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

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

Tony Evers, Governor
Dawn B. Crim, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
June 16, 2022

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

AGENDA

11:00 A.M.

(OR IMMEDIATELY FOLLOWING THE PHARMACY RULES COMMITTEE)

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of April 28, 2022 (5-7)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Review of Liaisons and Alternates
3) Board Members – Term Expiration Dates
   a. Kleppin, Susan – 7/1/2025
   b. O'Hagan, Tiffany – 7/1/2024
   c. Peterangelo, Anthony – 7/1/2023
   d. Walsh, Michael – 7/1/2024
   e. Weiss, Shana – 7/1/2023
   f. Weitekamp, John – 7/1/2022
   g. Wilson, Christa – 7/1/2025

E. Quarterly Board Chair Connection Meeting Report – Discussion and Consideration

F. ePDMP Medication Submission Processes – Discussion and Consideration

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. Administrative Rule Matters – Discussion and Consideration (8)
1) Adoption Order:
   a. Phar 8, Relating to Requirements for Controlled Substances **(9-16)**

b. Phar 15, Relating to Compounding Pharmaceuticals **(17-23)**

2) Preliminary Rule Draft: Phar 7 and 10, Relating to Consumer Discloures **(24-27)**
3) Emergency Rule: Phar 18, Relating to Licensre of Third-Party Logistics Providers **(28-29)**
   a. 2021 Wisconsin Act 25 **(30-32)**
4) Pending or Possible Rulemaking Projects **(33-34)**

I. Legislative and Policy Matters – Discussion and Consideration

1) 2021 Wisconsin Act 100 – Registration of Pharmacy Technicians, Extending the Time Limit for Emergency Rule Procedures, Providing an Exemption from Emergency Rule Procedures, and Granting Rule-Making Authority
2) 2021 Wisconsin Act 9 – Pharmacy Benefit Managers, Prescription Drug Benefits, and Granting Rule-Making Authority

J. Education and Examination Matters- Discussion and Consideration

1) Multistate Pharmacy Jurisprudence Examination (MPJE) Update

K. Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration

1) Travel Report: 2022 NABP 118th Annual Meeting on May 19-21, 2022 in Phoenix, AZ – Tiffany O'Hagan & John Weitekamp
2) 2022 Annual Meeting: NABP/American Association of Colleges of Pharmacy (AACP) District IV – November 6-8, 2022 – Madison, WI

L. COVID-19 – Discussion and Consideration

M. Pilot Program Matters – Discussion and Consideration

N. 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

O. 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.).

P. Credentialing Matters

1) Application Reviews

a. Tara Fakrhi – Pharmacist Applicant **(35-54)**

Q. Deliberation on Division of Legal Services and Compliance Matters

1) Rescind and Reissue Administrative Warning

a. 21 PHM 014 – O. **(55-57)**

2) Administrative Warnings

a. 21 PHM 082 – N.B. **(58-59)**
b. 21 PHM 082 – W.J.H. **(60-61)**
c. 21 PHM 082 – W.P. **(62-63)**
d. 21 PHM 117 – S.K. **(64-65)**
e. 21 PHM 153 – B.G.K. **(66-67)**
f. 22 PHM 027 – A.H.G. **(68-70)**

3) Case Closings

a. 20 PHM 075 – M.C.P. **(71-74)**
b. 20 PHM 102 – A.P. **(75-87)**
c. 20 PHM 175, 20 PHM 176 – O. **(88-96)**
d. 21 PHM 015 – S. **(97-105)**
e. 21 PHM 071 – O. **(106-114)**
f. 21 PHM 095 – W. **(115-123)**
g. 21 PHM 098 – H.P. **(124-127)**
h. 21 PHM 153 – C.P. **(128-133)**
i. 22 PHM 026 – C.V.S. **(134-137)**
j. 22 PHM 043 – P.A.B. **(138-141)**

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: SEPTEMBER 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 at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the deaf or 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.

PHARMACY EXAMINING BOARD
MEETING MINUTES
APRIL 28, 2022

PRESENT: Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp, Michael Walsh, Shana Weiss *(excused at 11:49 a.m.)*, Christa Wilson

STAFF: Brad Wojciechowski, Executive Director; Jameson Whitney, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Katlin Schwartz, Bureau Assistant; Kimberly Wood, Program Assistant Supervisor-Adv.; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:12 a.m. A quorum was confirmed with seven(7) 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 MARCH 3, 2022

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to approve the Minutes of March 3, 2022 as published. Motion carried unanimously.

BOARD CHAIR MEETING AND OPTIONS TO ADDRESS DEPARTMENT RESOURCES

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to make sure that adequate resources are allocated to DSPS to process initial licensures, renewals, and updates in a timely manner. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Scope Statement

Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to approve the Scope Statement revising Phar 1, 5, 7, 10, and 19, relating to Registration of Pharmacy Technicians, 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 carried unanimously.

Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to designate the Chairperson to approve the Scope Statement revising Phar 1, 5, 6, 7, and 8, relating to Remote Dispensing, 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 carried unanimously.

Shana Weiss was excused at 11:49 a.m.

CLOSED SESSION

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to convene to Closed Session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). John Weitekamp, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Susan Kleppin-yes; Tiffany O'Hagan-yes; Anthony Peterangelo-yes; Michael Walsh-yes; John Weitekamp-yes; and Christa Wilson-yes. Motion carried unanimously.

The Board convened into Closed Session at 11:56 a.m.

REVIEW OF ADMINISTRATIVE WARNING

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to rescind the administrative warning issued on 1/27/2022 and to issue the revised administrative warning in the matter of B.A.P., DLSC Case Number 21 PHM 010. Motion carried unanimously.

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

Administrative Warnings

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to issue an Administrative Warning the following DLSC Cases:

a. 21 PHM 154 – R.A.H.
b. 21 PHM 159 – P.G.
c. 21 PHM 160 – C.M.P.

Motion carried unanimously.

Case Closings

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

1. 18 PHM 075, 19 PHM 058 – R.F.P.C. – No Violation
2. 20 PHM 149 – P.N.S. – Insufficient Evidence
3. 21 PHM 141 – U.C. – No Violation
4. 21 PHM 027 – W. – No Violation
5. 21 PHM 084 – W. – No Violation
6. 21 PHM 154 – W. – No Violation
7. 21 PHM 156 – G.H. – Prosecutorial Discretion (P2)
8. 21 PHM 159 – M.I.A., M.R.S. – No Violation
9. 22 PHM 014 – M.D. – No Violation

Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

18 PHM 075, 19 PHM 058, 19 PHM 163, 21 PHM 049 – Paul F. Corcoran, Jr., 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 Paul F. Corcoran, Jr., R.Ph., DLSC Case Number 18 PHM 075, 19 PHM 058, 19 PHM 163, 21 PHM 049. 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 1:08 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

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

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

ADJOURNMENT

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

The meeting adjourned at 1:09 p.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**06/03/22** Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
06/16/22	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. **Adoption Order:** a. **Phar 8, Relating to Requirements for Controlled Substances** b. **Phar 15, Relating to Compounding Pharmaceuticals** 2. **Preliminary Rule Draft: Phar 7 and 10, Relating to Consumer Disclosures** 3. **Emergency Rule: Phar 18, Relating to Licensure of Third-Party Logistics Providers** a. **2021 Wisconsin Act 25** 4. **Pending or Possible Rulemaking Projects**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	**N/A**

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

Attachments:
1. Phar 8 Adoption Order
2. Phar 15 Adoption Order
3. Phar 7 and 10 Preliminary Rule Draft
4. Phar 18 – Scope Statement
5. 2021 WI Act 25
6. Rule Projects Chart

Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

11) Authorization

Nilajah D. Hardin — 06/03/22

Signature of person making this request — **Date**

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — **Date**

Directions for including supporting documents:
1. **This form should be attached to any documents submitted to the agenda.**
2. **Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.**
3. **If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 21-071)

ORDER

An order of the Pharmacy Examining Board to repeal and recreate ch. Phar 8 relating to requirements for controlled substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.31, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.11 (1b) (a) 1, 450.02 (2), 450.02 (3) (a), (b) (d) and (e), 961.31, and 961.38 (2), Stats.

Explanation of agency authority:
Section 15.08 (5) (b) provides that the board "[s]hall 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 450.11 (1b) (a) 1 states ""Health care facility" means a facility, as defined in s. 647.01 (4); any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10; and any other facility identified by the board by rule."

Section 450.02 (2) states 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) provides that "[t]he board may promulgate rules:
(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
(b) Establishing security standards for pharmacies.
…
(d) Necessary for the administration and enforcement of this chapter and ch. 961.
(e) Establishing minimum standards for the practice of pharmacy."

Section 961.31 gives the Pharmacy Examining Board authority to "promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state."

Section 961.38 (2) states that "In emergency situations, as defined by rule of the pharmacy examining board, schedule II drugs may be dispensed upon an oral prescription of a practitioner, reduced promptly to a written hard copy or electronic record and filed by the pharmacy. Prescriptions shall be retained in conformity with rules of the pharmacy examining board promulgated under s. 961.31. No prescription for a schedule II substance may be refilled."

Related statute or rule: N/A

Plain language analysis:
This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. The rule project simplifies recordkeeping requirements for controlled substances, removes restrictions on receipt of prescriptions via facsimile machine, partial dispensing, renewals, labeling, and emergency kits in long-term care facilities.

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: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.600 to 68/1330.800 outlines requirements for pharmacy standards and pharmacy operations. Illinois law requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA (IL 68/1330.710). Illinois administrative rule requires 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 (IAC 3100.360). Illinois 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. There does not appear to be a requirement that the prescriber follow up with a written prescription (IAC 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 (Iowa Admin. Code 657-10.36). Iowa also requires that pharmacies keep a perpetual inventory of all Schedule II drugs on hand (Iowa Admin. Code 657-10.18). 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 (Iowa Admin. Code 657-10.21). 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. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Iowa Admin. Code 657-10.26).

Michigan: Michigan requires theft or diversion of a controlled substance to be reported to the DEA within 10 days. There does not appear to be a separate requirement to report it to the Pharmacy Board (Mich. R 338.3141). Inventory must be taken of all controlled substances at least annually (Mich. R 338.3151 and 338.3152). Controlled substance records must be retained for at least 5 years, with the first 3 in hard copy form and in the last 2 may be kept electronically. 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. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Michigan R 338.3164 and 338.3165).

Minnesota: Minnesota requires a perpetual inventory of Schedule II substances which must be reconciled monthly (Minn. Admin. Code 6800.4600). Pharmacists must report loss or theft of controlled substances to the DEA immediately. There is no requirement that a separate report be made to the state (Minn. Admin. Code 6800.4800). All prescription information must be maintained for at least 2 years (Minn. Admin. Code 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.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact report:
The proposed rules were 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. 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8306; phone (608) 267-7139; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. Chapter Phar 8 is repealed and recreated to read:

Chapter Phar 8
REQUIREMENTS FOR CONTROLLED SUBSTANCES

Phar 8.01 Federal registration and compliance with federal, state, and local laws and regulations. (1) FEDERAL REGISTRATION REQUIRED. To possess, manufacture, distribute, dispense, or conduct research with controlled substances in this state, pharmacies and pharmacists shall register with the drug enforcement administration as required under federal law.
(2) CONTROLLED SUBSTANCES AUTHORIZATION UNDER FEDERAL REGISTRATION. As provided under s. 961.32 (1m) (a), Stats., pharmacies and pharmacists registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, and conduct research with those substances in this state to the extent authorized by their federal registration and in conformity with the provisions of ch. 961, Stats.
(3) COMPLIANCE WITH LAWS AND REGULATIONS. Failure to register with the drug enforcement administration or otherwise comply with applicable federal, state, and local laws and regulations relating to possessing, manufacturing, distributing, dispensing, or conducting research with controlled substances constitutes unprofessional conduct for purposes of s. 450.10, Stats.

Note: The United States Department of Justice Drug Enforcement Administration has published a pharmacist's manual, which provides an informational outline of the federal Controlled Substances Act. It can be found online at: https://www.deadiversion.usdoj.gov/pubs/manuals/index.html.

(4) EMERGENCY KITS IN LONG TERM CARE FACILITIES. Nothing in these rules shall prohibit long term care facilities from obtaining an emergency kit, from a DEA registered pharmacy, in compliance with federal law.

Phar 8.02 Purpose of issue of prescription order. Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

Phar 8.03 Valid prescription requirements. (1) A pharmacist may not dispense controlled substances for a prescription the pharmacist knows, or reasonably should know, is not a valid prescription under applicable federal, state, and local laws and regulations.
(2) An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid. A pharmacist knowingly dispensing pursuant to such a purported order, as well as the practitioner issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

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 information required to be provided in the notification to the drug enforcement administration.

Phar 8.05 Recordkeeping. (1) Records shall be maintained as required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats.
(2) The managing pharmacist shall oversee quarterly inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.

Phar 8.06 Identification card requirement under s. 450.11 (1b), Stats. (1) DEFINITION. In this section and s. 450.11 (1b) (e) 3., Stats., "health care facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community−based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.
(2) EXEMPTION. There shall be an exemption to the requirement for an identification card when the drug is lawfully delivered to the patient's home, or any address requested by the patient, through mail, common carrier or delivery service. A valid signature is required upon delivery.

Phar 8.07 Partial Dispensing. (1) A pharmacist may partially dispense a prescription containing a controlled substance listed in schedule III, IV and V.
(2) The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if one of the following conditions applies:

(a) If the pharmacist is unable to supply the full quantity called for in a written, electronic, or emergency oral prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written hard copy prescription order or written record of the electronic or emergency oral prescription order.
(b) If the patient requests partial dispensing.
(c) If the prescribing practitioner requests partial dispensing.

The remaining portion of any partially dispensed prescription under this section may be dispensed within 72 hours of the first partial dispensing. If the remaining portion is not dispensed within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.
(3) Prescription orders for schedule II controlled substances written for patients in long term care facilities (LTCF) or for patients with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities to include individual dosage units. The prescribing practitioner may document a terminal illness by writing upon the face of the prescription order the phrase "terminal illness" or words of similar meaning. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescribing practitioner prior to partially dispensing the prescription. Documentation of a terminal illness, whether substantiated by the presence of an appropriate phrase written upon the face of the prescription order or through pharmacist contact with the prescribing practitioner, shall be placed within the individual medication profile record maintained under s. Phar 7.07. The pharmacist shall record on the prescription order whether the patient is "terminally ill" or an "LTCF patient." A prescription order that is partially dispensed and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been dispensed in violation of this section. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription order or on another appropriate record, uniformly maintained and readily retrievable, the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. Subsequent partial dispensing is not permitted under this section if the patient becomes

deceased, or is no longer diagnosed as terminally ill, or no longer resides within an LTCF. The total quantity of a schedule II controlled substance dispensed by partial dispensing may not exceed the total quantity prescribed. Prescription orders for schedule II controlled substances for patients in an LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless terminated earlier by the discontinuance of medication.

(4) Information pertaining to current prescription orders for schedule II controlled substances for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

(a) Display or printout of: the original prescription order designation; date of issue; identification of prescribing practitioner; identification of patient; name and address of the LTCF or name and address of the hospital or residence of the patient; identification of medication authorized, including dosage form, strength and quantity; listing of partial quantities that have been dispensed under each prescription order and the information required in sub. (3).

(b) Immediate (real time) updating of the prescription order record each time there is partial dispensing of the prescription.

(c) Retrieval of partially dispensed schedule II prescription information identical to that required by s. Phar 7.05 (2) for all prescription renewal information.

Phar 8.08 Controlled substances in emergency kits for long term care facilities. Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances:

(1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.

(2) The pharmaceutical services committee of the facility shall establish security safeguards for each emergency kit stored in the LTCF which shall include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

(3) A pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.

(4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.

(5) Noncompliance with this rule may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.

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)

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 22-007)

ORDER

An order of the Pharmacy Examining Board to amend Phar 15.30 (11), (13), and (17), 15.33 (10), and 15.37 (1) (intro.), (c), and (d); create Phar 15.30 (10m), (14g) and (14r), and 15.37 (5), (6), and (7); and repeal and recreate Phar 15.34, relating to compounding pharmaceuticals.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.01 (16)

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

Explanation of agency authority:

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

The board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961 and establish minimum standards for the practice of pharmacy. [s. 450.02 (3) (d) and (e), Stats.]

Related statute or rule: N/A

Plain language analysis:

The objective of the rule is to review the updated United States Pharmacopeia (USP) 795 and 797 standards, which originally had a publication date of June 1, 2019 with an anticipated official date of December 1, 2019. However, due to appeals filed, the 2019 revisions of the USP are currently on hold. The 2008 USP 795 and 797 are the current standard for pharmacy compounding until those 2019 standards are published and effective.

Even though the Board will not be moving forward with the 2019 revisions at this time, there are still updates that need to be made to Phar 15 to align it with the 2008 USP 795 and 797 chapters that are currently in effect. It is the Board's intent to amend Phar 15 without creating an unnecessary burden on Wisconsin pharmacies, while still aligning it with the current USP chapters. When new updated standards are available, the Board will consider opening a new scope statement to address any further changes if applicable.

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

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

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

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: For patient-specific prescriptions, sterile and unsterile pharmaceutical compounding is governed by the USP 42-NF 37 from the 2019 USP Compounding Compendium, except for USP Chapter 800. Additionally, all pharmacies that compound drugs must maintain a set of minimum standards and equipment. These requirements include a specific area for compounding materials, accurate scales or measuring equipment, a separate area for compounding, a record keeping system for tracking compounded drugs, drug distribution procedures, and labelling. For non-patient specific or "office use" of non-sterile compounded drugs, additional requirements apply. Among them, retrievable records must be maintained for at least 5 years and specific labelling requirements for office use. Additional requirements for sterile compounding include current reference materials, pharmacist availability at all times to answer patient and health care professional questions, and emergency medications for adverse drug reactions to compounded sterile drugs. [Illinois Administrative Code s. 1330.640]

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. In addition, an FDA registered outsourcing facility must be licensed as a pharmacy in Iowa. [Iowa Administrative Code ss. 657.20.3, 657.20.4, and 657.20.6]

Michigan: Michigan requires a pharmacy that provides compounding services to be licensed as a pharmacy and authorized to provide compounding services. The pharmacy must be accredited through a national accrediting organization and be in compliance with USP standards. [Michigan Compiled Laws s. 333.17748]

Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow USP chapter 795 standards. Pharmacies compounding sterile drug preparations are required to follow USP chapter 797 standards. [Minnesota Administrative Rules s.6800.3300]

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board primarily utilized United States Pharmacopeia chapters 795 and 797 which are the recognized pharmacopeia standards.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact report:
The proposed rules were posted for a period of 30 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No economic impact 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 have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. and were submitted to the Small Business Regulatory Review Board for a determination on whether the rules will have a significant economic impact on a substantial number of small businesses. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

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

TEXT OF RULE

SECTION 1 Phar 15.30 (10m), (14g), and (14r) are created to read:

Phar 15.30 (10m) "High-risk level compounded sterile preparations" means preparations compounded from non-sterile ingredients or from ingredients that are incorporated using non-sterile equipment before terminal sterilization, or from commercially manufactured sterile products that lack effective antimicrobial preservatives and whose preparation, transfer, sterilization, and packaging is performed in air quality worse than ISO class 5 for more than one hour. High-risk level compounded sterile preparations include water containing preparations that are stored for more than six hours before terminal sterilization.

(14g) "Low-risk level compounded sterile preparations" means preparations compounded with aseptic manipulations entirely within ISO class 5 or better air quality using only sterile ingredients, products, components, and devices. The low-risk level sterile compounding process involves only transfer, measuring, and mixing, using no more than three commercially manufactured sterile products, and not more than two entries into one sterile container or package to make the compounded sterile preparations.

(14r) "Medium-risk level compounded sterile preparations" means preparations compounded under low-risk level conditions but which require multiple individual or small doses of sterile products to be combined or pooled to prepare compounded sterile preparations that will be administered either to multiple patients or to one patient on multiple occasions. The medium-risk level sterile compounding process includes complex aseptic manipulations other than single volume transfer, and requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

SECTION 2 Phar 15.30 (11), (13), and (17) are amended to read:

Phar 15.30 (11) "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 68 degrees to 77 degrees Fahrenheit <u>or 20 degrees to 25 degrees Celsius</u>.

(13) "Freezer" means a place in which the temperature is maintained between -13 degrees and 14 degrees Fahrenheit <u>or -25 degrees and -10 degrees Celsius</u>.

(17) "Refrigerator" means a cold place in which the temperature is maintained between 36 degrees and 46 degrees Fahrenheit <u>or 2 degrees and 8 degrees Celsius</u>.

SECTION 3 Phar 15.33 (10) is amended to read:

Phar 15.33 (10) Entry points on bags and vials shall be wiped with small sterile 70% isopropyl alcohol swabs or comparable method for disinfecting, allowing the isopropyl alcohol to dry before piercing stoppers with sterile needles and breaking necks of ~~ampuls~~ <u>ampules</u>. The surface of the sterile 70% isopropyl alcohol swabs used for disinfecting entry points of sterile package and devices may not contact any other object before contacting the surface of the entry point. Particle generating material may not be used to disinfect the sterile entry points of packages and devices.

SECTION 4 Phar 15.34 is repealed and recreated to read:

Phar 15.34 Immediate-use compounded sterile preparations. Immediate-use compounded sterile preparations are exempt from the requirements described for low-risk level, Category 1, and Category 2 compounding sterile preparations only when all the following criteria are met:

(1) The compounding process involves simple transfer of not more than three commercially manufactured sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or product of sterile infusion solution or administration container or device.

(2) Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.

(3) During preparation, aseptic technique is followed and, if not immediately administered, the finished compound sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compound sterile preparations, and direct contact of outside surfaces.

(4) Administration begins not later than 4 hours following the start of the preparation.

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

(6) If administration of the compounded sterile preparation has not begun within 4 hours following the start of preparation, it shall be promptly, properly, and safely discarded.

SECTION 5 Phar 15.37 (1) (intro.), (c), and (d) are amended to read:

Phar 15.37 (1) Sterility and stability considerations shall be taken into account when establishing a BUD. Either Category 1 and 2, or low, medium, and high-risk compounding preparation standards may be used, but not a combination of the two within the same pharmacy. The following dates and times for storage and initiation of administration of the compounded sterile preparations shall apply:

(c) For aseptically processed Category 2 ~~compounded~~ processed sterile preparations, one of the following:

1. ~~Prepared~~ No sterility testing performed or sterility testing not passed, and prepared with one or more nonsterile ~~ingredients~~ starting components, ~~which are sterilized with a validated sterilization procedure prior to compounding no preservative added and no sterility testing performed~~ one of the following:

a. Within ~~4 days~~ 1 day when the preparation is stored at controlled room temperature.

b. Within ~~7~~ 4 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

2. ~~Prepared only with sterile ingredients, no preservative added and no~~ No sterility testing performed or sterility testing not passed, and prepared with only sterile starting components, one of the following:

a. Within ~~6~~ 4 days when the preparation is stored at controlled room temperature.
b. Within ~~9~~ 10 days when the preparation is stored in a refrigerator.
c. Within 45 days when the preparation is stored in a freezer.

3. ~~Prepared only with sterile ingredients, preservative added and no sterility~~ Sterility testing performed and passed, one of the following:
a. Within ~~28~~ 30 days when the preparation is stored at controlled room temperature.
b. Within ~~42~~ 45 days when the preparation is stored in a refrigerator.
c. Within ~~45~~ 60 days when the preparation is stored in a freezer.

~~4. Prepared only with sterile ingredients, no preservative added and sterility testing, one of the following:~~
~~a. Within 28 days when the preparation is stored at controlled room temperature.~~
~~b. Within 42 days when the preparation is stored in a refrigerator.~~
~~c. Within 45 days when the preparation is stored in a freezer.~~

~~5. Prepared only with sterile ingredients, preservative added and sterility testing, one of the following:~~
~~a. Within 42 days when the preparation is stored at controlled room temperature.~~
~~b. Within 42 days when the preparation is stored in a refrigerator.~~
~~c. Within 45 days when the preparation is stored in a freezer.~~

(d) For Category 2 compounded sterile preparations, terminally sterilized by a validated procedure, one of the following:

1. ~~Prepared with no preservative and no~~ No sterility testing performed or sterility testing not passed, one of the following:
a. Within 14 days when the preparation is stored at controlled room temperature.
b. Within 28 days when the preparation is stored in a refrigerator.
c. Within 45 days when the preparation is stored in a freezer.

2. ~~Prepared with no preservative added and sterility~~ Sterility testing performed and passed, one of the following:
a. Within ~~28~~ 45 days when the preparation is stored at controlled room temperature.
b. Within ~~42~~ 60 days when the preparation is stored in a refrigerator.
c. Within ~~45~~ 90 days when the preparation is stored in a freezer.

~~3. Prepared with preservative added and no sterility testing performed, one of the following:~~
~~a. Within 28 days when the preparation is stored at controlled room temperature.~~
~~b. Within 42 days when the preparation is stored in a refrigerator.~~
~~c. Within 45 days when the preparation is stored in a freezer.~~

~~4. Prepared with preservative added and sterility testing performed, one of the following:~~
~~a. Within 42 days when the preparation is stored at controlled room temperature.~~
~~b. Within 42 days when the preparation is stored in a refrigerator.~~
~~c. Within 45 days when the preparation is stored in a freezer.~~

SECTION 6 Phar 15.37 (5), (6), and (7) are created to read:

Phar 15.37 (5) For low-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 48 hours when the preparation is stored at controlled room temperature.

(b) Within 14 days when the preparation is stored in a refrigerator.

(c) Within 45 days when the preparation is stored in a freezer.

(d) For products prepared in an airflow workbench not located in a buffer area, administration shall begin within 12 hours or less of preparation.

(6) For medium-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) within 30 hours when the preparation is stored at controlled room temperature.

(b) within nine days when the preparation is stored in a refrigerator.

(c) within 45 days when the preparation is stored in a freezer.

(7) For high-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 24 hours when the preparation is stored at controlled room temperature.

(b) Within three days when the preparation is stored in a refrigerator.

(c) Within 45 days when the preparation is stored in a freezer.

SECTION 7 EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to **create** Phar 7.15, 10.03 (20), and 10.03 (21), relating to consumer disclosures.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 15.08 (5) (b), 450.013 (5m), 450.013 (8m), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), 450.02 (3) (d), and 450.02 (3) (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 9

Plain language analysis: The objective of the proposed rule is to revise the Pharmacy administrative code, including but not necessarily limited to chs. Phar 7 and 10, to bring the code into compliance with current statutory provisions as modified by 2021 Wisconsin Act 9.

The Pharmacy Examining Board is required under Act 9 to create and maintain a list of the 100 most commonly prescribed generic drug product equivalents, including the generic and brand name of the drug, which shall be made available to each pharmacy on an annual basis either directly or on the board's website.

Act 9 created several new requirements for pharmacies as well. A pharmacy must make available to the public information on how to access the list of 100 most commonly prescribed generic drug product equivalents maintained by the Pharmacy Examining Board. Pharmacies also must make available to the public information on how to access the FDA's list of all currently approved interchangeable biological products. Finally, a pharmacy must maintain disclosures to the public in a conspicuous place near where drugs are dispensed regarding the ability of a pharmacist to substitute a less expensive drug or interchangeable biological product.

Summary of, and comparison with, existing or proposed federal regulation: Federal Regulations part: 21 CFR Subchapter D covers regulations for the FDA on Drugs for Human Use.

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation (IDFPR) under the State Board of Pharmacy, regulates pharmacists. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Illinois Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Iowa: Iowa pharmacists are regulated by the Board of Pharmacists. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Iowa Board of Pharmacists is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Michigan: The Michigan Department of Licensing and Regulatory Affairs (MDLRA) regulates pharmacists under the authority of the Michigan Board of Pharmacy. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Michigan Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Minnesota: In Minnesota, pharmacists are regulated by the Minnesota Department of Health, with input from the Minnesota Board of Pharmacy. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Minnesota Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Summary of factual data and analytical methodologies:
The proposed rules were developed by reviewing the current federal food and drug-approved interchangeable biological products; technical information provided by the American Pharmacists Association (APhA), and 2021Wisconsin Act 9, relating to pharmacy benefit managers, prescription drug benefits, and granting rule-making authority.

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

The rule will be 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.

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

Effect on small business:

These rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator, Dan Hereth, may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 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 a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.15 is created to read:

Phar 7.15 Consumer Disclosures.

(1) Each pharmacy shall post in a prominent place and maintain the consumer disclosures required in ss. 450.13 (5m) (b) and 450.13 (8m), Stats.

(2) The Board shall maintain a link to the 100 most commonly prescribed generic drug product equivalents on the Department website as required in s.450.13 (5m) (b), Stats.

Note: Copies of the required consumer disclosures are located on the Department of Safety and Professional Service's website: https://dsps.wi.gov

(3) Pursuant to s. 450.13 (5m) (c), Stats., each pharmacy shall have a list, available to the public, of the 100 most commonly prescribed drugs available for purchase and updated monthly, with all of the following information included:

(a) brand name
(b) generic equivalent drugs and biological products
(c) interchangeable biological products
(d) retail price

(4) The list required under Phar 7.15 (3) may differ depending on

SECTION 2. Phar 10.03 (20) and (21) are created to read:

Phar 10.03 (20) Violating or attempting to violate any provision or term of ch. 450, Stats., or of any valid rule of the board.

Phar 10.03 (21) Failure to comply with ss 450.013 (5m) or 450.013 (8m), Stats.

SECTION 3. 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)

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 18

Relating to: Licensure of third-party logistics providers.

Rule Type: Permanent and Emergency

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

2021 Act 25, Section 9 (1) provides:

"The pharmacy examining board may promulgate emergency rules under s. 227.24 implementing s. 450.075. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until June 30, 2023, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 227.24 (1) (a) and (3), the board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection."

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

The objective of the proposed rule is to revise the Pharmacy administrative code consistent with 2021 Act 25 to provide criteria for the Wisconsin licensure of third-party logistics providers.

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

The Board intends to update the Pharmacy code to bring it into alignment with the statutory provisions enacted by 2021 Act 25 relating to licensure of third-party logistics providers.

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

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."

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

Approximately 100 hours.

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

Pharmacies, pharmacists, licensed third-party logistics providers, those seeking licensure as a third-party logistics provider, and consumers of pharmaceuticals.

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

The rules will comply with the federal drug supply chain security act, 21 USC 360eee, et seq., which establishes national standards for third-party logistics providers.

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

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

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

Approved for publication:

Authorized Signature

9/3/2021

Date Submitted

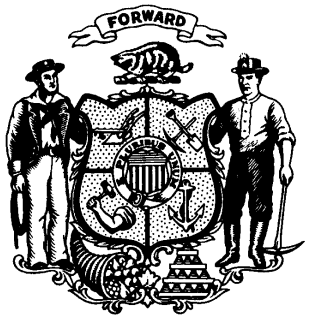
Approved for implementation:

Authorized Signature

1/19/2022

Date Submitted

State of Wisconsin



Date of enactment: **April 15, 2021**
2021 Assembly Bill 120 Date of publication*: **April 16, 2021**

2021 WISCONSIN ACT 25

AN ACT ***to amend*** 440.15, 450.01 (11m), 450.01 (21s) and 450.02 (1); and ***to create*** 440.08 (2) (a) 69g., 450.01 (13w), 450.01 (23) (p) and 450.075 of the statutes; **relating to:** third−party logistics providers, extending the time limit for emergency rule procedures, providing an exemption from emergency rule procedures, and granting rule−making authority.

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

SECTION 1. 440.08 (2) (a) 69g. of the statutes is created to read:

440.08 **(2)** (a) 69g. Third−party logistics provider: July 1 of each even−numbered year.

SECTION 2. 440.15 of the statutes is amended to read:

440.15 No fingerprinting. Except as provided under ss. 440.03 (13) (c), 441.51 (5) (a) 5., 448.980 (5) (b) 3., ~~and~~ 448.985 (3) (a) 4., 450.071 (3) (c) 9., and 450.075 (3) (c) 9., the department or a credentialing board may not require that an applicant for a credential or a credential holder be fingerprinted or submit fingerprints in connection with the department's or the credentialing board's credentialing.

SECTION 3. 450.01 (11m) of the statutes is amended to read:

450.01 **(11m)** "Facility" means a location where a wholesale distributor or 3rd−party logistics provider stores, distributes, handles, repackages, or offers ~~for sale~~ other services related to prescription drugs.

SECTION 4. 450.01 (13w) of the statutes is created to read:

450.01 **(13w)** "Out−of−state 3rd−party logistics provider" means a person located outside this state that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services within this state on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

SECTION 5. 450.01 (21s) of the statutes is amended to read:

450.01 **(21s)** "~~Third party~~ Third−party logistics provider" means a person that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

SECTION 6. 450.01 (23) (p) of the statutes is created to read:

450.01 **(23)** (p) The services of a 3rd−party logistics provider or out−of−state 3rd−party logistics provider.

SECTION 7. 450.02 (1) of the statutes is amended to read:

450.02 **(1)** The department shall keep a record of the proceedings and a register of the names and places of practice or business of pharmacies, manufacturers, wholesale distributors, 3rd−party logistics providers,

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

out–of–state 3rd–party logistics providers, and other persons licensed under this chapter, and the books, registers and records of the department shall be prima facie evidence of the matters recorded.

Section 8. 450.075 of the statutes is created to read:

450.075 Third–party logistics providers; licensure. (1) License allowed. A person acting as a 3rd–party logistics provider or an out–of–state 3rd–party logistics provider of any drug or device may apply to obtain a license from the board under this section. Where operations are conducted at more than one facility, a person acting as a 3rd–party logistics provider or out–of–state 3rd–party logistics provider may apply to obtain a license from the board for each such facility.

(2) Application. An applicant for a license under this section shall submit a form provided by the board showing all of the following and swear or affirm the truthfulness of each item in the application:

(a) The name, business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) Names, addresses, and telephone numbers of contact persons for all facilities used by the applicant for the warehousing, distribution, or other services on behalf of the manufacturer of prescription drugs.

(d) The type of ownership or operation for the applicant's business.

(e) If the applicant's 3rd–party logistics provider business is a partnership, the name of each partner and the name of the partnership.

(f) If the applicant's 3rd–party logistics provider business is a corporation, the name of each corporate officer and director, the name of the corporation, and the state of incorporation.

(g) If the applicant's 3rd–party logistics provider business is a sole proprietorship, the name of the sole proprietor and the name of the business entity.

(h) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to warehouse or distribute prescription drugs.

(i) The name, address, and telephone number of a designated representative.

(j) For the person identified as the designated representative in par. (i), a personal information statement that contains all of the following:

1. The person's date and place of birth.

2. The person's place of residence for the 7–year period immediately preceding the date of the application.

3. The person's occupations, positions of employment, and offices held during the 7–year period immediately preceding the date of the application.

4. The name and addresses for each business, corporation, or other entity listed in subd. 3.

5. A statement indicating whether the person has been, during the 7–year period immediately preceding the date of the application, the subject of any proceeding for the revocation of any business or professional license and the disposition of the proceeding.

6. A statement indicating whether the person has been, during the 7–year period immediately preceding the date of the application, 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.

7. A description of any involvement by the person during the past 7 years 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 a list of any lawsuits in which such a business was named as a party.

8. 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.

9. A photograph of the person taken within the 12–month period immediately preceding the date of the application.

(k) A statement that each facility used by the applicant for 3rd–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.

(3) Licensure. The board shall grant a license to an applicant to act as a 3rd–party logistics provider or an out–of–state 3rd–party logistics provider if all of the following apply:

(a) The applicant pays the fee specified in s. 440.05 (1).

(b) The inspections conducted pursuant to sub. (2) (k) satisfy requirements adopted by the board for 3rd–party logistics providers or out–of–state 3rd–party logistics providers.

(c) All of the following apply to each person identified by the applicant as a designated representative:

1. The person is at least 21 years old.

2. The person has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing of and distribution of, and record keeping related to, prescription drugs.

3. The person is employed by the applicant full time in a managerial position.

4. The person is physically present at the 3rd–party logistics provider's or out–of–state 3rd–party logistics provider's facility during regular business hours and is

involved in and aware of the daily operation of the 3rd–party logistics provider or the out–of–state 3rd–party logistics provider. This subdivision 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.

5. The person is actively involved in and aware of the daily operation of the 3rd–party logistics provider or the out–of–state 3rd–party logistics provider.

6. The person is a designated representative for only one applicant at any given time. This subdivision does not apply if more than one 3rd–party logistics provider or out–of–state 3rd–party logistics provider is located at the facility and the 3rd–party logistics providers or out–of–state 3rd–party logistics providers located at the facility are members of an affiliated group.

7. The person has not been convicted of violating any federal, state, or local law relating to distribution of a controlled substance.

8. The person has not been convicted of a felony.

9. The person submits to the department 2 fingerprint cards, each bearing a complete set of the applicant'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.

(d) The applicant satisfies any other requirements established by the board by rule.

(4) RULES. 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.

(5) ACCESS TO RECORDS. Applications for licensure under this section are not subject to inspection or copying under s. 19.35, and may not be disclosed to any person except as necessary for compliance with and enforcement of the provisions of this chapter.

(6) INSPECTIONS. A 3rd–party logistics provider or an out–of–state 3rd–party logistics provider shall allow the board and authorized federal, state, and local law enforcement officials to enter and inspect its facilities and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law, rule, or regulation.

(7) APPLICABILITY. (a) If the federal government establishes a licensing program for 3rd–party logistics providers, the board shall evaluate the federal licensing program to determine whether licensing by this state of resident 3rd–party logistics providers is required for a resident 3rd–party logistics provider to provide 3rd–party logistics provider services in another state. If the board determines under this subsection that licensing by this state is not required, this section does not apply.

(b) By 2 years after the effective date of this paragraph .... [LRB inserts date], and biennially thereafter, the board shall evaluate whether continued licensing by this state of resident 3rd–party logistics providers is required for a resident 3rd–party logistics provider to provide 3rd–party logistics provider services in another state and, if the board determines licensing in this state is required, submit to the legislative reference bureau for publication in the Wisconsin Administrative Register a notice continuing the licensing under this section. This section does not apply unless the board submits the notice under this paragraph.

SECTION 9. Nonstatutory provisions.

(1) EMERGENCY RULES RELATED TO 3RD–PARTY LOGISTICS PROVIDERS. The pharmacy examining board may promulgate emergency rules under s. 227.24 implementing s. 450.075. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until June 30, 2023, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 227.24 (1) (a) and (3), the board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.

(2) INTERIM LICENSURE OF 3RD–PARTY LOGISTICS PROVIDERS.

(a) In this subsection, the definitions under s. 450.01 apply.

(b) The board shall grant an interim license to an applicant to act as a 3rd–party logistics provider or an out–of–state 3rd–party logistics provider if, in the opinion of the board, the applicant is currently in compliance with federal law relating to 3rd–party logistics providers. The holder of an interim license under this subsection shall apply for a license under s. 450.075 on or after the date that emergency rules take effect under sub. (1), or the date on which permanent rules take effect, whichever is sooner. An interim license granted under this subsection expires 90 days after the date that emergency rules take effect under sub. (1), or 90 days after the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 440.05, no fee is required for an interim license issued under this subsection.

Pharmacy Examining Board
Rule Projects (updated 06/03/22)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Submitted to the Governor's Office for Review on 05/20/22	Publication in the Administrative Register
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	Phar 1,6, and 7	Remote Dispensing	Submitted to the Governor's Office for Review on 05/20/22	Publication in the Administrative Register
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
21-028	080-20	12/22/2022	Phar 2	Reciprocal Credentials for Service Members, Former Service Members, and their Spouses	Rule Effective on 05/01/22	N/A
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	Board Review of Preliminary Rules Draft at 06/16/22 Meeting	Board Approval for Posting for EIA Comments and Submission to Clearinghouse
21-071	074-19	2/12/2022	Phar 8	Controlled Substances Requirements	Adoption Order Presented at 06/16/22 Meeting	Submission for Publication; Anticipated Rule Effective Date of 08/01/22

Pharmacy Examining Board
Rule Projects (updated 06/03/22)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	096-19	03/09/2022	Phar 15	Compounding Pharmaceuticals	Adoption Order Presented at 06/16/22 Meeting	Submission for Publication; Anticipated Rule Effective Date of 08/01/22
Not Assigned Yet	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Drafting Both Emergency and Permanent Rules	Board Review and Approve for Posting for EIA Comments and Submission to Clearinghouse