements to allow them to practice pharmacy while waiting for their license to be granted.	
12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments. The rule will be posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.	
13. Identify the Local Governmental Units that Participated in the Development of this EIA. None.	
14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred) DSPS estimates a total of \$8,900 in one-time costs and \$2,800 in annual costs for staffing and an indeterminate IT impact to implement the rule. This rule permanently implements the statutory changes from the 2021 Wisconsin Act 101. The estimated one-time staffing need for .1 limited term employees (LTE) is for staff training, forms and sites updates, and developing reference materials to reflect new statutory provisions. The estimated annual staffing need addresses an increase in questions and workload related to processing submitted applications for the department, the applicant, and the call center, as well as necessary board coordination to implement the rule. The one-time and annual estimated costs cannot be absorbed in the currently appropriated agency budget.	
15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefits of implementing this rule are that the Pharmacy Examining Board's sections of the Administrative Code will be aligned with Wisconsin State Statutes.	
16. Long Range Implications of Implementing the Rule	

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

The long range implications of implementing this rule are clear rules for remote dispensing for pharmacies in Wisconsin.

17. Compare With Approaches Being Used by Federal Government

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.

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

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

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

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].

19. Contact Name Nilajah Hardin, Administrative Rules Coordinator	20. Contact Phone Number (608) 267-7139
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This document can be made available in alternate formats to individuals with disabilities upon request.

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

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

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
-

STATE OF WISCONSIN
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 044-23, was approved by the Governor on June 22, 2023, published in Register 811A2 on July 10, 2023, and approved by the Pharmacy Examining Board on September 5, 2023. This emergency rule was approved by the Governor on (date).

ORDER

An order of the Pharmacy Examining Board to create Phar 8.03 (3), amend Phar 8.04, and repeal and recreate Phar 8.07, relating to controlled substances requirements.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

The Pharmacy Examining Board finds that an emergency exists and that this rule is necessary for the immediate preservation of the public peace, health, safety, or welfare. A statement of facts constituting the emergency is: Clearinghouse Rule 21-071 went into effect on October 1, 2022. This rule repealed and recreated all of Wisconsin Administrative Code Chapter Phar 8. Upon receiving feedback and completing an additional review, the Pharmacy Examining Board has determined that additional changes are needed to Phar 8 to address areas where requirements are no longer in effect or do not match federal regulations. Emergency rules are needed to ensure that these requirements can be updated to protect patient safety and allow effective regulation of the profession until permanent rules can be promulgated.

ANALYSIS

Statutes interpreted: ss. 450.09, 450.11, and 961.31, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (2), 450.02 (3) (a), (d), and (e), 961.31, Stats.

Explanation of agency authority:

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

Section 450.02 (2), Stats. provides that the board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

Section 450.02 (3) (a), Stats. provides that the board “may promulgate rules [r]elating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

Section 450.02 (3) (d), Stats. provides that the board “may promulgate rules [n]ecessary for the administration and enforcement of this chapter and ch. 961.”

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

Section 961.31, Stats. provides that “[t]he pharmacy examining board may promulgate rules relating to the manufacture, distribution, and dispensing of controlled substances within this state.”

Related statute or rule: Wisconsin Administrative Code ch. Phar 7

Plain language analysis: This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. These revisions include the addition of language regarding changes to controlled substances prescriptions, amendments to remove language regarding suspicious controlled substances orders, and amendments to clarify that partial dispensing of controlled substances is allowed.

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: 225 Illinois Compiled Statutes 85 outlines Illinois’ Pharmacy Practice Act. These statutes are further described in the Illinois Administrative Code Title 68 Part 1330. Included in both are requirements for pharmacy standards and pharmacy operation [225 Illinois Compiled Statutes 85, Illinois Administrative Code Title 68 Chapter VII Subchapter b Part 1330 Sections 1330.600 to 1330.800]. Illinois law also requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA [Illinois Administrative Code Title 68 Chapter VII Subchapter b Part 1330 Sections 1330.710].

In the Illinois Controlled Substances Act, the rules require that inventory of controlled substances be done annually, with an exact count for Schedule II drugs and an approximation for Schedule III and IV. Illinois also requires that a record of all written prescription orders received and verbal prescriptions filled, compounded or dispensed for controlled substances be retained for at least 5 years [Illinois Administrative Code Title 77 Chapter XV Part 3100 Section 3100.360]. Illinois also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance in an emergency where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. There does not appear to be a requirement that the prescriber follow up with a written prescription [Illinois Administrative Code Title 77 Chapter XV Part 3100 Section 3100.400].

Iowa: The Iowa Pharmacy Board requires a pharmacy to maintain controlled substance records for at least 2 years and to segregate Schedule I and II drug records from other controlled substance records [657 Iowa Administrative Code Chapter 10 Section 10.36]. Iowa also requires that pharmacies keep a perpetual inventory of all Schedule II drugs on hand [657 Iowa Administrative Code Chapter 10 Section 10.18]. Iowa only requires a pharmacist to report theft or loss of controlled substances to the Pharmacy Board if there is reason to believe that the theft was committed by a pharmacy board licensee, otherwise it is sufficient to merely report to the DEA [657 Iowa Administrative Code Chapter 10 Section 10.21]. Iowa also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. The prescriber must then provide a written prescription within 7 days [657 Iowa Administrative Code Chapter 10 Section 10.26].

Michigan: Michigan requires theft or diversion of a controlled substance to be reported to the Michigan Department of Licensing and Regulatory Affairs within 15 days of completion of an investigation regarding a suspected theft or significant loss of a controlled substance, whether or not it is also reported to the DEA [Michigan Administrative Rules R 338.3141]. Inventory must be taken of all controlled substances at least annually and schedule II controlled substances must be stored separately [Michigan Administrative Rules R 338.3151]. Controlled substance records must be retained for at least 5 years. After two years from the date of dispensing, if the prescription is a hard copy and an electronic duplicate is made, the original hard copy may be destroyed [Michigan Administrative Rules R 338.3153]. Michigan also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. The prescriber must then provide a written prescription within 7 days [Michigan Administrative Rules R 338.3164 and 338.3165].

Minnesota: Minnesota requires a perpetual inventory of Schedule II substances which must be reconciled monthly [Minnesota Administrative Code Section 6800.4600]. Pharmacists, drug wholesalers, drug manufacturers, and controlled substance researchers must report loss or theft of controlled substances to the DEA immediately [Minnesota Administrative Code Section 6800.4800]. All prescription information must be maintained for at least 2 years [Minnesota Administrative Code Section 6800.3100].

Summary of factual data and analytical methodologies: The Pharmacy Examining Board completed a comprehensive review of ch. Phar 8, Requirements for Controlled Substances, in order to identify and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices. The board also evaluated ch. Phar 8 for ways to reduce the regulatory impact on pharmacies without negatively impacting public safety.

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) 266-2112.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

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

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

TEXT OF RULE

SECTION 1. Phar 8.03 (3) is created to read:

Phar 8.03 (3) Pharmacists are to use professional judgement to contact prescribers for changes to controlled substances prescriptions as needed and in accordance with federal law and s. Phar 7.02 (5).

SECTION 2. Phar 8.04 is amended to read:

Phar 8.04 Notification of suspicious orders for and theft or loss of controlled substances. A pharmacy or pharmacist shall notify the board of a ~~suspicious order or series of orders for controlled substances or the~~ theft or loss of controlled substances on the same day notification is required to be provided to the drug enforcement administration. Notification to the board shall include all of the information required to be provided in the notification to the drug enforcement administration.

SECTION 3. Phar 8.07 is repealed and recreated to read:

Phar 8.07 Partial Dispensing. Partial dispensing of controlled substances is allowed in accordance with federal law.

SECTION 4. This emergency rule shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)


Dated _____ Agency _____
Chairperson
Pharmacy Examining Board

**Pharmacy Examining Board
Rule Projects (updated 01/05/24)**

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	Public Hearing Held at 01/18/24 Meeting; Emergency Rule Effective 02/03/23-05/01/24	Drafting Final Rule and Legislative Report
23-054 (EmR 2213)	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Final Permanent Rule Reviewed at 01/18/24 Meeting; Emergency Rule Effective 11/01/22-05/01/24	Submission to Governor's Office and Legislature
Not Assigned Yet	Not Assigned Yet	TBD	Phar 7	Comprehensive Review	Scope Statement to be Revised	Revised Scope Statement to be Reviewed at 02/29/24 Meeting
23-015	102-21	05/01/2024	Phar 7 and 10	Consumer Disclosures	Drafting Adoption Order	Adoption Order to be Presented at 02/29/24 Meeting
Not Assigned Yet	044-23	01/10/2026	Phar 8	Controlled Substances Requirements	Board Review of Emergency Rule Draft at 01/18/24 Meeting	Board Approval of Emergency Rule Draft; Drafting Preliminary Permanent Rule
Not Assigned Yet	007-23	07/23/2025	Phar 15	Compounding Pharmaceuticals	Review of Preliminary Rule Draft at 02/29/24 Meeting	Board Approval of Permanent 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	Legislative Review	Board Approval of Adoption Order at a Future Meeting

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

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, Executive Director		2) Date when request submitted: 1/11/2024 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 1/18/2024	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislative and Policy Matters – Discussion and Consideration 1) 2023 Senate Bill 705/2023 Assembly Bill 626	
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 <Appearance Name(s)> <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if applicable: <Click Here to Add Case Advisor Name or N/A>	
10) Describe the issue and action that should be addressed: <Click Here to Add Description>			
11) Authorization			
		1/11/2024	
Signature of person making this request		Date	
Supervisor (Only required for post agenda deadline items)		Date	
Executive Director signature (Indicates approval for post agenda deadline items)		Date	
Directions for including supporting documents: 1. This form should be saved with any other documents submitted to the Agenda Items folders. 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.			



2023 SENATE BILL 705

November 21, 2023 - Introduced by Senators CABRAL-GUEVARA and NASS, cosponsored by Representatives MURPHY, SORTWELL, ARMSTRONG, BEHNKE, BODDEN, BRANDTJEN, EDMING, GOEBEN, MAGNAFICI, MICHALSKI, MURSAU, O'CONNOR, RETTINGER and TUSLER. Referred to Committee on Health.

1 **AN ACT** *to repeal* 450.095 (1) (a); *to amend* 50.36 (6), 450.095 (title), 450.095 (2)
2 (intro.), 450.095 (2) (a), 450.095 (2) (b) and 450.095 (2) (c); and *to create* 450.095
3 (1) (am), 450.095 (2) (am), 450.095 (2m) and 632.865 (6m) of the statutes;
4 **relating to:** the duty of a pharmacist to dispense lawfully prescribed drugs and
5 devices.

Analysis by the Legislative Reference Bureau

Under current law, a pharmacy has a duty to dispense lawfully prescribed contraceptive drugs and devices without delay unless certain factors apply, including that the prescription contains an obvious or known error or contains inadequate instructions, the prescription is contraindicated for the patient, the prescription is incompatible with another drug or device prescribed for the patient, or the prescription is potentially fraudulent. This bill expands that duty to require pharmacies to dispense any lawfully prescribed drug or device without delay. However, if any pharmacist at a pharmacy refuses to dispense a drug or device for reasons of conscience such that the pharmacy cannot fulfill the prescription order without delay, then the bill requires the pharmacy to transfer the prescription order to a different pharmacy, at the direction of the patient, that will dispense the prescribed drug or device without delay. The bill also specifies that a pharmacy may not dispense a lawfully prescribed drug or device if there is an absolute contraindication for the prescribed drug or device, rather than just a contraindication. Under the bill, “absolute contraindication” is defined to mean any

SENATE BILL 705

condition present in a patient that makes a particular drug or device inadvisable under any circumstances.

Further, the bill prohibits a pharmacy benefit manager from penalizing in any way a pharmacy or pharmacist from dispensing a prescribed drug or device that is prescribed for a use other than a use approved by the federal Food and Drug Administration if the prescribed drug or device is dispensed pursuant to a valid prescription order.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 50.36 (6) of the statutes is amended to read:

2 50.36 (6) If the department receives a credible complaint that a pharmacy
3 located in a hospital has violated its duty to dispense ~~contraceptive~~ drugs and devices
4 under s. 450.095 (2), the department shall refer the complaint to the department of
5 safety and professional services.

6 **SECTION 2.** 450.095 (title) of the statutes is amended to read:

7 **450.095 (title) Duty to dispense contraceptives.**

8 **SECTION 3.** 450.095 (1) (a) of the statutes is repealed.

9 **SECTION 4.** 450.095 (1) (am) of the statutes is created to read:

10 450.095 (1) (am) “Absolute contraindication” means any condition present in
11 a patient that renders a particular drug or device not safe to be used as prescribed
12 under any circumstance because of the severe or potentially life-threatening risks
13 involved.

14 **SECTION 5.** 450.095 (2) (intro.) of the statutes is amended to read:

15 450.095 (2) (intro.) Unless ~~one or more~~ any of the following applies, except as
16 provided in sub. (2m), a pharmacy shall dispense any lawfully prescribed
17 ~~contraceptive drugs and devices~~ drug or device and shall deliver ~~contraceptive drugs~~

SENATE BILL 705**SECTION 5**

1 ~~and devices restricted to distribution by a pharmacy~~ the drug or device to ~~a~~ the
2 patient without delay:

3 **SECTION 6.** 450.095 (2) (a) of the statutes is amended to read:

4 450.095 (2) (a) The prescription or prescription order contains an obvious or
5 known error or contains inadequate instructions.

6 **SECTION 7.** 450.095 (2) (am) of the statutes is created to read:

7 450.095 (2) (am) A pharmacist determines after reviewing the prescription
8 order and the patient's medical records that there is an absolute contraindication for
9 the prescribed drug or device.

10 **SECTION 8.** 450.095 (2) (b) of the statutes is amended to read:

11 450.095 (2) (b) The ~~prescription is contraindicated for the patient,~~ prescribed
12 drug or device is incompatible with another drug or device prescribed for the patient,
13 or is prohibited by state or federal law.

14 **SECTION 9.** 450.095 (2) (c) of the statutes is amended to read:

15 450.095 (2) (c) The prescription or prescription order is potentially fraudulent.

16 **SECTION 10.** 450.095 (2m) of the statutes is created to read:

17 450.095 (2m) If any pharmacist at a pharmacy refuses to dispense a lawfully
18 prescribed drug or device for reasons of conscience such that the pharmacy cannot
19 fulfill a prescription or prescription order without delay, then the pharmacy shall
20 transfer the prescription or prescription order to a different pharmacy, at the
21 direction of the patient, that will dispense the prescribed drug or device without
22 delay.

23 **SECTION 11.** 632.865 (6m) of the statutes is created to read:

24 632.865 (6m) OFF-LABEL THERAPIES. No pharmacy benefit manager may in any
25 way penalize a pharmacy or pharmacist for dispensing a prescribed drug or device

SENATE BILL 705

SECTION 11

1 that is prescribed for a use other than a use approved by the federal food and drug
2 administration if the prescribed drug or device is dispensed pursuant to a valid
3 prescription order, as defined in s. 450.01 (21).

4 (END)



2023 ASSEMBLY BILL 626

November 8, 2023 - Introduced by Representatives MURPHY, SORTWELL, ARMSTRONG, BEHNKE, BODDEN, BRANDTJEN, EDMING, GOEBEN, MAGNAFICI, MICHALSKI, MURSAU, O'CONNOR, RETTINGER and TUSLER, cosponsored by Senators CABRAL-GUEVARA and NASS. Referred to Committee on Health, Aging and Long-Term Care.

1 **AN ACT to repeal** 450.095 (1) (a); **to amend** 50.36 (6), 450.095 (title), 450.095 (2)
2 (intro.), 450.095 (2) (a), 450.095 (2) (b) and 450.095 (2) (c); and **to create** 450.095
3 (1) (am), 450.095 (2) (am), 450.095 (2m) and 632.865 (6m) of the statutes;
4 **relating to:** the duty of a pharmacist to dispense lawfully prescribed drugs and
5 devices.

Analysis by the Legislative Reference Bureau

Under current law, a pharmacy has a duty to dispense lawfully prescribed contraceptive drugs and devices without delay unless certain factors apply, including that the prescription contains an obvious or known error or contains inadequate instructions, the prescription is contraindicated for the patient, the prescription is incompatible with another drug or device prescribed for the patient, or the prescription is potentially fraudulent. This bill expands that duty to require pharmacies to dispense any lawfully prescribed drug or device without delay. However, if any pharmacist at a pharmacy refuses to dispense a drug or device for reasons of conscience such that the pharmacy cannot fulfill the prescription order without delay, then the bill requires the pharmacy to transfer the prescription order to a different pharmacy, at the direction of the patient, that will dispense the prescribed drug or device without delay. The bill also specifies that a pharmacy may not dispense a lawfully prescribed drug or device if there is an absolute contraindication for the prescribed drug or device, rather than just a contraindication. Under the bill, “absolute contraindication” is defined to mean any

ASSEMBLY BILL 626

condition present in a patient that makes a particular drug or device inadvisable under any circumstances.

Further, the bill prohibits a pharmacy benefit manager from penalizing in any way a pharmacy or pharmacist from dispensing a prescribed drug or device that is prescribed for a use other than a use approved by the federal Food and Drug Administration if the prescribed drug or device is dispensed pursuant to a valid prescription order.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 50.36 (6) of the statutes is amended to read:

2 50.36 (6) If the department receives a credible complaint that a pharmacy
3 located in a hospital has violated its duty to dispense ~~contraceptive~~ drugs and devices
4 under s. 450.095 (2), the department shall refer the complaint to the department of
5 safety and professional services.

6 **SECTION 2.** 450.095 (title) of the statutes is amended to read:

7 **450.095 (title) Duty to dispense contraceptives.**

8 **SECTION 3.** 450.095 (1) (a) of the statutes is repealed.

9 **SECTION 4.** 450.095 (1) (am) of the statutes is created to read:

10 450.095 (1) (am) “Absolute contraindication” means any condition present in
11 a patient that renders a particular drug or device not safe to be used as prescribed
12 under any circumstance because of the severe or potentially life-threatening risks
13 involved.

14 **SECTION 5.** 450.095 (2) (intro.) of the statutes is amended to read:

15 450.095 (2) (intro.) Unless ~~one or more~~ any of the following applies, except as
16 provided in sub. (2m), a pharmacy shall dispense any lawfully prescribed
17 ~~contraceptive drugs and devices~~ drug or device and shall deliver ~~contraceptive drugs~~

ASSEMBLY BILL 626**SECTION 5**

1 ~~and devices restricted to distribution by a pharmacy~~ the drug or device to ~~a~~ the
2 patient without delay:

3 **SECTION 6.** 450.095 (2) (a) of the statutes is amended to read:

4 450.095 (2) (a) The prescription or prescription order contains an obvious or
5 known error or contains inadequate instructions.

6 **SECTION 7.** 450.095 (2) (am) of the statutes is created to read:

7 450.095 (2) (am) A pharmacist determines after reviewing the prescription
8 order and the patient's medical records that there is an absolute contraindication for
9 the prescribed drug or device.

10 **SECTION 8.** 450.095 (2) (b) of the statutes is amended to read:

11 450.095 (2) (b) The ~~prescription is contraindicated for the patient,~~ prescribed
12 drug or device is incompatible with another drug or device prescribed for the patient,
13 or is prohibited by state or federal law.

14 **SECTION 9.** 450.095 (2) (c) of the statutes is amended to read:

15 450.095 (2) (c) The prescription or prescription order is potentially fraudulent.

16 **SECTION 10.** 450.095 (2m) of the statutes is created to read:

17 450.095 (2m) If any pharmacist at a pharmacy refuses to dispense a lawfully
18 prescribed drug or device for reasons of conscience such that the pharmacy cannot
19 fulfill a prescription or prescription order without delay, then the pharmacy shall
20 transfer the prescription or prescription order to a different pharmacy, at the
21 direction of the patient, that will dispense the prescribed drug or device without
22 delay.

23 **SECTION 11.** 632.865 (6m) of the statutes is created to read:

24 632.865 (6m) OFF-LABEL THERAPIES. No pharmacy benefit manager may in any
25 way penalize a pharmacy or pharmacist for dispensing a prescribed drug or device

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SECTION 11

1 that is prescribed for a use other than a use approved by the federal food and drug
2 administration if the prescribed drug or device is dispensed pursuant to a valid
3 prescription order, as defined in s. 450.01 (21).

4 (END)

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

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, Executive Director		2) Date when request submitted: 1/5/2024 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 1/18/2024	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Improving Pharmacist Workplace Satisfaction – Discussion and Consideration	
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 <Appearance Name(s)> <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if applicable: <Click Here to Add Case Advisor Name or N/A>	
10) Describe the issue and action that should be addressed: <Click Here to Add Description>			
11) Authorization			
		1/5/2024	
Signature of person making this request		Date	
Supervisor (Only required for post agenda deadline items)		Date	
Executive Director signature (Indicates approval for post agenda deadline items)		Date	
Directions for including supporting documents: 1. This form should be saved with any other documents submitted to the Agenda Items folders. 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.			