Wisconsin Department of Safety and Professional Services Division of Policy Development 4822 Madison Yards Way, 2<sup>nd</sup> Floor PO Box 8366 Madison WI 53708-8366



Phone: 608-266-2112 Web: http://dsps.wi.gov Email: dsps@wisconsin.gov

Tony Evers, Governor Dan Hereth, Secretary

### HYBRID (IN-PERSON/VIRTUAL) PHARMACY EXAMINING BOARD

Room N208, 4822 Madison Yards Way, 2<sup>nd</sup> Floor North, Madison, WI Contact: Brad Wojciechowski (608) 266-2112 November 3, 2022

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions of the Board. 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 September 1, 2022 (5-9)
- C. Reminders: Conflicts of Interest, Scheduling Concerns
- D. Administrative Matters Discussion and Consideration
  - 1) Department, Staff and Board Updates
  - 2) Board Members Term Expiration Dates
    - a. Kleppin, Susan  $-\frac{7}{1}/2025$
    - b. O'Hagan, Tiffany 7/1/2024
    - c. Peterangelo, Anthony -7/1/2023
    - d. Walsh, Michael -7/1/2024
    - e. Weiss, Shana  $-\frac{7}{1}/2023$
    - f. Weitekamp, John 7/1/2026
    - g. Wilson, Christa 7/1/2025
- E. Quarterly Board Chair Connection Meeting Report Discussion and Consideration
  - 1) Options for Addressing Department Resources
- F. Legislature Agenda Request: Status of Kratom Discussion and Consideration (10)
- G. Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State Boards of Pharmacy and the U.S. Food and Drug Administration Discussion and Consideration
- H. Credentialing Matters –Discussion and Consideration
  - 1) Review of Pharmacy Forms (11)

- 2) Remote Dispensing Communication (12)
- I. Legislative and Policy Matters Discussion and Consideration

### J. Administrative Rule Matters – Discussion and Consideration (13)

- 1) Emergency Rule Draft: Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians (14-23)
- 2) Preliminary Rule Draft: Phar 18, Relating to Third Party Logistics Provider Licensure (24-30)
- 3) Public Agenda Item: USP General Chapter <825> (31-34)
- 4) Pending or Possible Rulemaking Projects (35)

# K. Implement 2021 Wisconsin Act 9 – 100 Most Prescribed Drugs – Discussion and Consideration (36-40)

### L. Education and Examination Matters- Discussion and Consideration

- 1) Multistate Pharmacy Jurisprudence Examination (MPJE) Update
- M. Speaking Engagements, Travel, or Public Relation Requests, and Reports Discussion and Consideration
- N. COVID-19 Discussion and Consideration
- O. Pilot Program Matters Discussion and Consideration
- P. Discussion and Consideration on Items Added After Preparation of Agenda
  - 1) Introductions, Announcements and Recognition
  - 2) Nominations, Elections, and Appointments
  - 3) Administrative Matters
  - 4) Election of Officers
  - 5) Appointment of Liaisons and Alternates
  - 6) Delegation of Authorities
  - 7) Education and Examination Matters
  - 8) Credentialing Matters
  - 9) Practice Matters
  - 10) Legislative and Policy Matters
  - 11) Administrative Rule Matters
  - 12) Pilot Program Matters
  - 13) Variances
  - 14) Liaison Reports
  - 15) Board Liaison Training and Appointment of Mentors
  - 16) Informational Items
  - 17) Division of Legal Services and Compliance (DLSC) Matters
  - 18) Presentations of Petitions for Summary Suspension
  - 19) Petitions for Designation of Hearing Examiner
  - 20) Presentation of Stipulations, Final Decisions and Orders
  - 21) Presentation of Proposed Final Decisions and Orders
  - 22) Presentation of Interim Orders
  - 23) Pilot Program Matters
  - 24) Petitions for Re-Hearing
  - 25) Petitions for Assessments
  - 26) Petitions to Vacate Orders

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

### Q. Public Comments

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

### R. Deliberation on Division of Legal Services and Compliance Matters

- 1) Administrative Warnings
  - a. 21 PHM 115 O.S.S. (41-42)
- 2) Case Closings
  - a. 21 PHM 013 C.P., C.C. (43-53)
  - b. 21 PHM 113 H.F.P.A.S. (**54-58**)
  - c. 22 PHM 045 J.M.R. (**59-63**)
  - d. 22 PHM 046 A.P. (**64-71**)
  - e. 22 PHM 099 H.D.I. (**72-74**)
  - f. 22 PHM 111 F.S.S.P. (**75-77**)
  - g. 22 PHM 128 C. (**78-84**)
- 3) Proposed Stipulation and Final Decision and Orders
  - a. 22 PHM 061 Brenton M. Severson, R.Ph. (**85-91**)
- 4) Monitoring Matters (92-93)
  - a. Monitor Heller
    - 1. Peter Dickman, Pharmacist Requesting Full Licensure (94-111)
    - 2. Andrew Seidlitz, Pharmacist Requesting the Addition of Four (4) Hours Per Month as Pharmacist in Charge and/or Reduction in Drug and Alcohol Screens (112-144)
    - 3. Brad Spross, Pharmacist Requesting Full Licensure (145-183)
- S. 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
- T. Consulting with Legal Counsel

### RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

- U. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate
- V. Open Session Items Noticed Above Not Completed in the Initial Open Session

### **ADJOURNMENT**

**NEXT MEETING: DECEMBER 1, 2022** 

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

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

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer at 608-266-2112, or the Meeting Staff at 608-266-5439.

### VIRTUAL/TELECONFERENCE PHARMACY EXAMINING BOARD MEETING MINUTES SEPTEMBER 1, 2022

**PRESENT:** Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp,

Michael Walsh, Christa Wilson

**EXCUSED:** Shana Weiss

**STAFF:** Brad Wojciechowski, Executive Director; Jameson Whitney, Legal Counsel;

Nilajah Hardin, Administrative Rules Coordinator; Katlin Schwartz, Bureau Assistant; Dialah Azam, Bureau Assistant; Kimberly Wood, Program Assistant

Supervisor-Adv.; and other Department staff

### CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:17 a.m. A quorum was confirmed with six (6) members present.

### ADOPTION OF AGENDA

**MOTION:** Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to adopt the

Agenda as published. Motion carried unanimously.

**APPROVAL OF MINUTES OF JUNE 16, 2022** 

**MOTION:** Susan Kleppin moved, seconded by Anthony Peterangelo, to approve the

Minutes of June 16, 2022 as published. Motion carried unanimously.

### ADMINISTRATIVE RULE MATTERS

### **Emergency Rule Draft: Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing**

**MOTION:** Michael Walsh moved, seconded by Anthony Peterangelo, to authorize the

Chairperson to approve the emergency rule on Phar 1, 5, 6, 7, and 8, relating to Remote Dispensing for emergency rule submission to the Governor and publication in an official newspaper. Motion carried

unanimously.

### Preliminary Rule Draft: Phar 7 and 10, Relating to Consumer Disclosures

**MOTION:** Michael Walsh moved, seconded by Anthony Peterangelo, to approve the

preliminary rule draft of Phar 7 and 10, relating to Consumer Disclosures,

for posting for economic impact comments and submission to the

Clearinghouse. Motion carried unanimously.

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

# Consideration of Attendance: 2022 Annual Meeting: NABP/American Association of Colleges of Pharmacy (AACP) District IV- November 6-8, 2022 – Madison, WI

**MOTION:** Michael Walsh moved, seconded by Anthony Peterangelo, to designate

Tiffany O'Hagan, as the Board's delegate, to attend the 2022 Annual Meeting: NABP/American Association of Colleges of Pharmacy (AACP) District IV on November 6-8, 2022 in Madison, WI. Motion carried

unanimously.

**MOTION:** Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to designate

John Weitekamp to speak on the Board's behalf at the 2022 Annual Meeting: NABP/American Association of Colleges of Pharmacy (AACP) District IV on November 6-8, 2022 in Madison, WI. Motion carried

unanimously.

### **CLOSED SESSION**

**MOTION:** Susan Kleppin moved, seconded by Michael Walsh, 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 2:20 p.m.

### **CREDENTIALING MATTERS**

### **Application Reviews**

### Curexa and Curexa II – Out of State Pharmacy Applicants

MOTION: Michael Walsh moved, seconded by Christa Wilson, to approve the Out of

State Pharmacy application of Curexa and Curexa II, once all

requirements are met, and to refer the prior disciplinary history to the Division of Legal Service and Compliance to open an investigation and consider whether any disciplinary options would be appropriate. Motion

carried unanimously.

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

### **Administrative Warnings**

### 21 PHM 120 - B.D.D.C.

**MOTION:** Christa Wilson moved, seconded by Michael Walsh, to issue an

Administrative Warning in the matter of B.D.D.C., DLSC Case Number

21 PHM 120. Motion carried unanimously.

### **Case Closings**

**MOTION:** Tiffany O'Hagan moved, seconded by Anthony Peterangelo, to close the following DLSC Cases for the reasons outlined below:

- 1. 21 PHM 041, 21 PHM 059, 21 PHM 079 A.S.P. Prosecutorial Discretion (P2)
- 2. 21 PHM 072 C.P. No Violation
- 3. 21 PHM 083 N.A.H., A.A.A., M.E.S. Insufficient Evidence
- 4. 21 PHM 088 O.P. No Violation
- 5. 21 PHM 104 D.M.A., D.L.H. Insufficient Evidence
- 6. 21 PHM 117 W. No Violation
- 7. 21 PHM 138 C.P. No Violation
- 8. 22 PHM 025 H.P. Prosecutorial Discretion (P2)
- 9. 22 PHM 037 H. Prosecutorial Discretion (P1)
- 10. 22 PHM 048 E.S.P. No Violation

Motion carried unanimously.

### **Proposed Stipulations and Final Decisions and Orders**

### 21 PHM 143 – Barbara A. Koch, R.Ph.

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Barbara A. Koch, R.Ph., DLSC Case Number 21

PHM 143. Motion carried unanimously.

(Tiffany O'Hagan recused herself and left the room for deliberation and voting in the matter concerning Barbara A. Koch, R.Ph., DLSC Case Number 21 PHM 143.)

**MOTION:** Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings of the following cases:

- 1. 22 PHM 009 Stephen T. Tonsong, R.Ph.
- 2. 22 PHM 113 Jared G. Latus, R.Ph.

Motion carried unanimously.

### **Monitoring Matters**

### Jared Latus, Pharmacist Requesting to Surrender License

**MOTION:** Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to grant the

request of Jared Latus, Pharmacist to surrender his license. Motion carried

unanimously.

### Jennifer A. Hansen, Pharmacist Requesting Full Licensure

**MOTION:** Susan Kleppin moved, seconded by Michael Walsh, to grant the request of

Jennifer A. Hansen, Pharmacist for full licensure. Motion carried

unanimously.

(Tiffany O'Hagan recused herself and left the meeting connection for deliberation and voting in the matter concerning Jennifer A. Hansen, Pharmacist.)

(Michael Walsh was excused at 3:25 p.m.)

(Christa Wilson was excused at 3:30 p.m.)

### Walter P. Matoska, Pharmacist Requesting Approval for Fitness to Practice Evaluator

**MOTION:** Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to grant the

request of Walter P. Matoska, Pharmacist for approval of Dr. Joseph Bergs

to perform a new fitness to practice evaluation. Motion carried

unanimously.

### RECONVENE TO OPEN SESSION

**MOTION:** Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to reconvene

into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 3:32 p.m.

### VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

**MOTION:** Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to affirm all

motions made and votes taken in Closed Session. Motion carried

unanimously.

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

### **ADJOURNMENT**

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

The meeting adjourned at 3:33 p.m.



1) Name and title of person submitting the request:				2) Date when request submitted:	
Brad Wojciechowski				10/24/2022	
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Brad Wojciechowski				10/27/2022		
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11/03/2022	☐ Ye		Credentialing Matters - Review of Pharm Consideration		ew of Pharmacy Forms: Discussion and	
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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 mosting.						

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Nilajah Hardin			10/26/22		
Administrative Rules Coordinator			Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting		
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11/03/22	Attachments:	Administrative	Rule Matte	ers – Discussion and Consideration	
	│			<b>Draft: Phar 1, 5, 7, 10, and 19, Relating to</b>	
	I NO			armacy Technicians Draft: Phar 18, Relating to Third Party Logistics	
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Closed Session	☐ Yes				
	⊠ No				
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Attachments:					
	Emergency Rule	Draft			
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4. Rule Projects Cl					
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s/Brad Wojciechowski	(approved via em	nail)		10/26/22	
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## STATE OF WISCONSIN PHARMACY EXAMINING BOARD

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IN THE MATTER OF RULEMAKING : ORDER OF THE

PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD PHARMACY EXAMINING BOARD : ADOPTING EMERGENCY RULES

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

### <u>ORDER</u>

An order of the Pharmacy Examining Board to amend Phar 1.01, 1.02 (intro), 1.02 (Note), 5.01 (1) and (3), 5.04, 5.05 (1), (2), (2) (b), (3), (4), (4) (b) and (c), 5.06 (intro.) and (1), 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, 10.03 (2), (7), (17), and (19); create Phar 1.01 (11e) and ch. 19; and repeal Phar 7.14 (2) and subch. V relating to registration of pharmacy technicians.

Analysis prepared by the Department of Safety and Professional Services.

### EXEMPTION FROM FINDING OF EMERGENCY

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

### **ANALYSIS**

**Statutes interpreted:** s. 450.68, Stats.

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

### **Explanation of agency authority:**

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

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

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

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

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

Related statute or rule: s. 961.31, Stats.

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

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

### Comparison with rules in adjacent states:

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

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

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

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

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

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

### **Effect on small business:**

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

### **Agency contact person:**

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

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

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

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### 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 <u>1719</u> are adopted under authority of ss. 15.08 (5) (b), 227.11 (2), Stats, and ch. 450, Stats.

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

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

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

**Phar 1.01 (11e)** "Pharmacy technician" means a person registered by the board under s. 450.068, Stats.

SECTION 3. Phar 5.01 (1) and (3); 5.04; 5.05 (1), (2), (2) (b), (3), (4), (4) (b) and (c); and 5.06 (intro) and (1) are amended to read:

**Phar 5.01 (1)** Pharmacists, <u>pharmacy technicians</u>, pharmacies, manufacturers, distributors, and home medical oxygen providers licensed <u>or registered</u> under ch. 450, Stats., and otherwise qualified for renewal, may continue to be licensed biennially by applying for renewal and paying the fee as determined by the department under s. 440.03 (9) (a), Stats.

**Phar 5.01 (3)** No pharmacy, <u>pharmacy technician</u>, manufacturer, distributor, or home medical oxygen provider may operate without a current license or registration.

**Phar 5.04 Renewal prohibited.** Any person whose license <u>or registration</u> is currently suspended or revoked may not renew his or her license or registration.

- **Phar 5.05 (1)** General. A person with an expired license <u>or registration</u> may not reapply for a license <u>or registration</u> using the initial application process.
- **Phar 5.05 (2)** Renewal within 5 years. A person renewing the license <u>or registration</u> within 5 years shall do all of the following:
- Phar 5.05 (2) (b) Certify If renewing a pharmacist license, certify the completion of 30 hours of continuing education during the last biennium.
- **Phar 5.05 (3)** RENEWAL AFTER EXPIRATION DATE. Notwithstanding sub. (2), if a pharmacist <u>or pharmacy technician</u> fails to obtain renewal on or before the applicable renewal date, the board may suspend the pharmacist's license <u>or pharmacy technician's registration</u> and may require the pharmacist <u>or pharmacy technician</u> to pass an examination to the satisfaction of the board to restore that license or registration.
- **Phar 5.05 (4)** RENEWAL AFTER 5 YEARS, this subsection does not apply to license <u>or registration</u> holders who have unmet disciplinary requirements. A person renewing the license after 5 years shall do all of the following:
- Phar 5.05 (4) (b) Evidence If renewing a pharmacist license, evidence of having passed the multi-state pharmacy jurisprudence examination with Wisconsin designated as the primary state.
- Phar 5.05 (4) (c) If the person renewing the a pharmacist license does not have 2000 hours of practice as a pharmacist within last 24 months of submitting the application for renewal, the person shall meet one of the following requirements:
- **Phar 5.06 (intro.)** A licensee <u>or registrant</u> who has unmet disciplinary requirements and failed to renew the license within 5 years or whose license <u>or registration</u> has been surrendered or revoked may apply to have the license <u>or registration</u> reinstated in accordance with all of the following:
- **Phar 5.06 (1)** Evidence of completion of the requirements in s. Phar 5.05 (4) if the license or registration has not been active within 5 years.
- SECTION 4. Phar 7.07 (2); 7.14 (title); 7.14 (1) (a), (b) and (d); and 7.14 (2) are amended to read:
- **Phar 7.07 (2)** For all prescription drug product or device dispensing, the prescription record shall identify the pharmacist responsible for each part of the final check. If sub. (1) (a) or (b) is completed by delegate check-delegate pharmacy product verification technician-check-pharmacy technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the delegate pharmacy technician performing the check.

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

- (1) (a) "Delegate Pharmacy product verification technician" means a person registered pharmacy technician to whom the pharmacist has delegated the task of product verification.
- (1) (b) "Delegate-check-delegate Pharmacy product verification technician-check-pharmacy technician" means the process in which one delegate a pharmacy product verification technician conducts the task of product verification of technical dispensing functions completed by an unlicensed individual a pharmacy technician. A delegate pharmacy product verification technician may not conduct product verification as part of the final check of their own product preparation.
- (1) (d) ""Supervising pharmacist" means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a delegate pharmacy product verification technician and ensuring for direct supervision of the delegate pharmacy product verification technician.
- (2) DELEGATE PHARMACY PRODUCT VERIFICATION TECHNICIAN QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate pharmacy technician who meets all of the following:

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

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

- **Phar 7.14 (2) (b)** Completed an accredited <u>pharmacy</u> technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.
- (2) (c) 3. Eligible medications for <del>delegate check-delegate</del> pharmacy product verification technician-check-pharmacy technician.
- (2) (c) 6. A practical training designed to assess the competency of the delegate pharmacy technician prior to starting the validation process. The practical training shall include simulation of at least 2 occurrences of each of the following:
- (2) (d) 1. The delegate pharmacy technician being validated shall make a product verification on the work of a pharmacist or unlicensed person another pharmacy technician for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.
- (2) (d) 2. A pharmacist shall audit 100% of the product verifications made by the delegate pharmacy technician during the validation process.

- (2) (e) Notwithstanding pars. (a) (b) to (d), a delegate an individual who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the delegation pharmacy product verification technician qualifications unless the delegate individual fails to meet the quality assurance standards under sub. (4).
- (3) (a) Institutional pharmacies. The delegate pharmacy product verification technician may do the product verification in an institutional pharmacy if all of the following requirements are met:
- (3) (b) Community pharmacies. The delegate pharmacy product verification technician may do the product verification in a community pharmacy if all of the following requirements are met:
- (4) (a) A minimum of 5% of each <u>delegate's pharmacy</u> product <u>verification technician's</u> verifications shall be audited by a licensed pharmacist. The accuracy of each <u>delegate</u> <u>pharmacy product verification technician</u> shall be tracked individually.
- (4) (b) A record of each delegate check delegate pharmacy product verification technician-check-pharmacy technician audit shall include all of the following:
- (4) (b) 1. Name of the <u>pharmacy</u> product verification <del>delegate</del> <u>technician</u>.
- (4) (c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each delegate's pharmacy product verification technician's previous 12 months accuracy and correctness of delegate-check-delegate pharmacy product verification technician-check-pharmacy technician verifications including a review of the quality assurance log.
- (4) (d) A delegate pharmacy product verification technician shall be revalidated if the delegate individual fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed delegate-eheck-delegate pharmacy product verification technician-check-pharmacy technician verifications within the last 6 months.
- (5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate pharmacy product verification technician-check-pharmacy technician which shall be made available to the board upon request.
- (6) (a) 1. All validation records of each delegate pharmacy product verification technician that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

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

SECTION 7. Chapter Phar 7 Subchapter V is repealed.

SECTION 8. Phar 10.03 (2), (7), (17), and (19) are amended to read:

**Phar 10.03 (2)** Engaging in any pharmacy <u>or pharmacy technician</u> 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 <u>or pharmacy technician</u> which harmed or could have harmed a patient;

- (7) Failing to report to the pharmacy examining board any pharmacy or pharmacy technician practice which constitutes a danger to the health, safety or welfare of patient or public;
- (17) Having a pharmacist license <u>or pharmacy technician registration</u> revoked or suspended in another state or United States jurisdiction or having been subject to other disciplinary action by the licensing authority thereof;
- (19) Practicing without a current license or registration.

SECTION 9. Chapter Phar 19 is created to read:

# Chapter Phar 19 REGISTRATION OF PHARMACY TECHNICIANS

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

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

- (2) A person applying for a pharmacy technician registration shall satisfy all of the following:
  - (a) Submit a completed application form.

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

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

- (c) Subject to ss. 111.321, 111.322, and 111.335, stats., the applicant does not have an arrest or conviction record.
- (d) The applicant satisfies one of the following:
  - 1. Is at least 18 years of age and has graduated from high school or has attained high school graduation equivalency as determined by the department of public instruction.
  - 2. Is enrolled in a youth apprenticeship program for pharmacy technicians that is on the list of youth apprenticeship programs approved by the department of workforce development under s. 106.13 (2m), Stats.
- (3) Each pharmacy technician shall complete renewal of their registration every biennium as specified in chapter Phar 5.

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

Phar 19.04 Change of Address or Employer. Pursuant to s. 450.068 (3), each pharmacy technician shall notify the department in writing of an address change or change of employer in writing within 10 days of the change.

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

SECTION 10. Pursuant to 2021 Wisconsin Act 100 section 40 (1), this emergency rule shall take effect upon publication in the official state newspaper and remain in effect until May 1, 2024 or until the date on which permanent rules take effect, whichever is sooner.

	(END OF TEXT OF RULE)	
Dated	Agency	
	Chairperson	_
	Pharmacy Examining Board	

1) Name and title of pers	son submitting the	e request:	2) Date when request submitted:			
Nilajah Hardin			10/24/22			
Administrative Rules Coordinator			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 I	Board					
4) Meeting Date:	5)	6) How should the item be titled on the agenda page?				
11/03/22	Attachments:	Administrative Rule Matters – Discussion and Consideration				
	⊠ Yes   □ No	1. Prelim	inary Rule	Draft: Phar 18, Relating to Third Party Logistics		
			er Licensur	e m: USP General Chapter <825>		
				le Rulemaking Projects		
7) Diago Horriga	0) In an annual	and the Day		O) Nove of Occo Advisor(c) if we wind		
7) Place Item in:		ance before the Boa yes, please complete		9) Name of Case Advisor(s), if required:		
Open Session		guest for Non-DSPS		N/A		
☐ Closed Session	☐ Yes					
	⊠ No					
10) Describe the issue a	and action that sho	ould be addressed:				
Attachments:						
1. Phar 18 Prelimin						
<ul><li>2. Letter re: USP C</li><li>3. Rule Projects Ch</li></ul>						
3. Rule Hojeets Cl	iait					
Copies of current Box	ard Rule Projects	Can be Viewed He	ere: https://d	sps.wi.gov/Pages/RulesStatutes/PendingRules.aspx		
44)		A (1) . 2 .				
11)	4.3	Authoriza	ition	10/24/22		
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Signature of person ma	king tins request			Date		
Supervisor (if required)				Date		
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Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date						
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Directions for including  1. This form should be			d to the ager	nda.		
2. Post Agenda Deadlin	ne items must be a	uthorized by a Sup	ervisor and t	the Policy Development Executive Director.		
	original documen	nts 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 create Phar 18, relating to licensure of third-party logistics providers.

Analysis prepared by the Department of Safety and Professional Services.

### ANALYSIS

**Statutes interpreted:** s. 450.075 (4), Stats.

**Statutory authority:** ss. 15.08 (5) (b), 450.02 (3) (a), 450.02 (3) (d), and 450.075 (4),

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. Authorizes 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. provides that the board "may promulgate rules necessary for the administration and enforcement of this chapter and Ch. 961."

Section 450.075 (4), Stats. says: "The board shall promulgate rules implementing this section. The rules shall ensure compliance with the federal drug supply chain security act, 21 USC 360eee, et seq. The board may not promulgate rules that impose requirements more strict than the federal drug supply chain security act or any regulations passed under the federal drug supply chain security act. The board may not promulgate rules that require a license under this section."

Related statute or rule: Wisconsin Administrative Code Chapter Phar 18

**Plain language analysis:** The object of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 25.

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

21 U.S. Code s. 360eee includes national standards for third-party logistics providers. These standards include guidelines for a federal licensure program issued by the Secretary of the U.S. Department of Health and Human Services. This section also includes clarifications for those states that have a licensure program. Third-party logistics providers must either be licensed at the state level, if such a licensure program exists, or federally. On February 4, 2022, the U.S. Food and Drug Administration announced a proposed rule in National Standards for Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers. This rule has not been finalized yet.

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: No comments were received.

### Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of wholesale distribution in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Wholesale Distribution Act contains requirements for licensure of resident and non-resident third-party logistics providers. In addition to obtaining licensure, each third-party logistics provider must also submit the information of a designated representative responsible for operations at each site [225 Illinois Complied Statutes ch. 120 s. 25.5].

**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 licensure of third-party logistics providers. In addition to obtaining licensure, each third-party logistics provider must also submit the information of a facility manager responsible for operations at each site [657 Iowa Administrative Code ch. 43].

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 wholesale distribution in Michigan, among several other occupations. Wholesale distributor-brokers serve the same function as third-party logistics providers. In Michigan, wholesale distributor-brokers are required to be licensed and must designate a facility manager or pharmacist-in-charge to be responsible for each site [Michigan Compiled Laws s. 333.17748].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice and wholesale distribution in Minnesota. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes licensure requirements for third-party logistics providers. In Minnesota, the facility manager or designated representative responsible for each third-party logistic provider license cannot have any felony convictions relating to wholesale distribution and

must be fingerprinted as authorized by the Minnesota Board. [Minnesota Statutes s. 151.471].

**Summary of factual data and analytical methodologies:** The Board reviewed the statutory changes from 2021 Wisconsin Act 25 and added to the Wisconsin Administrative Code accordingly.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis: The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

**Fiscal Estimate and Economic Impact Analysis:** The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

**Effect on small business:** These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

#### Agency contact person:

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

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### **TEXT OF RULE**

SECTION 1. Chapter Phar 18 is created to read:

### CHAPTER PHAR 18 THIRD-PARTY LOGISTICS PROVIDERS

**Phar 18.01 Authority.** The rules in this chapter are adopted pursuant to the authority delegated by ss. 15.08 (5) (b), 450.02 (3), and 450.075 (4), Stats.

Phar 18.02 Definitions. In this chapter:

- (1) "Designated representative" means an individual who functions on behalf of a third-party logistics provider or an out-of-state third-party logistic provider as specified in Phar 18.05.
- (2) "Facility" has the meaning given in s. 450.01 (11m), Stats.
- (3) "Out-of-state third-party logistics provider" has the meaning given s. 450.01 (13w), Stats.
- (4) "Third-party logistics provider" has the meaning given in s. 450.01 (21s), Stats.

#### Phar 18.03 Licensure, Renewal, and Reinstatement.

- (1) LICENSE ALLOWED. A person acting as a third-party logistics provider or an out-ofstate third-party logistics provider of any drug or device may apply to obtain a license from the board.
- (2) LICENSURE. Except as provided under Phar 18.03 (4), the board shall grant a license to operate as a third-party logistics provider or out-of-state third-party logistics provider, to any applicant that satisfies all of the following requirements, as determined by the Board:
  - (a) The applicant shall submit all of the following:
    - A completed application form.
       Note: Application forms are available from the department of safety and professional services' website at <a href="http://dsps.wi.gov">http://dsps.wi.gov</a>.
    - 2. The fee specified in s. 440.05, Stats.
    - 3. All of the following information relating to a designated representative:
      - a. Name, address, and telephone number
      - b. Date and place of birth
      - c. A photograph of the person taken within the 12-month period immediately preceding the date of the application
      - d. A personal information statement that includes all of the following for the 7-year period immediately preceding the application:
        - i. Place of residence
        - ii. Occupations, positions of employment, and offices held
        - iii. The name and addresses for each business, corporation or entity listed in subs. ii.
        - iv. Whether the person has been the subject of any proceeding for the revocation of any business or professional licensure and the disposition of that proceeding.
        - Whether the person has been enjoined by a court, either temporarily
          or permanently, from possessing, controlling, or distributing any
          prescription drug, and a description of the circumstances
          surrounding the injunction
        - vi. A description of any involvement with any business, including investments other than the ownership of stock in a publicly traded

- company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and list of any lawsuits in which such a business was names as a party.
- e. A description of any misdemeanor or felony criminal offense of which the person was, as an adult, found guilty, whether adjudication of guilt was withheld, or the person pleaded guilty or no contest. If the person is appealing a criminal conviction, the application shall include a copy of the notice of appeal, and the person shall submit a copy of the final disposition of the appeal not more than 15 days after a final disposition is reached.
- f. Verification that the requirements in Phar 18.05 (1) have been met.
- 4. A statement that each facility used by the applicant for third-party logistics provider services has been inspected in the 3-year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each such inspection.
- **(b)** Subject to ss. 111.321, 111.322, and 111.335, Stats., the applicant does not have an arrest or conviction record.
- (c) Where operations are conducted at more than one facility, a person acting as a third-party logistics provider or out-of-state logistics provider may apply for a license for each such facility.
- (3) RENEWAL. (a) Each license shall be renewed biennially. The renewal date and fee are specified by s. 440.08 (2), Stats.
  - **(b)** Every even-numbered year, each license shall complete a renewal application and return it with the required fee prior to July 1 of that year.
    - Note: Instructions for renewal applications can be found on the department of safety and professional services' website at <a href="http://dsps.wi.gov">http://dsps.wi.gov</a>.
- (4) REINSTATEMENT. A licensee who has unmet disciplinary requirements and failed to renew the license within 5 years or whose license has been surrendered or revoked may apply to have the license reinstated in accordance with all of the following:
  - (a) Evidence of completion of the requirements in Phar 18.03 (2) if the license has not been active within 5 years.
  - **(b)** Evidence of completion of disciplinary requirements, if applicable.
  - (c) Evidence of rehabilitation or change in circumstances warranting reinstatement.

**Phar 18.04 Inspections.** A third-party logistics provider or out-of-state third-party logistics provider licensed under this chapter shall permit the board or its authorized representatives and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written

operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to the third-party logistics provider or out-of-state third-party logistics provider's premises and delivery vehicles.

**Phar 18.05 Responsible Persons. (1)** DESIGNATED REPRESENTATIVE. The individual acting as the designated representative for a third-party logistics provider or an out-of-state third-party logistics provider shall meet all of the following requirements:

- (a) Be at least 21 years old
- (b) Has been employed full-time for at least three years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing of and distribution of, and recordkeeping related to, prescription drugs.
- (c) Is employed full-time in a managerial position
- (d) Is physically present at the third-party logistics provider's or out-of-state third-party logistics provider's facility during regular business hours This subsection does not preclude the person from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.
- **(e)** Is actively involved in and aware of the daily operation of the third-party logistics provider or the out-of-state third-party logistics provider.
- **(f)** Is a designated representative for only one applicant at any given time. This subsection does not apply if more than one third-party logistics provider or out-of-state third-party logistics provider is located at the facility and the third-party logistics provider or out-of-state third-party logistics providers located at the facility are members of an affiliated group.
- (g) Have not been convicted of violating any federal, state, or local law relating to distribution of a controlled substance.
- (h) Has not been convicted of a felony
- (i) Submits to the department 2 fingerprint cards, each bearing a complete set of the person's fingerprints. The department of justice shall provide for the submission of the fingerprint cards to the federal bureau of investigation for purposes of verifying the identity of the person and obtaining the person's criminal arrest and conviction record.
- (2) OFFICERS, DIRECTORS AND MANAGERS. A third-party logistics provider or out-of-state third-party logistics provider licensed under this chapter shall maintain a list of officers, directors, and managers, including a description of their duties and a summary of their qualifications.

**Phar 18.06 Facility and Storage Requirements.** All facilities licensed as third-party logistics providers or out-of-state third-party logistics providers shall ensure the following:

- (1) Maintain access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;
- (2) Have written policies and procedures for all of the following:

Commented [HN-D1]: From 21 USC s. 360eee-3 21 U.S. Code § 360eee-3 - National standards for thirdparty logistics providers | U.S. Code | US Law | LII / Legal Information Institute (cornell.edu)

**Commented [HN-D2R1]:** Additional requirements from Phar 13.09 cannot be added per 2021 WI Act 25 section 8 (4)

- (a) Address receipt, security, storage, inventory, shipment, and distribution of a product;
- **(b)** Identify, record, and report confirmed losses or thefts;
- (c) Correct errors and inaccuracies in inventories;
- (d) Provide support for manufacturer recalls;
- (e) Prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;
- (f) Ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;
- (g) Maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and
- (h) Quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

Phar 18.07 Security Requirements. All facilities shall require the following:

- (1) Access from outside the premises is kept to a minimum and is well controlled;
- (2) The outside perimeter of the premises is well lighted;
- (3) Entry into areas where prescription drugs are held is limited to authorized personnel;
- (4) An alarm system is maintained to detect entry after hours; and
- (5) A security system is maintained that will provide suitable protection against theft and diversion, including, when appropriate, a system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

**Phar 18.08 Compliance.** A licensee who fails to comply with all applicable federal and state laws and regulations shall be subject to disciplinary action by the board under s. 450.10, Stats.

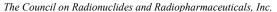
SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF	TEXT OF RULE)	

**Commented [HN-D3]:** Includes compliance with federal DSCSA











September 12, 2022

BY EMAIL: dsps@wisconsin.gov

Brad Wojciechowski
Executive Director
Department of Safety and Professional Services
Wisconsin Pharmacy Examining Board
P.O. Box 8366
Madison, WI 53708

Re: <u>USP General Chapter <825></u>

Dear Mr. Wojciechowski:

We are writing on behalf of the American Pharmacists Association, the Council on Radionuclides and Radiopharmaceuticals, Inc., the National Association of Nuclear Pharmacies, and the Society of Nuclear Medicine and Molecular Imaging to ask the Wisconsin Pharmacy Examining Board to adopt USP General Chapter <825>, "Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging." Our four industry and professional organizations together represent the major stakeholders in radiopharmaceutical manufacturing, nuclear pharmacy practice, and nuclear medicine practice in the U.S.

As you may know, General Chapter <825> is the first nationally applicable compendial standard for radiopharmaceutical preparation and compounding. This chapter was necessary to remedy the failure of General Chapter <797> (Pharmaceutical Compounding – Sterile Preparations) to address the unique challenges presented by radiopharmaceuticals, which require not only aseptic handling, but also radiation safety practices and attention to the abbreviated shelf-lives of these products. General Chapter <825> became official on December 1, 2020. However, it is considered merely

<sup>&</sup>lt;sup>1</sup> A copy of General Chapter <825> can be downloaded from the USP web site here.

informational until the finalization of USP General Chapters <795> and <797>, on pharmaceutical compounding of non-sterile and sterile preparations, respectively, both of which contain references to General Chapter <825>. When General Chapters <795> and <797> become official, General Chapter <825> will then also become compendial. General Chapters <795> and <797> are expected to be published later in this year, and will most likely have a six-month implementation period before they become official. Of course, states are free to adopt General Chapter <825> early, as USP has encouraged them to do. To date, seven states and the District of Columbia have adopted General Chapter <825>.²

We strongly recommend that the Wisconsin Pharmacy Examining Board adopt General Chapter <825> at the earliest possible time – before it becomes compendial if possible, but if not, as soon as practicable afterward. As you know, pharmacies play a much larger role in the preparation of radiopharmaceuticals than conventional drugs. Unlike conventional drugs, radiopharmaceuticals must, at the very least, be dispensed as sterile, ready for administration, patient doses by the nuclear pharmacy, and usually the nuclear pharmacy also plays a major role in preparing and radiolabeling the drug so that it is in usable form. All of this must be done in a manner that protects nuclear pharmacy personnel and health care workers from radiation exposure. The outsized role of nuclear pharmacies in the preparation of usable radiopharmaceuticals gives General Chapter <825> unusual importance among pharmacy standards. The General Chapter ensures the safety, efficacy, integrity, and quality of radiopharmaceuticals by establishing facility and engineering controls, equipment, personnel training and qualifications, and procedural standards for processing radiopharmaceuticals. It also sets forth radiation safety standards to protect the nuclear pharmacy personnel engaged in these activities. For sterile preparations, which comprise the great majority of radiopharmaceuticals, the standards also ensure aseptic handling practices to protect the safety of patients. Chapter <825> is the standard written specifically for our industry and is state of the art. The sooner it is adopted and implemented by all states, the better and more consistent will be nuclear pharmacy practice, and the safer will be nuclear pharmacy personnel.

Another reason for our urgency in requesting your state's prompt adoption of General Chapter <825> is that state standards for nuclear pharmacy practice, and for inspection of nuclear pharmacies, have become not only inconsistent among states, but also confusing within particular states. In certain states, nuclear pharmacy inspectors are unsure whether to enforce the old General Chapter <797>, new General Chapter <825>, or state-specific standards that are different from all of these. As a result, within a single state, different nuclear pharmacies are being held to different standards by different inspectors. The problem of inconsistent standards is

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<sup>&</sup>lt;sup>2</sup> The states are Connecticut, Iowa, Kentucky, Mississippi, New Mexico, Ohio, Washington, and the District of Columbia. In addition, 10 states are currently discussing adoption of General Chapter <825>: California, Idaho, Louisiana, Maine, New Jersey, New Mexico, South Dakota, Utah, Vermont, and Wyoming.

magnified for nuclear pharmacy providers that operate in multiple states.

We recognize that Wisconsin will need time to incorporate General Chapter <825> into its pharmacy regulations and/or policies, which is all the more reason to start the process now. We urge you to take the necessary steps to promptly adopt General Chapter <825> in Wisconsin. For your convenience, we have attached a simple model regulation that can be used to incorporate General Chapter <825> into Wisconsin's pharmacy regulations.

Please do not hesitate to contact Michael Guastella at <u>michael.guastella@corar.org</u> if you have any questions about our request.

Sincerely,



Nuclear Special Interest Group Coordinator

Michael Justella

The American Pharmacist Association

(APhA) Nuclear Pharmacy Practice SIG

Michael J. Guastella, MS, MBA

**Executive Director** 

Council on Radionuclides and Radiopharmaceuticals, Inc.

Jeff Norenberg, RPh, PharmD, PhD

**Executive Director** 

National Association of Nuclear Pharmacies

Munir Ghesani, MD, FACNM, FACR

Munit ahedani

President

Society of Nuclear Medicine and Molecular Imaging

### ATTACHMENT

### **Model Pharmacy Regulation**

(x) A nuclear pharmacy engaged in the preparation, compounding, dispensing, or repackaging of radiopharmaceuticals for human or veterinary use shall comply with United States Pharmacopeia (USP) General Chapter <825>, entitled "Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging".

## Pharmacy Examining Board Rule Projects (updated 10/24/22)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	052-22	12/27/2024	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Drafting of Emergency Rules	Board Approval of Emergency Rules for Submission to the Governor's Office and Publication
Not Assigned Yet	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Emergency Rule Effective on 11/01/22	Public Hearing for Emergency Rule at 12/01/22 Meeting
Not Assigned Yet	137-20	4/19/2023	Phar 1, 6, 7, 8, 12, 13	Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors	Drafting	Board Review and Approve for Posting for EIA Comments and Submission to Clearinghouse
21-074	079-20	12/22/2022	Phar 5, 6, 7, 11, 12	Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction	Incorporation of Standards Letter Pending Attorney General Approval	Submission of Final Rule Draft and Legislative Report to the Governor's Office for Approval
Not Assigned Yet	102-21	05/01/2024	Phar 7 and 10	Consumer Disclosures	Ready for EIA Comment Posting and Fiscal Estimate	Submission to Clearinghouse
Not Assigned Yet	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Board Review of Preliminary Rule Draft at 11/03/22 Meeting	Posting for EIA Comment and Submission to Clearinghouse

1) Name and title of pers	son subm	itting the request:		2) Date when request submitted:		
Brad Wojciechowski, on behalf of Chairperson John			1	10/24/2022		
Weitekamp				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, Comi	mittee, Co	ouncil, Sections:		deadine date which	it is a business days before the meeting	
Pharmacy Examining Bo	oard					
4) Meeting Date:	5) Attac	chments:	6) How	should the item be tit	tled on the agenda page?	
11/03/2022	⊠ Ye	es	Implement 2021 Wisconsin Act 9 – 100 Most Prescribed Drugs – Discuss			
			and Consideration			
7) Place Item in:		8) Is an appearan scheduled? (If ye.			9) Name of Case Advisor(s), if applicable:	
		Appearance Requi			<pre><click add="" advisor="" case="" here="" name="" or<br="" to="">N/A&gt;</click></pre>	
☐ Closed Session		☐ Yes <appear< td=""><td>rance Nar</td><td>me(s)&gt;</td><td>N/A&gt;</td></appear<>	rance Nar	me(s)>	N/A>	
		⊠ No		(0)		
10) Describe the issue a	nd action	that should be add	dressed:			
Review of 2022 Most Pro	escribed	Drugs List				
11)			Authoriza	tion		
SIAMIN					10/24/2022	
Signature of person ma	king this	request			Date	
Supervisor (Only required for post agenda deadline items)			Date			
Executive Director signs	ature (Ind	icates approval for	post age	nda deadline items)	Date	
Directions for including						
1. This form should be						
					y Development Executive Director. e to the Bureau Assistant prior to the start of a	
meeting						

### \*\*\* PUBLIC NOTICE \*\*\*

Under Wis. Stats. s. 450.13 (5m) (a), the Pharmacist may substitute a less expensive drug product equivalent, unless the consumer or prescribing practitioner have indicated otherwise.

### \*\*\* PUBLIC NOTICE \*\*\*

Under Wis. Stats. s. 450.135 (8m), the Pharmacist may substitute a less expensive interchangable biological product, unless the consumer or prescribing practitioner have indicated otherwise. The public may access a full list of interchangeable biological products that have been approved by the Food and Drug Administration (FDA) here: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information.

### \*\*\* PUBLIC NOTICE \*\*\*

Under Wis. Stats. s. 450.13 (5m) (b), each pharmacy must provide notice to the public on how it may access the Pharmacy Examining Board's list of the 100 most commonly prescribed generic drug product equivalents. The public may access this list here: https://dsps.wi.gov/Pages/BoardsCouncils/Pharmacy/Default.aspx

## **TOP 100 DRUGS A TO Z BRAND NAME**

<b>BRAND NAME</b>	DRUG GENERIC NAME	QUANTITY
ABILIFY	ARIPIPRAZOLE 10MG TAB	30
ACTOS	PIOGLITAZONE 15MG TAB	30
ACTOS	PIOGLITAZONE 30MG TAB	30
ADVAIR DISKUS	FLUTICASONE PROPIONATE/SALMETEROL DISKUS	60
AMARYL	GLIMEPIRIDE 2MG TAB	30
AMOXIL	AMOXICILLIN 500MG CAP	30
ARICEPT	DONEPEZIL 5MG TAB	30
AUGMENTIN	AMOX TR-K CLAV 875-125 MG TAB	20
AVAPRO	IRBESARTAN 150MG	30
BACTRIM DS	SULFAMETH/TRIMETH DS TAB	20
BACTROBAN	MUPIROCIN OINTMENT	22 GRAM
BENICAR	OLMESARTAN 20MG TAB	30
CATAPRES	CLONIDINE 0.1MG TAB	90
CELEBREX	CELECOXIB 200MG CAP	30

CELEXA	CITALOPRAM 20MG TAB	30
CIPRO	CIPROFLOXACIN 500MG TAB	20
COREG	CARVEDILOL 6.25MG TAB	60
COUMADIN	WARFARIN 5MG TAB	30
COZAAR	LOSARTAN 50MG TAB	30
CRESTOR	ROSUVASTATIN 10MG TAB	30
CYMBALTA	DULOXETINE 30MG CAP	30
DELTASONE	PREDNISONE 10MG TAB	30
DELTASONE	PREDNISONE 20MG TAB	30
DEPAKOTE	DIVALPROEX 500MG EC TAB	90
DESYREL	TRAZODONE 50MG TAB	30
DIFLUCAN	FLUCONAZOLE 150MG TAB	1
DILANTIN	PHENYTOIN SOD EXT 100 MG CAP	90
DIOVAN	VALSARTAN 80MG TAB	30
EFFEXOR XR	VENLAFAXINE XR 75MG CAP	30
FLAGYL	METRONIDAZOLE 500MG TAB	20
FLEXERIL	CYCLOBENZAPRINE 10MG TAB	30
FLOMAX	TAMSULOSIN 0.4MG CAP	30
FLONASE	FLUTICASONE 50MCG NASAL	16 GRAM
FLOVENT HFA	FLUTICASONE HFA 110MCG INHALER	12 GRAM
FOLVITE	FOLIC ACID 1MG TAB	30
FOSAMAX	ALENDRONATE 70MG TAB	4
GLUCOPHAGE	METFORMIN HCL 1,000 MG TABLET	60
GLUCOPHAGE	METFORMIN HCL 500 MG TABLET	60
GLUCOPHAGE XR	METFORMIN ER 500MG TAB	60
GLUCOTROL XL	GLIPIZIDE ER 10MG TAB	30
GLUCOTROL XL	GLIPIZIDE ER 5MG TAB	30
HYDRODIURIL	HYDROCHLOROTHIAZIDE 12.5MG CAP	30
HYDRODIURIL	HYDROCHLOROTHIAZIDE 25MG TAB	30
IMITREX	SUMATRIPTAN 100MG TAB	9
JANUVIA	SITAGLIPTAN 100MG TAB	30
K-DUR	POTASSIUM 20MEQ TAB	30

KEFLEX	CEPHALEXIN 500MG CAP	28
LAMICTAL	LAMOTRIGINE 25MG TAB	30
LAMISIL	TERBINAFINE 250MG TAB	30
LASIX	FUROSEMIDE 20MG TAB	30
LASIX	FUROSEMIDE 40MG TAB	30
LEXAPRO	ESCITALOPRAM 10MG TAB	30
LIPITOR	ATORVASTATIN 10MG TAB	30
LIPITOR	ATORVASTATIN 20MG TAB	30
LOPRESSOR	METOPROLOL 50MG TAB	60
LYRICA	PREGABALIN 50MG CAP	60
MACROBID	NITROFURANTOIN MONO 100MG CAP	14
MAXZIDE	TRIAMTERENE/HCTZ 37.5MG TAB	30
MOBIC	MELOXICAM 15MG TAB	30
MOTRIN	IBUPROFEN 600MG TAB	90
MOTRIN	IBUPROFEN 800MG TAB	90
NAPROSYN	NAPROXEN 500MG TAB	60
NEURONTIN	GABAPENTIN 300MG CAP	90
NEXIUM	ESOMEPRAZOLE 40MG CAP	30
NORVASC	AMLODIPINE 10MG TAB	30
PAXIL	PAROXETINE 20MG TAB	30
PLAVIX	CLOPIDOGREL 75MG TAB	30
PRAVACHOL	PRAVASTATIN 20MG TAB	30
PRILOSEC	OMEPRAZOLE 20MG CAP	30
PROCARDIA XL	NIFEDIPINE ER 30MG TAB	30
PROSCAR	FINASTERIDE 5MG TAB	30
PROTONIX	PANTOPRAZOLE 40MG TAB	30
PROZAC	FLUOXETINE 20MG CAP	30
RISPERDAL	RISPERIDONE 1MG TAB	30
SEROQUEL	QUETIAPINE 100MG TAB	30
SINGULAIR	MONTELUKAST SOD 10 MG TABLET	30
SYNTHROID	LEVOTHYROXINE 100MCG	30
SYNTHROID	LEVOTHYROXINE 50MCG	30

TENORMIN	ATENOLOL 25MG TAB	30
TENORMIN	ATENOLOL 50MG TAB	30
TOPAMAX	TOPIRAMATE 50MG TAB	30
TOPROL XL	METOPROLOL XL 50MG TAB	30
TRICOR	FENOFIBRATE 145MG TAB	30
V CILLIN K	PENICILLIN -VK 500MG TAB	40
VALTREX	VALACYCLOIVIR 500MG TAB	30
VASOTEC	ENALAPRIL 10MG TAB	30
VENTOLIN INHALER	ALBUTEROL HFA INHALER	18 GRAM
VIBRAMYCIN	DOXYCYCLINE 100MG CAP	30
WELLBUTRIN SR	BUPROPION SR 150MG TAB	60
XALATAN	LATANOPROST 0.005% DROPS	2.5 ML
ZESTORETIC	LISINOPRIL/HCTZ 20/12.5MG	30
ZESTRIL	LISINOPRIL 10MG TAB	30
ZESTRIL	LISINOPRIL 20MG TAB	30
ZETIA	EZETIMIBE 10MG TAB	30
ZITHROMAX	AZITHROMYCIN 250MG TAB	6
ZOCOR	SIMVASTATIN 20MG TAB	30
ZOCOR	SIMVASTATIN 40MG TAB	30
ZOLOFT	SERTRALINE 100MG TAB	30
ZOLOFT	SERTRALINE 50MG TAB	30
ZYLOPRIM	ALLOPURINOL 100MG TAB	30
ZYPREXA	OLANZAPINE 5MG TAB	30
ZIFNEAM	OLANZAPINE SIVIG TAD	30