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Division of Policy Development
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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
June 15, 2023

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 27, 2023 (5-9)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements, and Recognition

E. 11:00 A.M. Public Hearing for Clearinghouse Rule 23-015 on Phar 7 and 10, Relating to Required Disclosures to Consumers (10-17)
1) Review Public Hearing Comments and Respond to Clearinghouse Report

F. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) 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. Weitekamp, John – 7/1/2026
   f. Wilson, Christa – 7/1/2025

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. Legislative and Policy Matters – Discussion and Consideration

I. Administrative Rule Matters – Discussion and Consideration (18)

1) Preliminary Rule Draft: Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing **(19-24)**
2) Pending or Possible Rulemaking Projects **(25)**

J. Pharmacy Tech Apprenticeship Program Outreach – Discussion and Consideration (26)

K. Aurora Pharmacy Patient Consultation Sign – Discussion and Consideration (27-31)

L. Speaking Engagements, Travel, or Public Relation Requests, and Reports
1) Travel Report: NABP 119th Annual Meeting – Nashville, TN – May 10-12, 2023 – Tiffany O'Hagan and John Weitekamp
2) Consideration of Attendance: NABP's DSCSA Interoperability Summit – August 2-3, 2023 – Chicago, IL **(32-33)**

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) Public Health Emergencies
13) Pilot Program Matters
14) Variances
15) Liaison Reports
16) Board Liaison Training and Appointment of Mentors
17) Informational Items
18) Division of Legal Services and Compliance (DLSC) Matters
19) Presentations of Petitions for Summary Suspension
20) Petitions for Designation of Hearing Examiner
21) Presentation of Stipulations, Final Decisions and Orders
22) Presentation of Proposed Final Decisions and Orders
23) Presentation of Interim Orders
24) Pilot Program Matters
25) Petitions for Re-Hearing
26) Petitions for Assessments
27) Petitions to Vacate Orders
28) Requests for Disciplinary Proceeding Presentations
29) Motions
30) Petitions
31) Appearances from Requests Received or Renewed
32) Speaking Engagements, Travel, or Public Relation Requests, and Reports

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. Creative Compounds Inc – Out of State Pharmacy Applicant **(34-110)**
b. Joshua Grutza – Pharmacist Applicant **(111-160)**
c. Shane Urness – Pharmacy Tech Applicant **(161-218)**

Q. Deliberation on Division of Legal Services and Compliance Matters

1) Administrative Warning

a. 22 PHM 056 – P.M.I. **(219-220)**
b. 22 PHM 168 – W. **(221-222)**
c. 23 PHM 026 – N.L.A. **(223-224)**

2) Case Closings

a. 22 PHM 060 – F.L. **(225-228)**
b. 22 PHM 135 – T.M. **(229-232)**
c. 22 PHM 152 – C.V.S. **(233-270)**
d. 22 PHM 160 – E.S.I. **(271-276)**
e. 22 PHM 189 – C.V.S. **(277-280)**
f. 22 PHM 191 – C.S.P. **(281-284)**
g. 22 PHM 196 – O.R.X. **(285-290)**
h. 22 PHM 197 – P. **(291-297)**
i. 23 PHM 008 – C.V.S. **(298-301)**
j. 23 PHM 026 – W. **(302-305)**

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: AUGUST 31, 2023

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

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

HYBRID (IN-PERSON/VIRTUAL)
PHARMACY EXAMINING BOARD
MEETING MINUTES
APRIL 27, 2023

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

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

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:02 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

Amendments to the Agenda:

- Under item O. 2) c. CHANGE to 2**2** PHM 066 – K.L.G.

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

APPROVAL OF MINUTES OF MARCH 2, 2023

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to approve the Minutes of March 2, 2023 as published. Motion carried unanimously.

INTRODUCTIONS, ANNOUNCEMENTS, AND RECOGNITION

Recognition of Shana Weiss, Public Member (Resigned: 3/20/2023)

MOTION: Tiffany O'Hagan moved, seconded by John Weitekamp, to recognize and thank Shana Weiss for her years of dedicated service to the Board and State of Wisconsin. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Adoption Order: Phar 5, 6, 7, 11, and 12, Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to designate Susan Kleppin to serve as liaison to DSPS staff to discuss the inspection process. Motion carried unanimously.

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to approve the Adoption Order for Clearinghouse Rule CR 21-074 Phar 5, 6, 7, 11, and 12, Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction. Motion carried unanimously.

Scope Statement: Phar 8, Relating to Controlled Substances Requirements

MOTION: Tiffany O'Hagan moved, seconded by Anthony Peterangelo, to approve the Scope Statement revising Phar 8, relating to Controlled Substances Requirements, 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.

VARIANCES

Pharmacy Technician Apprenticeship Program Variance Request

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to deny the April 17, 2023 request for variance from Walgreens. Reason for Denial: not meeting the statutory requirements of Wis. Stat. sec. 450.02(3m). Motion carried. Abstained: Tiffany O'Hagan

CLOSED SESSION

MOTION: Anthony Peterangelo 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 12:31 p.m.

CREDENTIALING MATTERS

David Hauge – Predetermination Applicant

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to issue a determination that David Hauge is not disqualified from obtaining a pharmacist credential due to his conviction record as of the date of this determination. Motion carried unanimously.

Jennifer Weiland – Pharmacy Technician Applicant

MOTION: Tiffany O'Hagan moved, seconded by Michael Walsh, to approve the Pharmacy Technician application of Jennifer Weiland, once all requirements are met. Motion carried unanimously.

(Anthony Peterangelo recused himself and left the room for deliberation and voting in the matter concerning Jennifer Weiland – Pharmacy Technician Applicant.)

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

Administrative Warnings

MOTION: Anthony Peterangelo moved, seconded by Susan Kleppin, to issue an Administrative Warning in the following DLSC Cases:

a. 22 PHM 047 – C.R.B.
b. 22 PHM 118 – C.V.S.
c. 22 PHM 152 – S.K.

Motion carried unanimously.

Proposed Stipulations and Final Decisions and Orders

22 PHM 147 – Mary M. Stieber, R.Ph.

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Mary M. Stieber, R.Ph., DLSC Case Number 22 PHM 147. Motion carried unanimously.

Monitoring Matters

Jin Ryu, R.Ph.
Requesting Reduction in Drug Screens, Reduction of AA/NA Meetings to Once Per Week, and the Termination of the Treatment Requirement

MOTION: Christa Wilson moved, seconded by Susan Kleppin, to deny the request of Jin Ryu, R.Ph., for a reduction in drug screens and reduction in AA/NA meetings to once per week, but to grant the request for termination of AODA treatment and to modify the order to require participation in mental health and wellness therapy by a Board approved treater with a quarterly reporting requirement. **Reason for Denial**: Failure to demonstrate continuous and successful compliance under the terms of the Board Order (9/21/2017). Motion carried unanimously.

Case Closings

22 PHM 152 – C.V.S.

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to send back DLSC Case Number 22 PHM 152, against C.V.S. to DLSC for further investigation. Motion carried unanimously.

22 PHM 114 – S.R.X.

MOTION: Tiffany O'Hagan moved, seconded by Susan Kleppin, to refer back DLSC Case Number 22 PHM 114, against S.R.X., to DLSC for further investigation. Motion carried unanimously.

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

1. 21 PHM 075 – A.S.P. – Insufficient Evidence
2. 21 PHM 096 – W. – Insufficient Evidence
3. 22 PHM 066 – K.L.G. – Insufficient Evidence
4. 22 PHM 071 – E.S.P. – No Violation
5. 22 PHM 072 – A.P. – Prosecutorial Discretion (P1)
6. 22 PHM 124 – C.V.S., K.H.K. – No Violation
7. 22 PHM 161 – H.Z. – Insufficient Evidence
8. 22 PHM 171 – M.P. – Prosecutorial Discretion (P2)
9. 22 PHM 172 – M.P. – Prosecutorial Discretion (P2)
10. 22 PHM 173 – M.P. – Prosecutorial Discretion (P2)
11. 22 PHM 186 – J.C.W. – No Violation
12. 23 PHM 028 – A.J.V. – Prosecutorial Discretion (P1)
13. 23 PHM 039 – A.H.G. – No Violation

Motion carried unanimously.

RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 2:36 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

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

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

ADJOURNMENT

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

The meeting adjourned at 2:37 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**	**05/30/23** 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?
06/15/23	☒ Yes ☐ No	**11:00 A.M. Public Hearing for Clearinghouse Rule 23-015 on Phar 7 and 10, Relating to Required Disclosures to Consumers** 1. **Review Public Hearing Comments and Respond to Clearinghouse Report**

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:

The Board will hold a public hearing on this rule as required by the rulemaking process.

11) Authorization

Nilajah D. Hardin — 05/30/23

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

Supervisor (if required) — **Date**

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

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

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING 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), 450.13 (5m), 450.135 (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 was posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens. No comments were received.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:
These 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:

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

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

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, at 11:00 a.m. June 15, 2023, 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) and 450.135 (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 maintain and make available to the public a list of the drugs from the list in Phar 7.15 (2) that are available for purchase at that pharmacy. The list shall be 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 whether the drugs on the list from Phar 7.15 (2) are available for purchase at a specific pharmacy.

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 450.13 (5m) or 450.135 (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)

LCRC
FORM 2

Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **23-015**

AN ORDER to create Phar 7.15 and 10.03 (20) and (21), relating to consumer disclosures.

Submitted by **PHARMACY EXAMINING BOARD**

04-19-2023 RECEIVED BY LEGISLATIVE COUNCIL.
05-11-2023 REPORT SENT TO AGENCY.

SG:KAM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☐ NO ☑

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

Wisconsin Legislative Council
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Margit Kelley
Clearinghouse Assistant Director

Anne Sappenfield
Legislative Council Director

CLEARINGHOUSE RULE 23-015

Comments

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

2. Form, Style and Placement in Administrative Code

a. In SECTION 1 of the proposed rule, cross-references should follow the style prescribed in s. 1.15 (2) (c), Manual. For example, "Phar 7.15 (3)" should be written "sub. (3)".

b. In SECTION 1 of the proposed rule, in s. Phar 7.15 (3), a period should follow the text in pars. (a) to (d).

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

a. The plain language analysis draws heavily from the scope statement underlying the proposed rule. However, the general nature of these documents are different, and the speculative language present at the time the scope statement was issued should be made more specific in the plain language analysis. For example, by the time a proposed rule is submitted for Clearinghouse review, the scope of the treatments in the proposed rule is known, not "including but not necessarily limited to" particular code chapters, as indicated in the scope statement. As such, the plain language analysis should be revised to more specifically describe the contents of the proposed rule.

b. In SECTION 1 of the proposed rule, the proposed text restates the statutes interpreted with minimal additional detail (the statute requires updates of pharmacy lists at least monthly while the rule requires updates monthly, for example). Consider whether the proposed rule is necessary, or alternatively, whether the proposed rule should be revised in order to add additional detail. For example, it could be clarified to include how, under s. Phar 7.15 (2), generic drug product equivalents are determined to be "most commonly" prescribed.

c. In SECTION 2 of the proposed rule, it is unnecessary to refer to compliance with a "valid" rule. Rhetorically, why would a person be required to comply with an invalid rule? Additionally, and related to comment b., above, are the provisions created by SECTION 2 merely duplicative of s. 450.10 (1) (a) 2., Stats.?

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**	**05/30/23** 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?
06/15/23	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. **Preliminary Rule Draft: Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing** 2. **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 1, 5, 6, 7, and 8 Preliminary Rule Draft
2. 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 — 05/30/23

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

Supervisor (if required) — **Date**

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

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

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING 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 1.02 (10m) and (14m), 5.01 (4), 6.025, and 8.01 (5); repeal Phar 1.02 (9), 7.43 (1) and (3); and amend Phar 7.43 (2), (4) (b), (5) (b), (6) (title), (6) (a), (6) (a) 5, (6) (b), and (7), and 7.62 (1), relating to remote dispensing.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

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

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

Plain language analysis: The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 101. The Board also added a definition of pharmacy graduates, and modified requirements to allow them to practice pharmacy while waiting for their license to be granted.

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

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

Comparison with rules in adjacent states:

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

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

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and include requirements for remote dispensing in hospital pharmacies. Additionally, a pharmacist is required to be onsite at a telepharmacy site for at least 16 hours per month and can otherwise monitor the site remotely. The telepharmacy site is a separate licensure category from a correctional, hospital, nuclear, or general pharmacy site. If the average number of prescriptions dispensed per day exceeds 150 at a telepharmacy site, the pharmacist is required to be on site 100

percent of the time and the site must apply for licensure as a general pharmacy [657 Iowa Administrative Code sections 7.7 and 13.9 (6)].

In Iowa, graduates of a college of pharmacy approved by the Iowa Board can register as a "pharmacist-intern." Pharmacist-interns are required to practice under the supervision of a licensed pharmacist. This registration automatically terminates upon the pharmacist-intern receiving "licensure to practice pharmacy in any state, lapse in the pursuit of a degree in pharmacy, or one year following graduation from the college of pharmacy," whichever happens sooner [657 Iowa Administrative Code sections 4.1 and 4.6 (3)].

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

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

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

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

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

Board also identified a need to create a definition of a Pharmacy Graduate and include them in certain pharmacy practice circumstances.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule 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 proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

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

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

TEXT OF RULE

SECTION 1 Phar 1.02 (9) is repealed.

SECTION 2 Phar 1.02 (10m) and (14m) are created to read:

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

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

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

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

SECTION 4 Phar 6.025 is created to read:

Phar 6.025 Licenses; remote dispensing sites. A pharmacy may be subject to rules that apply only to remote dispensing sites if a pharmacist remotely supervises the location for any period of time. The following conditions shall also be met:

(1) The Licensee provides notice to the Board of all of the information outlined in s. 450.06, Stats.

(2) The site meets all of the requirements listed in Phar 7.43.

(3) The site is any of the location types listed under s. 450.09 (2) (b) 1., Stats.

(4) A managing pharmacist shall report to the Board if they are responsible for 5 or more remote dispensing sites. A managing pharmacist shall not be responsible for more than 10 remote dispensing sites at any given time without approval from the Board.

SECTION 5 Phar 7.43 (1) is repealed.

SECTION 6 Phar 7.43 (2) is amended to read:

Phar 7.43 (2) LOCATION. A ~~pharmacist or a~~ person engaged in the practice of pharmacy under s. 450.03 (1) (f), or (g), ~~or (i),~~ Stats., a pharmacy technician registed under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) may dispense at any of the locations under s. ~~450.62 (1) to (4)~~ 450.09 (2) (b) 1. a. to d., Stats

SECTION 7 Phar 7.43 (3) is repealed.

SECTION 8 Phar 7.43 (4) (b); (5) (b); (6) (title), (6) (a), (6) (a) 5, and (6) (b); and (7) are amended to read:

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

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

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

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

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

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

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

SECTION 9 Phar 7.62 (1) is amended to read:

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

SECTION 10 Phar 8.01 (5) is created to read:

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

SECTION 11 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)

Pharmacy Examining Board
Rule Projects (updated 05/30/23)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet (EmR 2303)	052-22	12/27/2024	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Emergency Rule Public Hearing Held at 03/02/23 Meeting; Emergency Rule Effective 02/03/23-05/01/24	Drafting Permanent Rule
Not Assigned Yet (EmR 2213)	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Preliminary Permanent Rule Draft Reviewed at 06/15/23 Meeting; Emergency Rule Effective 11/01/22-05/01/24	Board Approval of Preliminary Permanent Rule Draft
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	Rule Effective 07/01/23	N/A
23-015	102-21	05/01/2024	Phar 7 and 10	Consumer Disclosures	Public Hearing at 06/15/23 Meeting	Drafting Final Rule and Legislative Report
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	Phar 8	Controlled Substances Requirements	Scope Submitted for Governor's Approval on 05/22/23	Scope Submitted for Publication in the Administrative Register
Not Assigned Yet	007-23	07/23/2025	Phar 15	Compounding Pharmaceuticals	Drafting	Board Review and Approval of Preliminary Rule Draft
Not Assigned Yet	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Ready for Submission to Clearinghouse for Review	Public Hearing Anticipated for 08/31/23 Meeting

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski		**2) Date when request submitted:** 6/7/2023 **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: 6/15/2023	**5) Attachments:** ☐ Yes ☒ No	**6) How should the item be titled on the agenda page?** Pharmacy Tech Apprenticeship Program Outreach	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☒ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>	
10) Describe the issue and action that should be addressed: <Click Here to Add Description>			
11) **Authorization**			
			**6/7/2023**
Signature of person making this request			**Date**
Supervisor (Only required for post agenda deadline items)			**Date**
Executive Director signature (Indicates approval for post agenda deadline items)			**Date**

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

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Whitney DeVoe, Board Counsel		2) Date when request submitted: 06/06/23 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 06/15/2023	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? Aurora Pharmacy Patient Consultation Sign – Discussion and Consideration	
7) Place Item in: ☒ Open Session ☐ Closed Session	8) Is an appearance before the Board being scheduled? ☐ Yes ☒ No	9) Name of Case Advisor(s), if applicable: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of Aurora Pharmacy's request for approval of proposed patient consultation sign pursuant to Phar 7.08(8).			
11) Authorization Whitney DeVoe Signature of person making this request			06/06/23 Date
Supervisor (Only required for post agenda deadline items)			Date
Executive Director signature (Indicates approval for post agenda deadline items)			Date

Directions for including supporting documents:
1. This form should be saved with any other documents submitted to the Agenda Items folders.
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3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

DeVoe, Whitney - DSPS

From: Re, Lori <Lori.Re@aah.org>
Sent: Wednesday, May 24, 2023 10:19 AM
To: Wojciechowski, Brad - DSPS; DeVoe, Whitney - DSPS
Cc: Weitekamp, John; Re, Lori; Singh, Thomy; Hill, Patricia; Nemcek, Paul
Subject: Aurora Pharmacy - Delivery Insert requirement
Attachments: Phar7DeliveryInsert (full page).pdf; KV1267b_Aurora_Pharmacy_Delivery_sign with location (002).pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Hello,

I received your contact information from John Weitekamp. I work for Aurora Pharmacy and am applying for a non-resident pharmacy license in the state of Ohio for our mail order pharmacy. Within the Ohio application, They require the following:

> Provide a written description detailing how the applicant will comply with the requirement that an offer to counsel the patient be issued with every prescription filled. The offer shall be made by telephone or in writing on a separate document and shall accompany the prescription. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy?s primary patient population. The pharmacy shall have a sufficient telephone service to provide reasonable access to incoming callers.

We currently use the board approved template provided by the state, see Attachment 1. What we are proposing and asking for approval, to both comply with Ohio regulations as well as exceed notification requirements for the state of WI, is Attachment 2.

This notification would be used for all our mail order pharmacy patients notifying them that counseling is available for *all delivered prescriptions* along with the mail order pharmacy hours, contact information, phone, and email.

Please let me know if you have any additional questions, or if there is someone else I need to contact regarding this request.

Thank you in advance for your time.

Lori Re
Retail Pharmacy Operations Coordinator, Aurora Pharmacy

3189 Voyager Dr
Green Bay, WI 54311
F: 414.643.1617
Working Remotely. Please contact via TEAMs or e-mail.

Wisconsin law requires the pharmacist to consult with you about any new or changed prescriptions.

You may contact the pharmacy about any prescription.

Contact the pharmacy about any delivery concerns including:

- Timeliness of delivery.
- Condition of the prescription drug upon delivery.
- Failure to receive the proper prescription drug product or device

Any prescription which is damaged or lost due to delivery must be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement leads to an interruption in therapy, the dispensing pharmacy must take steps to reduce patient harm.

If a pharmacist fails to consult or resolve your delivery concern, you may contact:

Wisconsin Dept. of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190
(608) 266-2112
dsps@wisconsin.gov
https://dsps.wi.gov *(click on File A Complaint)*

Aurora Pharmacy* | We are AdvocateAuroraHealth

To comply with various state pharmacy laws, pharmacist counseling is available for all dispensed prescriptions.

You may contact the pharmacy about any delivered prescription.

Aurora Specialty Pharmacy

Hours of Operation (CST):

Monday – Friday 8 a.m. to 6 p.m.

Saturday 9 a.m. to 1 p.m. | Sunday Closed

Phone: 877-409-0148 | **Email:** Pharmacy@aah.org

Contact the pharmacy about any delivery concerns including:

- Timeliness of delivery.
- Condition of the prescription drug upon delivery.
- Failure to receive the proper prescription drug product or device.

Any prescription which is damaged or lost due to delivery must be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement leads to an interruption in therapy, the dispensing pharmacy must take steps to reduce patient harm.

If a pharmacist fails to consult or resolve your delivery concern, you may contact:

Wisconsin Dept. of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190 | Madison, WI 53707-7190
(608) 266-2112 | dsps@wisconsin.gov
https://dsps.wi.gov *(click on File A Complaint)*

Aurora Pharmacy®

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, Executive Director		**2) Date when request submitted:** 6/7/2023 **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: <Click Here to Add Date: M/D/YYYY>	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Speaking Engagements, Travel, or Public Relations Requests, and Reports – Discussion and Consideration 2) NABP's DSCSA Interoperability Summit, August 2-3, 2023, Chicago, IL	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☒ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>	
10) Describe the issue and action that should be addressed: <Click Here to Add Description>			
11) Authorization 6/7/2023 **Signature of person making this request** — **Date** **Supervisor (Only required for post agenda deadline items)** — **Date** **Executive Director signature (Indicates approval for post agenda deadline items)** — **Date**			
Directions for including supporting documents: 1. This form should be saved with any other documents submitted to the Agenda Items folders. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

NABP
National Association of Boards of Pharmacy

1600 Feehanville Dr
Mount Prospect, IL 60056

1.847.391.4406
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Josh Bolin, Associate Executive Director, Federal Affairs/Strategy

DATE: May 25, 2023

RE: NABP's DSCSA Interoperability Summit

With November 27, 2023 rapidly approaching, collaboration and communication between and among state regulators and trading partners will be critical to ensure the integrity of the prescription drug supply chain, but also ensure that the flow of medications is not disrupted in a way that negatively impacts patient access.

Over the past several years, NABP has worked to facilitate regulator-trading partner communication and collaboration through our DSCSA pilots and our efforts with Pulse by NABP. To continue this effort, NABP is hosting a DSCSA Interoperability Summit. The Summit will be hosted at the Hyatt Rosemont Near O'Hare-Chicago on August 2-3, 2023.

Participants will include representatives from the manufacturing, distribution, third party logistics provider and pharmacy communities, as well as other DSCSA stakeholders and experts. NABP has also invited the Food and Drug Administration (FDA) to attend.

While the program is still under development, the Summit will consist of educational programs, panel discussions with DSCSA experts, breakout sessions and simulated regulatory scenarios for product tracing and product verification.

NABP will cover the costs for one attendee from each state board of pharmacy. Based on space/availability, NABP may open up additional slots for states that wish to pay for additional attendees.

Please register for the Summit and complete travel information here. In the meantime, if you have any questions, please email me at jbolin@nabp.pharmacy.

cc: NABP Executive Committee