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Tony Evers, Governor
Dawn B. Crim, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Christine Poleski (608) 266-2112
December 3, 2020

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

9:00 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 October 22, 2020 (5-7)

C. Conflicts of Interest

D. Introductions, Announcements and Recognition

E. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Board Members – Term Expiration Dates

F. Legislative and Policy Matters – Discussion and Consideration

G. 9:00 A.M. PRELIMINARY PUBLIC HEARING: Scope Statement, SS 136-20 – Phar 15, Relating to Re-Use of Personal Protective Equipment (8-10)
1) Review and Respond to Public Comments

H. 9:00 A.M. PRELIMINARY PUBLIC HEARING: Scope Statement, SS 137-20 – Phar 1, 6, 7, 8, 12 and 13, Relating to Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors (8, 11-12)
1) Review and Respond to Public Comments

I. Administrative Rule Matters – Discussion and Consideration (13)
1) Phar 5, 6, 7, 11, and 12, Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References and Technical Correction **(14-)**
2) Phar 2, Relating to Endorsement Requirements for Pharmacists **(15-17)**
   a. Proposals for Emergency Rule

b. Consideration of a Permanent Rule

3) Phar 15, Relating to Re-Use of Personal Protective Equipment **(18-19)**
   a. Proposals for Emergency Rule
   b. Consideration of a Permanent Rule
4) Administrative Rules Reporting Requirement Under 227.29, Stats **(20-22)**
   a. Review of Statutory Requirement and 2019 Report
   b. Proposals for 2021 Report
5) Pending or Possible Rulemaking Projects

J. Public Agenda Request: 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

K. Variances – Discussion and Consideration
1) Review, Discussion and Consideration of All Current Variances
2) Review, Discussion and Consideration of Any Proposed Variances
   a. Pharmacy Society of Wisconsin Variance Request
   b. Milwaukee Alternate Care Facility Request
   c. Variance Requests Received After Preparation of the Agenda

L. Education and Examination Matters – Discussion and Consideration
1) Multistate Pharmacy Jurisprudence Examination (MPJE) Question Writing Review and Related Matters

M. Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration
1) National Association of Boards of Pharmacy (NABP)/American Association of Colleges of Pharmacy (AACP) District IV – 2021 Annual Meeting Planning

N. COVID-19 – Discussion and Consideration

O. Pilot Program Matters – Discussion and Consideration

P. Discussion and Consideration on Items Added After Preparation of Agenda
1) Introductions, Announcements and Recognition
2) Nominations, Elections, and Appointments
3) Administrative Matters
4) Election of Officers
5) Appointment of Liaisons and Alternates
6) Delegation of Authorities
7) Education and Examination Matters
8) Credentialing Matters
9) Practice Matters
10) Legislative and Policy Matters
11) Administrative Rule Matters
12) Pilot Program Matters
13) Variances
14) Liaison Reports
15) Board Liaison Training and Appointment of Mentors
16) Informational Items
17) Division of Legal Services and Compliance (DLSC) Matters
18) Presentations of Petitions for Summary Suspension

19) Petitions for Designation of Hearing Examiner
20) Presentation of Stipulations, Final Decisions and Orders
21) Presentation of Proposed Final Decisions and Orders
22) Presentation of Interim Orders
23) Pilot Program Matters
24) Petitions for Re-Hearing
25) Petitions for Assessments
26) Petitions to Vacate Orders
27) Requests for Disciplinary Proceeding Presentations
28) Motions
29) Petitions
30) Appearances from Requests Received or Renewed
31) Speaking Engagements, Travel, or Public Relation Requests, and Reports

Q. Public Comments

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

R. Deliberation on Division of Legal Services and Compliance Matters

1) Case Closings

a. 18 PHM 109 – D.R.K., S.R., & H.H. **(23-27)**
b. 19 PHM 024 – P.N.S.P. **(28-31)**
c. 19 PHM 137 – I.P.C. **(32-42)**
d. 19 PHM 159 – V.R.D. **(43-46)**
e. 19 PHM 244 – A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., P.D.S.I., P.L.S.I., P.L.S.I., P.L.S.I., P.L.S.I., P.L.S.I., P.V.S.I., P.V.S.I. **(47-56)**
f. 20 PHM 014 – P.C. **(57-60)**

2) Proposed Stipulations, Final Decisions, and Orders

a. 18 PHM 109 – Thomas F. Shaw, R.Ph. **(61-66)**
b. 19 PHM 020 – Marc C. Ertz, R.Ph. **(67-72)**
c. 19 PHM 073 – Mark Kobin, R.Ph. **(73-79)**
d. 19 PHM 169 – Paul A. Blazkovec, R.Ph. **(80-85)**
e. 19 PHM 284 & 20 PHM 009 – Kari L. Seelig, R.Ph. **(86-94)**
f. 20 PHM 115 – Kelly L. Fausek, R.Ph. **(95-101)**

3) Monitoring Matters (102)

a. Brad Spross, R.Ph. – Requesting Reduction in Drug and Alcohol Screens **(103-132)**

S. Deliberation of Items Added After Preparation of the Agenda
1) Education and Examination Matters
2) Credentialing Matters
3) Application Reviews
4) DLSC Matters
5) Monitoring Matters

6) Professional Assistance Procedure (PAP) Matters
7) Petitions for Summary Suspensions
8) Petitions for Designation of Hearing Examiner
9) Proposed Stipulations, Final Decisions and Orders
10) Proposed Interim Orders
11) Administrative Warnings
12) Review of Administrative Warnings
13) Proposed Final Decisions and Orders
14) Matters Relating to Costs/Orders Fixing Costs
15) Case Closings
16) Board Liaison Training
17) Petitions for Assessments and Evaluations
18) Petitions to Vacate Orders
19) Remedial Education Cases
20) Motions
21) Petitions for Re-Hearing
22) Appearances from Requests Received or Renewed

T. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

U. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate

V. Open Session Items Noticed Above Not Completed in the Initial Open Session

ADJOURNMENT

NEXT MEETING: JANUARY 28, 2020

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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 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the deaf or hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, 608-266-2112, or the Meeting Staff at 608-266-5439.

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
MEETING MINUTES
OCTOBER 22, 2020

PRESENT: Tiffany O'Hagan, Anthony Peterangelo, Philip Trapskin, John Weitekamp, Cathy Winters, Michael Walsh

EXCUSED: Shana Weiss

STAFF: Christine Poleski, Executive Director; Jameson Whitney, Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Kimberly Wood, Program Assistant Supervisor-Advanced; Daniel Betekhtin, Bureau Assistant; Megan Glaeser, Bureau Assistant; and other Department staff

CALL TO ORDER

Philip Trapskin, Chairperson, called the meeting to order at 11:03 a.m. A quorum was confirmed with six (6) board members present.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES OF SEPTEMBER 24, 2020

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to approve the Minutes of September 24, 2020 as published. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Department, Staff and Board Updates

MOTION: John Weitekamp moved, seconded by Michael Walsh, to commend and thank Sharon Henes for her exemplary and dedicated service to the Pharmacy Examining Board and the State of Wisconsin. Motion carried unanimously.

VARIANCES

MOTION: Cathy Winters moved, seconded by Tiffany O'Hagan, to extend the variances regarding wholesale delivery to board-approved addresses, relaxing consulting requirements, re-use of PPE for sterile compounding, and dispensing in locations that are not licensed pharmacies to January 1, 2021. The Board specifically finds that the requirements of § 450.02(3m) have been met. Motion carried unanimously.

CLOSED SESSION

MOTION: Philip Trapskin moved, seconded by John Weitekamp, 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.). Philip Trapskin, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Tiffany O'Hagan-yes, Anthony Peterangelo-yes; Philip Trapskin-yes; Michael Walsh-yes; John Weitekamp-yes; and Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 3:52 p.m.

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

Administrative Warnings

18 PHM 087 – C.K.Z.

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to issue an Administrative Warning in the matter of C.K.Z., DLSC Case Number 18 PHM 087. Motion carried unanimously.

Case Closings

MOTION: Cathy Winters moved, seconded by John Weitekamp, to close the following DLSC Cases for the reasons outlined below:

1. 18 PHM 087 – C. – No Violation
2. 19 PHM 234 – R.S.D.S. – Prosecutorial Discretion (P2)
3. 19 PHM 235 – R.A. – Prosecutorial Discretion (P5)
4. 19 PHM 245 – L.H.P. – Prosecutorial Discretion (P2)
5. 19 PHM 255 – A.P. – Prosecutorial Discretion (P2)
6. 19 PHM 263 – A.H.F.P. – Prosecutorial Discretion (P2)
7. 19 PHM 269 – A.S.P. – Prosecutorial Discretion (P2)

Motion carried unanimously.

20 PHM 060 – W.P.M.

MOTION: Cathy Winters moved, seconded by Michael Walsh, to close DLSC Case Number 20 PHM 060 against W.P.M. for Prosecutorial Discretion (P1). Motion carried unanimously.

MOTION: Cathy Winters moved, seconded by Tiffany O'Hagan, to request that Monitoring relay the following information to the fitness to practice evaluator to be pre-approved by Monitoring under Respondent's prior case: "Respondent was ordered to complete an AODA assessment and a psychiatric/psychological evaluation as soon as possible and comply with

recommended treatment, in connection with underlying criminal court case". Motion carried unanimously.

20 PHM 091 – W. & M.N.S.

MOTION: Cathy Winters moved, seconded by Michael Walsh, to close DLSC Case Number 20 PHM 091 against W. & M.N.S. for Prosecutorial Discretion (P2). Motion carried.

(Tiffany O'Hagan recused herself and left the room for deliberation and voting in the matter concerning W. & M.N.S., DLSC Case Number 20 PHM 091.)

Stipulations, Final Decisions and Orders

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to reject the Findings of Fact, Conclusions of Laws and Orders in the matter of the following cases and refer to DLSC for further action.

1. 17 PHM 152 – Wells Pharmacy Network, LLC
2. 18 PHM 170 – Cynthia R. Hennen, R.Ph.
3. 20 PHM 115 – Kelly L. Fausek, R.Ph.

Motion carried unanimously.

18 PHM 087 – Richard D. Moe, R.Ph.

MOTION: Cathy Winters moved, seconded by Michael Walsh, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Richard D. Moe, R.Ph., DLSC Case Number 18 PHM 087. Motion carried unanimously.

RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 4:52 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Cathy Winters moved, seconded by John Weitekamp, 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: Cathy Winters moved, seconded by Michael Walsh, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 4:53 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:
Dale Kleven **Administrative Rules Coordinator**	**11/20/20** 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?
12/3/20	☒ Yes ☐ No	**9:00 A.M. Preliminary Public Hearing: Scope Statement SS 136-20 – Phar 15, Relating to Re-use of Personal Protective Equipment** **1. Review and Respond to Public Comments** **9:00 A.M. Preliminary Public Hearing: Scope Statement SS 137-20 – Phar 1, 6, 7, 8, 12 and 13, Relating to Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors** **1. Review and Respond to Public Comments**

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

Dale Kleven — *November 20, 2020*

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.

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 15

Relating to: Re-use of personal protective equipment

Rule Type: Emergency

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

On March 17, 2020, the Pharmacy Examining Board granted a variance of s. Phar 15.32 (5), pursuant to s. 450.02 (3m) (b), Stats., to allow pharmacists and compounding personnel to re-use personal protective equipment subject to the pharmacist's professional judgment regarding the condition of the equipment and suitability for re-use. The purpose of the request was to compensate for a shortage of PPE during the COVID-19 emergency. The variance was in effect for 90 days. On July 23, 2020 the Pharmacy Examining Board determined that the requirements of s. 450.02(3m)(b), Stats. have been met and extended the variance for another 90 days.

The Pharmacy Examining Board recognizes that there remains a shortage of professional personal protective equipment. The Pharmacy Examining Board determines that the preservation of the public health and safety necessitates an emergency rule to allow for compounding personnel to be able to use the pharmacist's professional judgment regarding the condition of the equipment and suitability for re-use. Without an emergency rule, the ability to compound pharmaceuticals will be impacted resulting in patients not receiving their medications.

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

The objective of the rule is to allow sterile compounding personnel to re-use coveralls, shoe coverings, hair and facial hair covers, face masks, eye shields and gloves when in the pharmacist's professional judgment the condition of the equipment and suitability for re-use.

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

Current rule states that when compounding personnel the buffer or segregated compounding area, a gown may be removed and retained in the ante area or segregated compounding area if not visibly soiled, to be worn again during the same work shift. Coveralls, shoe covers, hair and facial hair covers, face masks, eye shields, and gloves shall be replaced with new ones before re-entering the compounding area.

On March 17, 2020, the Pharmacy Examining Board granted a variance of s. Phar 15.32 (5), pursuant to s. 450.02 (3m) (b), Stats., to allow pharmacists and compounding personnel to re-use personal protective equipment subject to the pharmacist's professional judgment regarding the condition of the equipment and suitability for re-use. The purpose of the request was to compensate for a shortage of PPE during the COVID-19 emergency. The variance was in effect for 90 days. On July 23, 2020 the Pharmacy Examining Board determined that the requirements of s. 450.02(3m)(b), Stats. have been met and extended the variance for another 90 days.

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

15.08 (5) (b) 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.

450.02 (3) (e) The board may promulgate rules establishing minimum standards for the practice of pharmacy.

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

70 hours

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

Pharmacies, including pharmacies located within hospitals, and pharmacists.

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

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

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

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

Minimal or no economic impact.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

Authorized Signature

September 30, 2020
Date Submitted

STATEMENT OF SCOPE

Pharmacy Examining Board

Rule No.: Phar 1, 6, 7, 8, 12 and 13

Relating to: Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors

Rule Type: Permanent

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

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

The objective of the proposed rule is to implement 2007 Act 20 as it relates to electronic track and trace pedigree system and the federal Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act). In addition, the Pharmacy Examining Board will conduct a comprehensive review of chapters Phar 12 and 13 and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices.

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

The new policies proposed are to implement an electronic track and trace pedigree system in Wisconsin as well as drug supply chain security.

In addition, the Pharmacy Examining Board will be conducting a comprehensive review of chs. Phar 12 and 13. The Pharmacy Examining Board will make revisions to these chapters to create clarity, remove obsolete provisions and ensure statutory compliance.

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

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

450.02 (3) The board may promulgate rules:
(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
(b) Establishing security standards for pharmacies.
(c) Relating to the manufacture, distribution and dispensing of hypodermic syringes, needles and other objects used, intended for use or designed for use in injecting a drug.
(d) Necessary for the administration and enforcement of this chapter and ch. 961.
(e) Establishing minimum standards for the practice of pharmacy.

450.071 (4) The board may set, by rule, continuing education requirements for designated representatives under this section.

450.073 (3) The board shall promulgate rules implementing an electronic track and trace pedigree system. Not later than July 1, 2010, the board shall determine the date on which the system will be implemented. The system may not be implemented before July 1, 2011, and the board may delay the implementation date in increments if the board determines that the technology to implement the system is not yet universally available across the prescription drug supply chain or is not capable of adequately protecting patient safety.

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

300 hours

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

Pharmacies, pharmacists, manufacturers, distributors, and consumers.

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

The Drug Quality and Security Act (DQSA) was enacted in 2013 and the Title II of that Act, the Drug Supply Chain Security Act (DSCSA), outlines requirements for an electronic, interoperable system to identify and trace prescription drugs as they move through the supply chain in the United States. The system is to enhance the Food and Drug Administration's ability to protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful, and to improve detection and removal of potentially dangerous drugs from the drug supply chain to protect consumers. DSCSA requires the establishment of national licensure standards for wholesale distributors and third-party logistics providers.

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

This rule is anticipated to have a moderate economic impact and may have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

Authorized Signature

July 23, 2020
Date Submitted

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:
Dale Kleven **Administrative Rules Coordinator**	**11/20/20** 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?
12/3/20	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Phar 5, 6, 7, 11, and 12, Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References and Technical Correction** **2. Phar 2, Relating to Endorsement Requirements for Pharmacists** **a. Proposals for Emergency Rule** **b. Consideration of a Permanent Rule** **3. Phar 15, Relating to Re-use of Personal Protective Equipment** **a. Proposals for Emergency Rule** **b. Consideration of a Permanent Rule** **4. Administrative Rules Reporting Requirement Under 227.29, Stats.** **a. Review of Statutory Requirement and 2019 Report** **b. Proposals for 2021 Report** **5. Pending or 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

Dale Kleven — *November 20, 2020*

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.

TEXT OF RULE

SECTION 1. Phar 5.02 (1) and (2) are amended to read:

Phar 5.02 (1) A pharmacist shall notify the board ~~in writing~~ when his or her name has been legally changed, within 30 days of the change.
(2) A pharmacist shall notify the board ~~in writing~~ when his or her address has been changed, within 30 days of the change.

SECTION 2. Phar 6.04 (1) is amended to read:

Phar 6.04 (1) PROFESSIONAL SERVICE AREA. ~~The professional service area of a pharmacy shall not be less than 250 sq. ft. No more than 20% of the space may be used for storage of bulk pharmaceuticals.~~ If the ~~pharmacy~~ building is open at any time ~~solely as a non-prescription or sundry outlet, without a pharmacist present~~ while the professional service area is closed, the professional service area shall be secured as specified in sub. (3). ~~A variance to the 250 sq. ft. professional service area requirement may be authorized by the board upon submission of a specific plan describing the manner in which the proposed professional service plan varies from the requirement~~.

SECTION 2. Phar 6.04 (2) is repealed.

SECTION 3. Phar 6.04 (3) (title), (a) (intro.), and 2. are amended to read:

Phar 6.04 (3) ~~PROFESSIONAL SERVICE AREA~~ REQUIREMENTS ~~WHERE PHARMACIST IS ABSENT~~ WHEN THE PROFESSIONAL SERVICE AREA IS CLOSED

(a) ~~Except as provided in par. (c), if no pharmacist is present in the professional service area, a pharmacy may convert to a non-prescription or sundry outlet if~~ When the pharmacy professional service area is closed, the pharmacy shall meet all of the following requirements ~~are met:~~

1. A locked, secure physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by ~~unlicensed~~ unauthorized personnel. A secured barrier may be constructed of other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

~~2. The barrier is locked in the absence of the pharmacist authorized personnel.~~

SECTION 4. Phar 6.04 (3) (a) 3. is repealed.

SECTION 5. Phar 6.04 (3) (a) 5. and 6. are amended to read:

Phar 6.04 (3) (a) 5. Signs of reasonable size are posted at ~~the entrance of the building and~~ the professional service area prominently displaying the hours the ~~pharmacist will be on duty~~ professional services are available.

6. The manner in which the telephone is answered does not imply that the ~~location is, at that time, operating as a pharmacy~~ professional services are available.

SECTION 6. Phar 6.04 (3) (a) 7., (b) and (c) and (4) are repealed.

SECTION 7. Phar 7.04 (3) (intro.) as affected by CR 19-145 is amended to read:

7.04 (3) (intro.) The transfer of original prescription information for a controlled substance listed in Schedule III – ~~IV~~ V shall meet the following requirements:

SECTION 8. Chapter Phar 11 is repealed.

SECTION 9. Phar 12.04 is amended to read:

Phar 12.04 Inspections. Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets ~~the standards in 21 USC 351 and 352 (1984) and 21 CFR 210 and 211 (1985)~~ federal and state laws and regulations.

SECTION 10. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 2

Relating to: Endorsement requirements for pharmacists

Rule Type: Emergency

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

On March 25, 2020, the Pharmacy Examining Board granted a variance of s. 450.03 (1), Stats., pursuant to s. 450.02 (3m) (b), Stats., to allow pharmacists who are licensed in good standing in other states, United States territories and the District of Columbia to practice pharmacy in the state of Wisconsin without a Wisconsin license. The purpose of the variance was to compensate for a shortage of pharmacy staff during the pandemic. The variance was in effect for 90 days. Subsequently, the provisions of the variance were superseded by Emergency Order #16 and it was rescinded on April 3, 2020. Then 2019 Act 185 was signed into law which expired on June 10, 2020. On June 4, 2020, the Pharmacy Examining Board reviewed and reissued the variance until August 1, 2020. On July 23, 2020 the Pharmacy Examining Board determined that the requirements of s. 450.02(3m)(b), Stats. were met and extended the variance for another 90 days.

The Pharmacy Examining Board has received information from stakeholders that there remains a shortage of pharmacy staff and the inability to receive a license due to the impact the pandemic has had on the availability of the multi-state pharmacy jurisprudence examination. The Pharmacy Examining Board determines that the preservation of the public health and safety necessitates an emergency rule to temporarily suspend the requirement for applicants who hold a license in another state from taking the multi-state pharmacy jurisprudence examination with Wisconsin as primary state.

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

The objective of the rule is to remove the multi-state pharmacy jurisprudence examination requirement for applicants who hold a license in another jurisdiction.

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

Current rule requires an applicant who holds a license in another jurisdiction to pass the multi-state pharmacy jurisprudence examination in order to obtain a Wisconsin license. This rule would temporarily remove this requirement in order to reduce the delay in applicant's obtaining a Wisconsin license. This is necessary to address the pharmacist workforce shortage during the pandemic.

The Pharmacy Examining Board granted a variance of s. 450.03 (1), Stats., pursuant to s. 450.02 (3m) (b), Stats., to allow pharmacists who are licensed in good standing in other states, United States territories and the District of Columbia to practice pharmacy in the state of Wisconsin without a Wisconsin license. The purpose of the variance was to compensate for a shortage of pharmacy staff during the pandemic. The variance had been extended. At this time the Pharmacy Examining Board is pursuing an emergency rule to address the obstacle for pharmacists who hold a license in another state to obtain a Wisconsin license.

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

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

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

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

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

60 hours

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

Pharmacist applicants

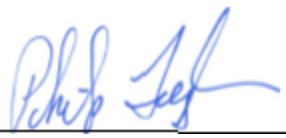
7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

None

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

No anticipated economic impact of implementing the rule and the rule is not likely to have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377



Authorized Signature

September 30, 2020
Date Submitted

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 15

Relating to: Re-use of personal protective equipment

Rule Type: Emergency

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

On March 17, 2020, the Pharmacy Examining Board granted a variance of s. Phar 15.32 (5), pursuant to s. 450.02 (3m) (b), Stats., to allow pharmacists and compounding personnel to re-use personal protective equipment subject to the pharmacist's professional judgment regarding the condition of the equipment and suitability for re-use. The purpose of the request was to compensate for a shortage of PPE during the COVID-19 emergency. The variance was in effect for 90 days. On July 23, 2020 the Pharmacy Examining Board determined that the requirements of s. 450.02(3m)(b), Stats. have been met and extended the variance for another 90 days.

The Pharmacy Examining Board recognizes that there remains a shortage of professional personal protective equipment. The Pharmacy Examining Board determines that the preservation of the public health and safety necessitates an emergency rule to allow for compounding personnel to be able to use the pharmacist's professional judgment regarding the condition of the equipment and suitability for re-use. Without an emergency rule, the ability to compound pharmaceuticals will be impacted resulting in patients not receiving their medications.

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

The objective of the rule is to allow sterile compounding personnel to re-use coveralls, shoe coverings, hair and facial hair covers, face masks, eye shields and gloves when in the pharmacist's professional judgment the condition of the equipment and suitability for re-use.

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

Current rule states that when compounding personnel the buffer or segregated compounding area, a gown may be removed and retained in the ante area or segregated compounding area if not visibly soiled, to be worn again during the same work shift. Coveralls, shoe covers, hair and facial hair covers, face masks, eye shields, and gloves shall be replaced with new ones before re-entering the compounding area.

On March 17, 2020, the Pharmacy Examining Board granted a variance of s. Phar 15.32 (5), pursuant to s. 450.02 (3m) (b), Stats., to allow pharmacists and compounding personnel to re-use personal protective equipment subject to the pharmacist's professional judgment regarding the condition of the equipment and suitability for re-use. The purpose of the request was to compensate for a shortage of PPE during the COVID-19 emergency. The variance was in effect for 90 days. On July 23, 2020 the Pharmacy Examining Board determined that the requirements of s. 450.02(3m)(b), Stats. have been met and extended the variance for another 90 days.

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

15.08 (5) (b) 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.

450.02 (3) (e) The board may promulgate rules establishing minimum standards for the practice of pharmacy.

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

70 hours

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

Pharmacies, including pharmacies located within hospitals, and pharmacists.

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

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

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

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

Minimal or no economic impact.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

Authorized Signature

September 30, 2020
Date Submitted

on which the petition and proposed rule were submitted to the committee.

3. Following receipt of the petition and proposed rule submitted by the legislative council staff under subd. 2., the joint committee for review of administrative rules shall review the petition and proposed rule and may do any of the following:

a. Approve the agency's petition if the committee determines that the proposed rule would repeal an unauthorized rule.

b. Deny the agency's petition.

c. Request that the agency make changes to the proposed rule and resubmit the petition and proposed rule under subd. 1.

4. The committee shall inform the agency in writing of its decision as to the petition.

(c) If the joint committee for review of administrative rules approves a petition to repeal an unauthorized rule as provided in par. (b) 3. a., the agency shall promulgate the proposed rule by filing a certified copy of the rule with the legislative reference bureau under s. 227.20, together with a copy of the committee's decision.

SECTION 7. 227.29 of the statutes is created to read:

227.29 Agency review of rules and enactments. (1) By March 31 of each odd−numbered year, each agency with any rules published in the code shall submit a report to the joint committee for review of administrative rules listing all of the following rules promulgated or otherwise administered by that agency:

(a) Unauthorized rules, as defined in s. 227.26 (4) (a), together with a description of the legislation that eliminated the agency's authority to promulgate any such rule.

(b) Rules for which the authority to promulgate has been restricted, together with a description of the legislation that restricted that authority.

(c) Rules that are obsolete or that have been rendered unnecessary, together with a description of why those rules are obsolete or have been rendered unnecessary.

(d) Rules that are duplicative of, superseded by, or in conflict with another rule, a state statute, a federal statute or regulation, or a ruling of a court of competent jurisdiction, together with a citation to or the text of any such statute, regulation, or ruling.

(e) Rules that the agency determines are economically burdensome.

(2) The report under sub. (1) shall also include all of the following:

(a) A description of the agency's actions, if any, to address each rule listed in the report. If the agency has not taken any action to address a rule listed in the report, the agency shall include an explanation for not taking action.

(b) A description of the status of each rule listed in the previous year's report not otherwise listed.

(c) If the agency determines that there is no rule as described under sub. (1) (a), (b), (c), (d), or (e), a statement of that determination.

(3) If an agency identifies an unauthorized rule under sub. (1) (a) and is not otherwise in the process of promulgating a rule that repeals the unauthorized rule, the agency shall, within 30 days after the agency submits the report, submit a petition to the legislative council staff under s. 227.26 (4) (b) 1. to repeal the unauthorized rule if the agency has not previously done so.

(4) (a) In this subsection, "enactment" means an act or a portion of an act that is required to be published under s. 35.095 (3) (a).

(b) Each agency shall review enactments to determine whether any part of an enactment does any of the following:

1. Eliminates or restricts the agency's authority to promulgate any rules promulgated or otherwise administered by that agency.

2. Renders any rules promulgated or otherwise administered by that agency obsolete or unnecessary.

3. Renders, for any reason, any rules promulgated or otherwise administered by that agency not in conformity with or superseded by a state statute, including due to statutory numbering or terminology changes in the enactment.

4. Requires or otherwise necessitates rule making by the agency.

(c) If an agency determines that any consequence specified in par. (b) 1. to 4. results from an enactment or part of an enactment, within 6 months after the applicable effective date for the enactment or part of the enactment, the agency shall do one or more of the following, as applicable, to address the consequence identified by the agency and notify the joint committee for review of administrative rules of its action:

1. Submit a statement of the scope of a proposed rule under s. 227.135 (2), unless the enactment requires otherwise or unless the agency submits a notice to the committee explaining why it is unable to submit the statement of scope within that time period and an estimate of when the agency plans to submit the statement of scope.

2. In the case of an affected rule that the agency determines is an unauthorized rule, as defined in s. 227.26 (4) (a), submit a petition to the legislative council staff under s. 227.26 (4) (b) 1.

3. In the case of a consequence specified under par. (b) 3. that can be addressed by the legislative reference bureau using its authority under s. 13.92 (4) (b), submit a request to the legislative reference bureau to use that authority.

SECTION 8. Initial applicability.

(1) The treatment of section 227.29 (4) of the statutes first applies to enactments published by the legislative

PHARMACY EXAMINING BOARD

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March 22, 2019

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: Report Submitted in Compliance with s. 227.29 (1), Stats.

Dear Senator Nass and Representative Ballweg:

This report has been prepared and submitted in compliance with s. 227.29 (1), Stats.

I. Unauthorized rules, as defined in s. 227.26 (4) (a):

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules are unauthorized.

II. Rules for which the authority to promulgate has been restricted:

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules have restricted authority.

III. Rules that are obsolete or that have been rendered unnecessary:

Rule	Description of why the rule is obsolete or has been rendered unnecessary.	Action taken to address or reason for not taking an action
Phar 5.02	It is no longer necessary for a pharmacist to notify the Board in writing of a name or address change. The change is typically done electronically.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.
Ch. Phar 7	This chapter has not had a comprehensive review in over 15 years. There are several obsolete and unnecessary provisions, particularly in the areas of technology.	The Board is currently working on an entire rewrite of this chapter to reflect current pharmacy standards and practice, and reduce the regulatory impact on pharmacies without negatively impacting public safety.

IV. Rules that are duplicative of, superseded by, or in conflict with another rule, a state statute, a federal statute or regulation, or a ruling of a court of competent jurisdiction:

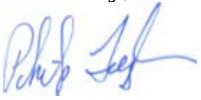
Rule	Citation or the text of the statute, regulation, or ruling.	Action taken to address or reason for not taking an action
Phar 11.01	Procedures for disciplinary proceedings. Procedures for disciplinary proceedings before the board are set forth in ch. SPS 2. This provision is unnecessary.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.
Phar 12.04	Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets the standards in 21 USC 351 and 352 (1984) and 21 CFR 210 and 211 (1985). The referenced federal statute has been superseded.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.

V. Rules that are economically burdensome:

Rule		**Action taken to address or reason for not taking an action**
Phar 6.04	Floor design, professional service area, and prescription counter space are economically burdensome and do not correspond with the evolving types of pharmacies.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.
Phar 6.07	Storage requirements are economically burdensome and do not correspond with the evolving types of pharmacies.	The Board is currently drafting a rule to update this section.
Phar 6.075	Temperature and humidity requirements were based upon nationally accepted standards. Stakeholders informed the Board of challenges and burdens in meeting these provisions.	The Board is currently drafting a rule to update this section.
Ch. Phar 7	This chapter has not had a comprehensive review in over 15 years. There are several provisions which are economically burdensome.	The Board is currently working on an entire rewrite of this chapter to reflect current pharmacy standards and practice, and reduce the regulatory impact on pharmacies without negatively impacting public safety.

Thank you.

Cordially,



Philip Trapskin
Chairperson