Wisconsin Department of Safety and Professional Services
Division of Policy Development
1400 E. Washington Ave
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Scott Walker, Governor
Laura Gutiérrez, Secretary

PHARMACY EXAMINING BOARD
Room 121A, 1400 East Washington Avenue, Madison, WI 53703
Contact: Dan Williams (608) 266-2112
May 24, 2018

Notice: 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 action and deliberation of the Board.

AGENDA

8:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. **Adoption of Agenda (1-4)**

B. **Approval of Minutes of April 11, 2018 (5-9)**

C. **Administrative Updates – Discussion and Consideration**
1) Staff Updates
2) Board Member – Term Expiration Date
   a. Grace Degner – 7/1/2018
   b. Franklin LaDien – 7/1/2020 *(reappointed, not yet confirmed)*
   c. Terry Maves – 7/1/2018
   d. Thaddeus Schumacher – 7/1/2019
   e. Kristi Sullivan – 7/1/2020 *(reappointed, not yet confirmed)*
   f. Philip Trapskin – 7/1/2021 *(reappointed, not yet confirmed)*
   g. Cathy Winters – 7/1/2021 *(reappointed, not yet confirmed)*

D. **Legislative/Administrative Rule Matters – Discussion and Consideration (10-16)**
1) Adoption of CR 17-090 Relating to Definitions and Authority
2) Petition to Joint Committee for Review of Administrative Rules (JCRAR) for Partial Repeal of Phar 13.02 (12) Relating to 3rd Party Distributors
3) Update on Legislation and Pending and Possible Rulemaking Projects

E. **Pilot Program Matters – Discussion and Consideration (17-21)**
1) Aurora-West Allis Pilot Program Request

F. PDMP Update – Discussion and Consideration

G. **Speaking Engagements, Travel, or Public Relations Requests**
1) Travel Report: Cathy Winters Attendance at the 2018 National Association of Boards and Pharmacy (NABP) on May 5 – 8, 2018 in Denver, CO

H. **Informational Items (22-23)**

1) Memo from National Association of Boards of Pharmacy (NABP) Regarding Update to NAPLEX Scoring Model

I. Items Received After Preparation of the Agenda

1) Introductions, Announcements and Recognition
2) Election of Officers
3) Appointment of Liaison(s)
4) Delegation of Authorities
5) Administrative Updates
6) Education and Examination Matters
7) Credentialing Matters
8) Practice Matters
9) Legislative/Administrative Rule Matters
10) Liaison Reports
11) Board Liaison Training and Appointment of Mentors
12) Informational Items
13) Division of Legal Services and Compliance (DLSC) Matters
14) Disciplinary Matters
15) Presentations of Petitions for Summary Suspension
16) Petitions for Designation of Hearing Examiner
17) Presentation of Stipulations, Final Decisions and Orders
18) Presentation of Stipulations and Interim Orders
19) Presentation of Proposed Final Decision and Orders
20) Presentation of Interim Orders
21) Pilot Program Matters
22) Prescription Drug Monitoring Program (PDMP) Matters
23) Petitions for Re-Hearing
24) Petitions for Assessments
25) Petitions to Vacate Orders
26) Requests for Disciplinary Proceeding Presentations
27) Motions
28) Petitions
29) Appearances from Requests Received or Renewed
30) Speaking Engagement(s), Travel, or Public Relation Request(s)
31) Consulting with Legal Counsel
32) Liaison Report(s)
    a. Appointed to Controlled Substances Board per Wis. Stats. §15.405(5g): Philip Trapskin
    b. Continuing Education (CE) and Education and Examinations Liaison: Terry Maves
    c. Credentialing Liaison(s): Cathy Winters, Terry Maves, Philip Trapskin
    d. Digest Liaison: Philip Trapskin
    e. DLSC Liaison: Thaddeus Schumacher, Cathy Winters
    f. Legislative Liaison: Philip Trapskin, Thaddeus Schumacher, Terry Maves
    g. Monitoring Liaison(s): Franklin LaDien, Cathy Winters-Alternate
    h. PHARM Rep to State Council on Alcohol and Other Drug Abuse (SCAODA): Kristi Sullivan
    i. Pharmacy Rules Committee: Thaddeus Schumacher, Franklin LaDien, Philip Trapskin
    j. Professional Assistance Procedure (PAP) Liaison: Franklin LaDien
    k. Screening Panel: Franklin LaDien, Cathy Winters, Kristi Sullivan
    l. Pilot Program Report Liaison(s): Philip Trapskin, Cathy Winters

J. 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.).

K. **Deliberation on Division of Legal Services and Compliance (DLSC) Matters**

1) **Stipulations, Final Decisions and Orders**
   a. 16 PHM 142 – PRN Rx, LLC **(24-30)**
   b. 16 PHM 200 – Michelle M. Hayek, R.Ph. **(31-37)**
   c. 17 PHM 121 – DCA Pharmacy **(38-43)**

2) **Case Closings**
   a. 16 PHM 193 – P.D.W. **(44-50)**
   b. 16 PHM 193 – T.M.S. **(51-57)**
   c. 17 PHM 056 – M.P.J. & C.J.D. **(58-63)**
   d. 17 PHM 114 – W. **(64-68)**
   e. 17 PHM 115 – C. **(69-73)**
   f. 17 PHM 115 – J.R.J. **(74-78)**
   g. 17 PHM 115 – P.D.F. **(79-83)**
   h. 17 PHM 127 – K.M. **(84-87)**
   i. 17 PHM 174 – K.A.K. **(88-91)**

3) **Monitoring**
   a. **APPEARANCE** – Robert Stevens, R.Ph. – Requesting Unsupervised Practice and a Reduction in Testing Frequency **(92-171)**
   b. Christopher Kachel, R.Ph. – Requesting a Reduction in Testing Frequency **(172-189)**

L. Consulting with Legal Counsel

M. Deliberation of Items Received After Preparation of Agenda
1) Education and Examination Matters
2) Credentialing Matters
3) DLSC Matters
4) Disciplinary Matters
5) Monitoring Matters
6) Professional Assistance Procedure (PAP) Matters
7) Petitions for Summary Suspension
8) Petitions for Designation of Hearing Examiner
9) Stipulations, Final Decisions and Orders
10) Proposed Interim Orders
11) Administrative Warnings
12) Review of Administrative Warnings
13) Proposed Final Decisions and Orders
14) Orders Fixing Costs/Matters Related to Costs
15) Case Closings
16) Board Liaison Training
17) Interim Orders

18) Petitions for Assessments and Evaluations
19) Petitions to Vacate Orders
20) Remedial Education Cases
21) Motions
22) Petitions for Re-Hearing
23) Appearances from Requests Received or Renewed

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

N. **Voting on Items Considered or Deliberated upon in Closed Session, if Voting is Appropriate**

O. Board Meeting Process (Time Allocation, Agenda Items) – Discussion and Consideration

P. Board Strategic Planning and its Mission, Vision, and Values – Discussion and Consideration

ADJOURNMENT

NEXT SCHEDULED MEETING: SEPTEMBER 27, 2018

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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 at 1400 East Washington Avenue, 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. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

PHARMACY EXAMINING BOARD
MEETING MINUTES
April 11, 2018

PRESENT: Grace Degner, Franklin LaDien, Terry Maves, Thaddeus Schumacher, Cathy Winters, Kristi Sullivan, Philip Trapskin

STAFF: Dan Williams, Executive Director; Kate Stolarzyk, Bureau Assistant; Sharon Henes, Administrative Rules Coordinator, and other Department staff

CALL TO ORDER

Thaddeus Schumacher, Chair, called the meeting to order at 11:13 a.m. A quorum of seven (7) members was confirmed.

ADOPTION OF AGENDA

Amendments to the Agenda:

- Add or move the items listed in the sub-bullets below to the Open Session following Closed Session after item "O. Board meeting process (time, allocation, agenda items)"
    - C. Administrative Updates
        - 4) DLSC Request for Delegation
        - 5) DLSC Request for Motion Regarding Continuing Education (CE) Material
        - 6) Revisions to Self-Inspection Forms
- Correct the title of item "D. Pilot Program Matters; 1) Aurora West Allis and Monroe Clinic Pilot Program Request" removing the words "and Monroe Clinic"

MOTION: Franklin LaDien moved, seconded by Cathy Winters, to adopt the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF MARCH 13, 2018

MOTION: Franklin LaDien moved, seconded by Terry Maves, to approve the minutes of March 13, 2018 as published. Motion carried unanimously.

PILOT PROGRAM MATTERS

Aurora West Allis Pilot Program Request

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to acknowledge that Aurora West Allis Pilot Program request was withdrawn. Motion carried unanimously.

LEGISLATIVE/ADMINISTRATIVE RULE MATTERS

Petition for Repeal of Phar 5.03

MOTION: Cathy Winters moved, seconded by Terry Maves, to approve the proposed rule repealing Phar 5.03, relating to a requirement that a pharmacist display his or her license at the pharmacy, and to authorize the Chair to petition the Joint Committee for Review of Administrative Rules for repeal of Phar 5.03 using the process under s. 227.26(4). Motion carried unanimously.

Scope for Phar 6.07, Relating to Storage

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to authorize the Chair to approve the Scope Statement revising Phar 6.07 and 6.075, relating to storage requirements for a pharmacy, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board moves to authorize the Chair to approve the Scope Statement for implementation no less than 10 days after publication. Motion carried unanimously.

Scope for Phar 8, Relating to Requirements for Controlled Substances

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to authorize the Chair to approve the Scope Statement revising Phar 8, relating to requirements of Controlled Substances, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board moves to authorize the Chair to approve the Scope Statement for implementation no less than 10 days after publication. Motion carried unanimously.

SPEAKING ENGAGEMENTS, TRAVEL, OR PUBLIC RELATIONS REQUESTS

Designation of Cathy Winters to Attend the 2018 National Association of Boards and Pharmacy (NABP) on May 5-8, 2018 in Denver, CO

MOTION: Grace Degner moved, seconded by Terry Maves, to designate Cathy Winters, as the Board's delegate, to attend the 2018 National Association of Boards and Pharmacy (NABP) on May 5-8, 2018 in Denver, CO and to authorize travel. Motion carried unanimously.

ITEMS RECEIVED AFTER PREPARATION OF THE AGENDA

Appointment of Board Liaisons

2018 LIAISON APPOINTMENTS	
Credentialing Liaison(s)	Terry Maves, Philip Trapskin, Cathy Winters

MOTION: Kristi Sullivan moved, seconded by Cathy Winters, to acknowledge the Chair's updated appointment of Credentialing Liaisons, so that Terry Maves becomes a primary liaison, and adding Philip Trapskin as an additional liaison. Motion carried unanimously.

CLOSED SESSION

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, 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.). Thaddeus Schumacher, Chair, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Grace Degner-yes; Franklin LaDien-yes; Terry Maves-yes; Thaddeus Schumacher-yes; Kristi Sullivan-yes; Philip Trapskin-yes; and Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 2:14 p.m.

RECONVENE TO OPEN SESSION

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to reconvene into open session. Motion carried unanimously.

The Board reconvened into Open Session at 3:02 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Terry Maves moved, seconded by Cathy Winters, 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.)

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

Administrative Warnings

17 PHM 028 (H.A.Z.)

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to issue an Administrative Warning in the matter of DLSC case number 17 PHM 028 (H.A.Z.). Motion carried unanimously.

Stipulations, Final Decisions and Orders

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against:

1. 16 PHM 127, Cassidy L. Rockey, R.Ph.
2. 17 PHM 015, Bentley Pharmacies, Inc.
3. 17 PHM 077, Specialty Veterinary Pharmacy
4. 17 PHM 131, Robert M. Stresing, R.Ph.

Motion carried unanimously.

Case Closings

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to close the DLSC cases for the reasons outlined below:

1. 17 PHM 023 (O.P. and K.A.B.) – Insufficient Evidence
2. 17 PHM 028 (H.P.) – Prosecutorial Discretion (P3)
3. 17 PHM 064 (B.R.X., LLC) – Insufficient Evidence
4. 17 PHM 071 (N.L.P., LLC) – Insufficient Evidence
5. 17 PHM 086 (J.S.K.) – Prosecutorial Discretion (P3)

Motion carried unanimously.

17 PHM 072

MOTION: Terry Maves moved, seconded by Kristi Sullivan, to close DLSC case number 17 PHM 072, against N.B. and W. for Prosecutorial Discretion (P2). Motion carried.

17 PHM 122

MOTION: Terry Maves moved, seconded by Kristi Sullivan, to close DLSC case number 17 PHM 122, against A.J. and W. for Insufficient Evidence. Motion carried.

(Franklin LaDien recused himself and left for the room for deliberation and voting in the matter of disciplinary proceedings against DLSC case numbers 17 PHM 072 and 17 PHM 122.)

Recusal of Board from 17 PHM 111 and 17 PHM 157

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to delegate to Department Chief Legal Counsel to preside over and resolve any violation(s) with appropriate discipline in the matter of disciplinary proceedings in DLSC case numbers 17 PHM 111 and 17 PHM 157. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Delegated Authority Update

MOTION: Philip Trapskin moved, seconded by Terry Maves, to grant the Rules Committee the ability to address all rulemaking language. Motion carried unanimously.

Revisions to Self-Inspection Form

MOTION: Terry Maves moved, seconded by Kristi Sullivan, to authorize Philip Trapskin and Thaddeus Schumacher to work with DLSC staff to revise Pharmacy Inspection forms. Motion carried unanimously.

Department of Legal Services and Compliance (DLSC) Request for Delegation

MOTION: Terry Maves moved, seconded by Kristi Sullivan, to delegate to DLSC the following prescreening authority: to prescreen complaints prior to a meeting of the screening panel to open any case that demonstrates a clear violation of law; to close at prescreening any case that clearly demonstrates that no violation took place; to close at prescreening complaints that the Board has already reviewed and acted upon that are the result of multiple-state discipline based on original violations. Motion carried unanimously.

DLSC Request for Motion Regarding Continuing Education (CE) Material

MOTION: Philip Trapskin moves, seconded by Kristi Sullivan to delegate to DLSC staff, the authority to prescreen complaints for the purpose of reviewing submitted CE materials and to determine if CE requirements are met. If CE requirements are met, then DLSC staff should remove such CE documentation from the screening materials prior to screening. If the submitted documentation does not clearly establish that CE requirements are met, such documentation shall be forwarded to the screening panel for review. Motion carried unanimously.

ADJOURNMENT

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 3:35 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:
Sharon Henes **Administrative Rules Coordinator**	**15 May 2018** Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 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?
24 May 2018	☐ Yes ☐ No	**Legislation and Rule Matters – Discussion and Consideration** **1. Adoption of CR 17-090 Relating to Definitions and Authority** **2. Petition to JCRAR for Partial Repeal of Phar 13.02 (12) Relating to 3rd Party Distributors** **3. Update on Legislation and Pending and Possible Rulemaking Projects**

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes (Fill out Board Appearance Request) ☐ No	

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

11) Authorization

Sharon Henes

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	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 17-090)

ORDER

An order of the Pharmacy Examining Board to amend Phar 1.01 and Phar 1.02 (intro.) relating to authority and definitions.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.03 (2) (b), Stats.

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

Explanation of agency authority:

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

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

Related statute or rule: n/a

Plain language analysis:

Currently the authority and definition sections indicate the authority and definitions apply to chapters Phar 1 to 16. Chapter Phar 17 Pharmacy Internship was created in 2002 and that rulemaking order inadvertently did not expand the authority and definitions to include ch. Phar 17. This rule clarifies the authority and definition extend to ch. 17.

Summary of, and comparison with, existing or proposed federal regulation: None

Comparison with rules in adjacent states:

Illinois: Illinois requires approved educational programs to contain an externship and clerkship experience.

Iowa: Iowa has administrative rules governing pharmacist internships.

Michigan: Michigan has administrative rules governing pharmacist internships.

Minnesota: Minnesota has administrative rules governing pharmacist internships.

Summary of factual data and analytical methodologies:

This rule is for clarification that the authority and definitions apply to all of the Pharmacy Code chapters.

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

This rule revises the authority and definition chapter to apply to all of the pharmacy code chapters and does not have an economic impact.

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 Kirsten.Reader@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 1.01 and 1.02 (intro.) are amended to read:

Phar 1.01 Authority. Rules in chs. Phar 1 to ~~16~~ 17 are adopted under authority of ss. 15.08 (5) (b), 227.11 (2), Stats, and ch. 450, Stats.

Phar 1.02 Definitions. As used in chs. Phar 1 to ~~16~~ 17:

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 _____

Chair of the Pharmacy Examining Board

Thaddeus Schumacher
Chairperson

Philip Trapskin
Vice Chairperson

Franklin LaDien
Secretary

PHARMACY EXAMINING BOARD

1400 E Washington Ave
PO Box 8366
Madison WI 53708-8366

Email: dsps@wisconsin.gov
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24 May 2018

Senator Stephen Nass, Senate Co-Chairperson
Joint Committee for Review of Administrative Rules
Room 10 South, State Capitol
Madison, WI 53702

Representative Joan Ballweg, Assembly Co-Chairperson
Joint Committee for Review of Administrative Rules
Room 210 North, State Capitol
Madison, WI 53702

RE: Petition for Authorization to Partially Repeal Rule Phar 13.02 (12)

Dear Senator Nass and Representative Ballweg:

I am petitioning for authorization to partially repeal rule Phar 13.02 (12). A copy of the proposed rule is attached.

Phar 13.02 (12) defines "wholesale distributor". 2017 Act 328 amended s. 450.01 (24) which defines "wholesale distributor" by removing 3rd party logistics providers from the definition.

Therefore, the Pharmacy Examining Board is requesting authorization to amend the rule to remove "3rd party logistics providers" by utilizing the expedited process under s. 227.26 (4), Stats.

Thank you.

Sincerely,

Chairperson
Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES

The Pharmacy Examining Board is petitioning the
Joint Committee for Review of Administrative Rules to
partially repeal a rule the Pharmacy Examining Board has determined to be
an unauthorized rule using the process under s. 227.26 (4), Stats.

PROPOSED ORDER

An order of the Pharmacy Examining Board to amend Phar 13.02 (12) relating to 3rd party logistics providers.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.01 (24), Stats.

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

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

Related statute or rule: n/a

Plain language analysis:

Section Phar 13.02 (12) includes 3rd party logistics providers in the definition of "wholesale distributors".

2017 Act 328 amended s. 450.01 (24), Stats., to remove 3rd party logistics providers from the definition of "wholesale distributors".

Therefore, the board has determined that the inclusion of 3rd party logistics providers in s. Phar 13.02 (12) is unauthorized and seeks to amend the rule to remove these entities from the definition under s. 227.26 (4), Stats.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 13.02 (12) is amended to read:

Phar 13.02 (12) "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturers' exclusive distributors; manufacturers' authorized distributors of record; prescription drug wholesalers and distributors; independent wholesale prescription drug traders; ~~3rd party logistics providers;~~ retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

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)

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:
Dan Williams	Items will be considered late if submitted after 4:30 p.m. and less than: ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others

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

Wisconsin Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
May 24, 2018	☒ Yes ☐ No	**Aurora-West Allis pilot program request – Discussion and Consideration**

7) Place Item in:	8) Is an appearance before the Board being scheduled? If yes, who is appearing?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes by ☐ No	N/A

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

See attachment.

May 10th, 2018

Aurora West Allis Medical Center
8901 W Lincoln Ave.
West Allis, WI 53227

Dear Pharmacy Examining Board,

Wisconsin law mandates that a pharmacist perform the final product verification for all medication products prior to the medication being dispensed or administered to the patient.[1] Tech-check-tech pilot programs are variances granted by the Wisconsin Pharmacy Examining Board (PEB) that allow for a trained pharmacy technician to perform the final product verification check, instead of a pharmacist.[2] Currently, tech-check-tech (TCT) pilot programs exist for the community setting and institutional setting. However, neither of these programs include tech-check-tech for sterile products.[3]

Last month, Aurora Health Care presented to the PEB a proposed new pilot program for sterile products. During the meeting there was good discussion regarding the proposed new pilot program. A few of the main areas of discussion were on technician training requirements, eligible medications, and automation mechanisms. The revised document now includes required technician certification and a minimum of 1,000 hours of experience in the sterile products area. The document also now excludes medications for any patients under the age of 18 years old and antineoplastic agents for all patients. Lastly, multiple automation mechanisms should be used; however a minimum of bar-code scanning must be utilized for all eligible medications.

Please see my attached PEB pilot program for sterile products document for further details on this new pilot program. The layout of the document is very similar to the current PEB institutional tech-check-tech pilot program document. I would welcome the opportunity to discuss more details about this potential new pilot program at a future PEB meeting.

Sincerely,

Rachel Miller, PharmD

Reference:

1. Pharmacy Examining Board: Chapter Phar 7.01.
2. Pharmacy Examining Board: Chapter 450.02 (3r).
3. Pharmacy Examining Board: Institutional Tech-Check-Tech Pilot Program Information.

Pharmacy Examining Board

Mail To: P.O. Box 8935
Madison, WI 53708-8935
FAX #: (608) 261-7083
Phone #: (608) 266-2112

1400 E. Washington Avenue
Madison, WI 53703
E-Mail: DSPSCredPharmacy@wisconsin.gov
Website: http://dsps.wi.gov

Sterile Products Tech-Check-Tech Pilot Program
Information

Authority:
Pursuant to Wisconsin Stat. § 450.02(3r)(a), this pilot program is related to the practice of pharmacy or prescription verification and the Board determines that the program will improve the safety, quality or efficiency of the practice of pharmacy in this state. **The Board may modify the parameters of the Pilot Program at any time and participants shall remain in the Pilot Program at the discretion of the Board.**

Purpose: The purpose of institutional tech-check-tech (TCT) pilot program is to study the safety, quality, and efficiency of a pharmacy technician to make a final check of another pharmacy technician on the accuracy and correctness of the final dispensed medication. Implementation of a tech-check-tech program is not intended to reduce pharmacist staffing levels but is intended to increase the availability of a pharmacist for involvement for other patient care activities.

Waives: Phar 7.01(1)(c) and (d), and 7.015(3) (a) and (4), Phar 15.09 (5), Wis. Admin. Code

Pilot Duration: TBD

Pharmacy Eligibility:
1. The pharmacy shall be located and licensed in the state of Wisconsin.
2. A supervising pharmacist, licensed in the state of Wisconsin, shall be identified for each pharmacy to be accountable for the operations and outcomes of the TCT program. The final checks made by the validated technicians will be considered delegated acts of the supervising pharmacist. In the event of change of the supervising pharmacist, the managing pharmacy shall notify the Board of change within 5 days on a Board approved form.

Program Requirements:
1. Validated Technicians
   a. Initial Validation: In order to become a validated technician, the following requirements must be met and maintained:
      i. Employment averaging at least 20 hours per week at the pilot pharmacy
      ii. A minimum of 2000 hours of experience as a pharmacy technician and at least 6 months of employment at the pilot pharmacy
      iii. A minimum of 1000 hours of experience as a pharmacy technician working in the sterile products area
      iv. Certified pharmacy technician (CPhT) or equivalent
      v. Completion of a didactic and practical training curriculum that includes the following:
         1. Elements of a package label (i.e. drug name, dose, dosage form, control or lot number and expiration date)
         2. Medication and pharmacy abbreviations needed to match ordered medication with dispensed medication (e.g., mg, mEq, ER, IR, tab, cap)
         3. Calculations review specific to sterile products.
         4. Common dispensing medication errors and concepts (i.e. wrong medication, wrong dose, wrong dosage form, expired medication, wrong beyond use date, wrong product labeling, look-alike sound-alike errors, high-alert medications).
         5. Organizational policies and procedures on reporting of medication errors
         6. Overview of the organizations medication use process (i.e. procurement, ordering, dispensing, administration, and monitoring).
         7. A practical training designed to assess the competency of the technician prior to starting the validation process.
      vi. Completion of the following validation process:
         1. The technician being validated shall make a final check on the work of another technician for accuracy and correctness of a minimum of 250 final checks over a minimum of 10 separate days and achieve an accuracy rate of 99.8% or greater.

2. At least one occurrence each of wrong drug, wrong dose, wrong dosage form, wrong product labeling, wrong beyond use date and, expired dose shall be artificially introduced by a pharmacist who will ensure they are removed prior to delivery to a patient care area.
3. A pharmacist shall audit 100% of the final checks made by the technician during the validation process.

b. Re-validation:

i. An assessment of validated technician accuracy shall be completed quarterly of the previous 12 months of TCT final checks. A technician shall be revalidated if a validated technician fails to maintain a final check accuracy rate of 99.8% or has not performed TCT final checks within the last 6 months.

2. Eligible Medications
   a. Medications are to be sterile products, which may include compounded, packaged or manufactured medications with the following exceptions:
      i. Medications for patients less than 18 years old
      ii. Antineoplastic
   b. Preferably, multiple automation mechanisms should be utilized, however at a minimum all medications must be prepared utilizing bar-code scanning
   c. The supervising pharmacist shall ensure a process is in place for a pharmacist to prospectively review the clinical appropriateness of the medication order prior to leaving the pharmacy.
   d. The medication shall be administered by an individual authorized to administer medications at the institution where the medication is administered.
3. Quality Assurance

   a. A minimum of 5% of all TCT final checks shall be audited by a licensed pharmacist each day that TCT is performed.

   b. The accuracy of each validated technician shall be tracked individually.
4. Policies and Procedures

   a. Each pharmacy shall maintain policies, procedures, and training materials for the TCT program that will be made available to the Board upon request.
5. Records

   a. Each pharmacy shall maintain records for 5 years, available to the Board upon request, of the following:
      i. All initial validation and revalidation records of each validated technician that include the dates that the validation occurred, the number of final checks performed, the number of final check errors, and overall accuracy rate.
      ii. Names the supervising TCT pharmacist including start date and end date of supervision responsibilities.
      iii. Daily quality assurance logs of the 5% pharmacist TCT audit including the name of technician, total number of final checks performed, number of final checks audited by the pharmacist, percentage of final checks audited by pharmacist, number of final check errors identified, and type of error (i.e., wrong drug, wrong dose, wrong dosage form, wrong product labeling, wrong beyond use date and, expired dose)
6. Reporting Requirements
   a. The supervising pharmacist of the tech-check-tech program shall annually submit to the Board, on a form approved by the Board, all of the following:
      i. Total number of TCT final checks
      ii. Total number TCT final checks audited by a pharmacist
      iii. Total number of errors identified in the TCT final check pharmacist audit that were of the type of wrong drug, wrong dose, wrong dosage form, wrong product labeling, wrong beyond use date and, expired dose
      iv. Total number of pharmacist hours reallocated to other patient care activities and description of those activities

Application: The managing pharmacist shall submit a Board approved application and receive approval of the Board to participate in the Pilot Program.

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: April 19, 2018

RE: Update to NAPLEX Scoring Model

The National Association of Boards of Pharmacy (NABP) Competency Assessment programs adhere to robust psychometric standards as well practice standards defined by the state boards of pharmacy. Important considerations of NABP examinations are the integrity and accuracy of all components of the examinations and processes. The scoring process employed by NABP for its examinations is undoubtedly one of the critical components of the overall process and an area that is under continuous review and refinement.

NABP examinations are scored using item response theory (IRT). IRT uses a mathematical model to specify the relationship between an examinee's ability and their probability of responding correctly to a test question. IRT methodology has a long and well-accepted history of use in scoring high-stakes examinations (Rasch, 1960; Lord & Novick, 1968). There are several different IRT models, and one of the most commonly used is called the Rasch model. This model is widely used by licensure/certification examination programs, including the NCLEX (National Council of State Boards of Nursing, 2017), United States Medical Licensing Examination (Wainer, 2014), and National Board of Osteopathic Medical Examiners (NBOME) examinations (NBOME, 2017).

The Rasch model has been used to score all NABP examinations except the North American Pharmacist Licensure Examination (NAPLEX), which has used a slightly different model based on considerations that define pharmacy practice. In the spring of 2018, the NAPLEX will transition to Rasch scoring to improve the desired accuracy of the scoring process and incorporate all of the prior practice considerations. Transitioning NAPLEX to the Rasch model has two advantages. First, it will allow more standardization and accuracy in processes across NABP exam programs. Second, it will help increase the production of new test questions.

NABP takes all measures to adhere to industry standards in testing. Extensive analysis was done to assess the impact of transitioning the NAPLEX to the Rasch model. The results indicated an improved process across all areas of consideration. Correlations between test scores using the old IRT model and the new Rasch model were extremely high and pass rates unchanged. The Rasch transition will be seamless to stakeholders. NABP is releasing notice of this transition to adhere with industry best-practices as stated in Standard 6.3 of the *Standards for Educational*

and Psychological Testing (American Educational Research Association, American Psychological Association, and National Council on Measurement in Education, 2014): "Changes … [to exam] scoring should be documented and reported to the test user." Information on the transition will be included in the subsequent revision of the candidate bulletin.

If you have any questions, please feel free to contact me via email at ExecOffice@nabp.pharmacy.

cc: NABP Executive Committee

References

American Educational Research Association, American Psychological Association, National Council on Measurement in Education, Joint Committee on Standards for Educational, & Psychological Testing. (2014). *Standards for educational and psychological testing*. Washington, DC: American Educational Research Association.

Lord, F.M. and Novick, M.R. (1968). *Statistical theories of mental test scores*. Addison-Wesley, Menlo Park.

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National Council of State Boards of Nursing (2017). 2016 NCLEX® examination statistics. *NCSBN Research Brief*, *70*, 1-49. Retrieved from https://www.ncsbn.org/11276.htm

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Wainer, H. (2014). The route to the USMLE: The shibboleth of modern medical licensure. *Journal of Medical Regulation, 100*, 21-28. Retrieved from https://www.researchgate.net/publication/292637489_The_route_to_the_USMLE_The_shibboleth_of_modern_medical_licensure