



**TELECONFERENCE/VIRTUAL
PHARMACY EXAMINING BOARD**
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Christian Albouras (608) 266-2112
July 23, 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

11:00 A.M.

(OR IMMEDIATELY FOLLOWING PHARMACY RULES COMMITTEE MEETING)

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of June 4, 2020 (5-10)

C. Conflicts of Interest

D. Introductions, Announcements and Recognition

- 1) Tiffany O’Hagan, Pharmacist Member (Will Replace: LaDien), Expiration 7/1/2024

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. Administrative Rule Matters – Discussion and Consideration (11)

- 1) Scope to Amend Phar 1, 6, 7, 12, 13 Relating to Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers and Distributors **(12-14)**
- 2) Phar 2 Relating to Reciprocal Credentials for Service Members, Former Service Members and their Spouses **(15)**
- 3) Phar 5, 6, 7, 11, and 12 Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction **(16-17)**
- 4) Designation of Gabapentin as a Monitored Drug in the Prescription Drug Monitoring Program
- 5) Pending or Possible Rulemaking Projects

H. COVID-19 – Discussion and Consideration (18-28)

- 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. Variance Requests Received After Preparation of the Agenda
- 3) § 450.035, Wis. Stat. – Administration of Drug Products and Devices: Vaccines and Any Needed Variances to Help with Vaccinations this Fall

I. Pilot Program Matters – Discussion and Consideration

- 1) Automated Technology Final Check Expansion

J. Email Blast Planning & Distribution – Discussion and Consideration

K. Forms Review Project – Discussion and Consideration

L. Revisions to the Pharmacy Examining Board Rules and Statute Web Page – Discussion and Consideration

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

- 1) National Association of Boards of Pharmacy (NABP)-American College of Clinical Pharmacy (ACCP) District IV 2022 Annual Meeting Planning

N. Discussion and Consideration on Items Added After Preparation of Agenda

- 1) Introductions, Announcements and Recognition
- 2) Nominations, Elections, and Appointments
- 3) Administrative Matters
- 4) Election of Officers
- 5) Appointment of Liaisons and Alternates
- 6) Delegation of Authorities
- 7) Education and Examination Matters
- 8) Credentialing Matters
- 9) Practice Matters
- 10) Legislative and Policy Matters
- 11) Administrative Rule Matters
- 12) Pilot Program Matters
- 13) Liaison Reports
- 14) Board Liaison Training and Appointment of Mentors
- 15) Informational Items
- 16) Division of Legal Services and Compliance (DLSC) Matters
- 17) Presentations of Petitions for Summary Suspension
- 18) Petitions for Designation of Hearing Examiner
- 19) Presentation of Stipulations, Final Decisions and Orders
- 20) Presentation of Proposed Final Decisions and Orders
- 21) Presentation of Interim Orders
- 22) Pilot Program 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 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. Deliberation on Division of Legal Services and Compliance Matters

1) Administrative Warnings

- a. 18 PHM 057 – K.M.H. **(29-30)**

2) Case Closings

- a. 18 PHM 057 – H.A. **(31-34)**
b. 18 PHM 121 – E.P. **(35-39)**
c. 18 PHM 147 – M.R.S., W. **(40-43)**
d. 19 PHM 035 – B.P.I. **(44-47)**
e. 19 PHM 043 – L.D. **(48-50)**
f. 19 PHM 076 – C.C.P. **(51-53)**
g. 19 PHM 077 – M.R.C. **(54-56)**
h. 19 PHM 112 – A.R.X. **(57-59)**
i. 19 PHM 146 – R.D.M., C. **(60-62)**
j. 19 PHM 176 – A.P. **(63-66)**
k. 19 PHM 193 – I.P. **(67-79)**
l. 19 PHM 202 – B.B.P.L. **(80-84)**
m. 19 PHM 207 – C. **(85-89)**
n. 19 PHM 208 – D.P. **(90-94)**
o. 19 PHM 210 – E.P.L. **(95-99)**
p. 19 PHM 213 – F.R.C.P. **(100-140)**
q. 19 PHM 216 – G.G.P. **(141-145)**
r. 19 PHM 222 – M.D.E.P. **(146-150)**
s. 19 PHM 225 – P.D.S. **(151-155)**
t. 19 PHM 227 – P.D. **(156-160)**
u. 20 PHM 045 – M.P. **(161-164)**

3) Stipulations and Final Decisions and Orders

- a. 20 PHM 043 – ImprimisRx **(165-170)**

Q. 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

R. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

- S. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate
- T. Open Session Items Noticed Above Not Completed in the Initial Open Session
- U. Board Meeting Process (Time Allocation, Agenda Items) – Discussion and Consideration
- V. Board Strategic Planning and its Mission, Vision, and Values – Discussion and Consideration

ADJOURNMENT

NEXT MEETING: SEPTEMBER 24, 2020

 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. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112, or the Meeting Staff at 608-266-5439.

**TELECONFERENCE/VIRTUAL
PHARMACY EXAMINING BOARD
MEETING MINUTES
JUNE 4, 2020**

PRESENT: Franklin LaDien, Anthony Peterangelo, Philip Trapskin, John Weitekamp, Cathy Winters, Michael Walsh

EXCUSED: Shana Weiss

STAFF: Christian Albouras, DPD Division Administrator; Jameson Whitney, Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Megan Glaeser, Bureau Assistant; and other Department staff

CALL TO ORDER

Philip Trapskin, Chairperson, called the meeting to order at 11:01 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

MOTION: Cathy Winters moved, seconded by Franklin LaDien, to adopt the Minutes of March 5, 2020 as published. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Board Members – Term Expiration Dates

MOTION: Cathy Winters moved, seconded by John Weitekamp, to recognize and thank Franklin “Rocky” LaDien for his years of service to the Pharmacy Examining Board and the State of Wisconsin as he reaches the end of his term. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Adopt CR 19-145, Relating to the Practice of Pharmacy

MOTION: Cathy Winters moved, seconded by John Weitekamp, to approve the Adoption Order for Clearinghouse Rule CR 19-145, relating to the practice of Pharmacy. Motion carried unanimously.

MOTION: Cathy Winters moved, seconded by Michael Walsh, to direct department staff to submit Clearinghouse Rule CR 19-145 in a manner that allows the rule to go into effect on January 1, 2021. Motion carried unanimously.

Adopt CR 19-164, Relating to Internships

MOTION: Franklin LaDien moved, seconded by John Weitekamp, to approve the Adoption Order for Clearinghouse Rule CR 19-164, relating to internships. Motion carried unanimously.

Adopt CR 19-165, Relating to Pharmacy Storage

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to approve the Adoption Order for Clearinghouse Rule CR 19-165, relating to pharmacy storage. Motion carried unanimously.

Scope Amending Phar 2 Relating to Service Member Reciprocal License (2019 Act 143)

MOTION: Cathy Winters moved, seconded by Michael Walsh, to approve the Scope Statement amending Phar 2, relating to Service Member Reciprocal License (2019 Act 143), 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. Motion carried unanimously.

Scope Amending Phar 5, 6, 7, 11, and 12, Relating to Changes Identified in the Board's Report Pursuant to s. 227.29, Wis. Stat., and Technical Correction

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to approve the Scope Statement amending Phar 5, 6, 7, 11, and 12, relating to Changes Identified in the Board's Report Pursuant to s. 227.29, Wis. Stat., and Technical Correction, 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. Motion carried unanimously.

COVID-19

Variances

MOTION: Cathy Winters moved, seconded by John Weitekamp, to direct board legal counsel to extend all active variances issued during the COVID-19 emergency to August 1, 2020 because the Board determines the extension is necessary to protect public health, safety and welfare. Motion carried unanimously.

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to direct board legal counsel to draft a variance that will allow pharmacists licensed in other states to practice pharmacy in the State of Wisconsin temporarily without first obtaining a Wisconsin license under the same conditions that were outlined in Emergency Order 16. Motion carried unanimously.

NEWSLETTER MATTERS

MOTION: Franklin LaDien moved, seconded by Anthony Peterangelo, to delegate authority to the Digest Liaison to handle all matters relating to newsletters or digests. Motion carried unanimously.

CLOSED SESSION

MOTION: Cathy Winters 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: Franklin LaDien-yes; Anthony Peterangelo-yes; Philip Trapskin-yes; John Weitekamp-yes; and Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 2:16 p.m.

(Michael Walsh was disconnected for this vote.)

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

Administrative Warnings

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to issue an Administrative Warning in the matter of the following cases.

1. 17 PHM 171 – C.P.K.
2. 17 PHM 183 – P.R.N.
3. 18 PHM 035 – G.R.K.
4. 18 PHM 117 – B.E.N.
5. 18 PHM 117 – M.C.P.
6. 18 PHM 126 – M.E.M.
7. 18 PHM 155 – A.T.O.
8. 18 PHM 173 – J.A.K.
9. 20 PHM 045 – D.G.K.

Motion carried unanimously.

Case Closings

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

1. 17 PHM 097 – K.L.G. & W.P. – Prosecutorial Discretion (P3)
2. 17 PHM 106 – A.K.S. – Insufficient Evidence
3. 17 PHM 147 – W.P. & P.E.T. – No Violation

4. 17 PHM 171 – W.P., M.O., & E.N. – No Violation
5. 17 PHM 183 – L.M.A. – No Violation
6. 18 PHM 035 – S.P., S.M.G., & R.L.S. – No Violation
7. 18 PHM 053 – A.I. – No Violation
8. 18 PHM 112 – C.L.R. & D.B.B. – No Violation, Prosecutorial Discretion (P2)
9. 18 PHM 114 – C.D.R & S.P. – Prosecutorial Discretion (P3)
10. 18 PHM 126 – S.P. & M.J.P. – No Violation
11. 18 PHM 127 – J.M.F. & W.P. – Insufficient Evidence
12. 18 PHM 132 – W.P. – Prosecutorial Discretion (P2)
13. 18 PHM 132 – C.P. – No Violation
14. 18 PHM 155 – W.P. – No Violation
15. 18 PHM 173 – S.P., S.P. Inc., & S.P. LTC – No Violation
16. 18 PHM 193 – C.D.B. – No Violation
17. 18 PHM 125 – S.P. – Insufficient Evidence
18. 18 PHM 222 – S.Y.R.X. – Insufficient Evidence
19. 19 PHM 057 – L.H.P. – Prosecutorial Discretion (P2)
20. 19 PHM 102 – W.P. – Insufficient Evidence
21. 19 PHM 108 –H.P. – Insufficient Evidence
22. 19 PHM 110 –P.C.I. – Prosecutorial Discretion (P5)
23. 19 PHM 119 –C.P.K.L. – Insufficient Evidence
24. 19 PHM 141 –W.P. & J.P.A. – Insufficient Evidence
25. 19 PHM 153 –R.K.K. & W. – Insufficient Evidence
26. 19 PHM 108 –H.P. – Insufficient Evidence
27. 19 PHM 161 –A.L.L. – Prosecutorial Discretion (P5)
28. 19 PHM 186 –W.P. & C.G. – No Violation
29. 19 PHM 196 –A.P. – Prosecutorial Discretion (P2)
30. 19 PHM 197 – A.P.S. – Prosecutorial Discretion (P2)
31. 19 PHM 198 –A.P. – No Violation
32. 19 PHM 199 –B.A.P. – Prosecutorial Discretion (P1)
33. 19 PHM 200 –B.S.P. – Prosecutorial Discretion (P2)
34. 19 PHM 201 –S.S.P. – Prosecutorial Discretion (P2)
35. 19 PHM 203 –C.P. – Prosecutorial Discretion (P3)
36. 19 PHM 204 – C.A.W.P. – Prosecutorial Discretion (P2)
37. 19 PHM 205 –C.P. – Prosecutorial Discretion (P2)
38. 19 PHM 206 – C.P.S.T. – No Violation
39. 19 PHM 209 –E.L.P. – Prosecutorial Discretion (P3)
40. 19 PHM 211 –E.P. – Prosecutorial Discretion (P3)
41. 19 PHM 212 –F.P. – Prosecutorial Discretion (P2)
42. 19 PHM 214 –G.P. – Prosecutorial Discretion (P3)
43. 19 PHM 215 –G.P. – No Violation
44. 19 PHM 217 –G.H.P. – Prosecutorial Discretion (P2)
45. 19 PHM 218 –H.M.P. – Prosecutorial Discretion (P2)
46. 19 PHM 219 –J.C.A.W. – Prosecutorial Discretion (P2)
47. 19 PHM 220 –L.H. – Prosecutorial Discretion (P2)
48. 19 PHM 221 –M.H. – Prosecutorial Discretion (P2)
49. 19 PHM 223 –M.P.I. – Prosecutorial Discretion (P3)
50. 19 PHM 224 – O.M.H.P. – Prosecutorial Discretion (P2)

51. 19 PHM 226 –P.C.P. – Prosecutorial Discretion (P3)
52. 19 PHM 228 – P.C.P.L. – Prosecutorial Discretion (P3)
53. 19 PHM 232 –R.P. – Prosecutorial Discretion (P1)
54. 19 PHM 233 –W.P. & C.G. – Prosecutorial Discretion (P2)
55. 19 PHM 237 –S.P. – Prosecutorial Discretion (P2)
56. 19 PHM 239 –T.D.S. – Prosecutorial Discretion (P2)
57. 19 PHM 240 –W.H.P. – Prosecutorial Discretion (P2)
58. 19 PHM 243 – M.F.P. – Prosecutorial Discretion (P2)
59. 19 PHM 244 – E.T.P. – Prosecutorial Discretion (P2)
60. 19 PHM 247 – M.M.C. & W.P. – Prosecutorial Discretion (P2)
61. 19 PHM 257 – D.I.P.C.L. – Prosecutorial Discretion (P2)
62. 19 PHM 258 – S.R.X.P. – Prosecutorial Discretion (P3)
63. 19 PHM 259 – R.P. – Prosecutorial Discretion (P1)
64. 19 PHM 261 – L.S.P. – Prosecutorial Discretion (P3)
65. 19 PHM 267 – G.G.P. – Prosecutorial Discretion (P1)
66. 19 PHM 270 – B.P. – Prosecutorial Discretion (P2)
67. 19 PHM 294 – H.P. – Prosecutorial Discretion (P1)

Motion carried unanimously.

Stipulations, Final Decisions and Orders

MOTION: Michael Walsh moved, seconded by Cathy Winters, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings of the following cases:

1. 17 PHM 097– Gina L. Lusic, R.Ph.
2. 17 PHM 106– Medpoint Pharmacy, Inc.
3. 18 PHM 112– CVS Pharmacy #5390
4. 18 PHM 121– Michael Eanneli, R.Ph.
5. 18 PHM 124– Jay R. Joshi, R.Ph.
6. 19 PHM 060– Kayla F. Brisson, R.Ph.
7. 19 PHM 155– Guaranteed Returns

Motion carried unanimously.

Matters Relating to Costs/Orders Fixing Costs

Walter P. Matoska, R.Ph. (DHA Case Number SPS-19-0050/DLSC Case Number 18 PHM 001)

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo to adopt the Order Fixing Costs in the matter of disciplinary proceedings against Walter P. Matoska, R.Ph., Respondent DHA Case Number SPS-19-0050/DLSC Case Number 18 PHM 001. Motion carried unanimously.

(Phillip Trapskin recused himself and disconnected for deliberation and voting in the matter concerning Walter P. Matoska, R.Ph., DHA Case Number SPS-19-0050/DLSC Case Number 18 PHM 001.)

RECONVENE TO OPEN SESSION

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

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

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: John Weitekamp 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.)

ADJOURNMENT

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

The meeting adjourned at 3:42 p.m.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 13 July 2020 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: 23 July 2020	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Administrative Rule Matters <ol style="list-style-type: none"> 1. Scope to Amend Phar 2 Relating to Foreign Educated Pharmacists 2. Scope to Amend Phar 1, 6, 7, 12, 13 Relating to Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers and Distributors 3. Phar 2 Relating to Reciprocal Credentials for Service Members, Former Service Members and their Spouses 4. Phar 5, 6, 7, 11, and 12 Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction. 5. Designation of Gabapentin as a Monitored Drug in the Prescription Drug Monitoring Program 6. Updates on Pending or Possible Rulemaking Projects 	
7) Place Item in: <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed:			
11) Authorization			
<i>Sharon Henes</i>		<i>13 July 2020</i>	
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	

State of Wisconsin
Department of Safety & Professional Services

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 1, 6, 7, 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.

Rev. 3/6/2012

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

Department Head or Authorized Signature

Date Submitted

TEXT OF RULE

SECTION 1. Phar 2.06 is created to read:

Phar 2.06 Application procedure for service members, former service members, and their spouses. (1) In this section:

- (a) “Former service member” means a person who was discharged from the U.S. armed forces under conditions other than dishonorable within 4 years of the date on which the service member or the spouse of the service member applies for a reciprocal license under this section.
 - (b) “Service member” means a member of the U.S. armed forces, a reserve unit of the U.S. armed forces, or the national guard of any state.
 - (c) “Spouse” includes the spouse of a person who died while in the service in the U.S. armed forces or in forces incorporated as part of the U.S. armed forces.
- (2) A service member, a former service member, or the spouse of a service member shall submit all of the following:
- (a) Completed application form with the signature of the applicant and fee as determined by the department under s. 440.04, Stats.
 - (b) Statement that the individual resides in this state.
 - (c) Documentation that the individual is a service member, former service member or the spouse of a service member. If an individual is unable to provide the documentation, the individual may submit an affidavit to the board stating that the individual is a service member, former service member, or the spouse of a service member or former service member.
 - (d) Evidence of holding a license, in good standing, that was granted by a governmental authority in a jurisdiction outside of Wisconsin that qualifies the individual to perform acts authorized under a pharmacy license granted by the board.
- (3) A license granted under this subsection expires on the applicable renewal date specified in s. 440.08 (2) (a), except that if the first renewal date specified in s. 440.08 (2) (a) after the date on which the license is granted is within 180 days of the date on which the license is granted, the license expires on the 2nd renewal date specified in s. 440.08 (2) (a) after the date on which the license is granted.

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)

Chapter Phar 6

PHARMACY LICENSES AND EQUIPMENT

Phar 6.01	Licenses; application.	Phar 6.06	Laws and other references.
Phar 6.02	Licenses; change of location or ownership.	Phar 6.07	Storage.
Phar 6.03	Changes in managing pharmacist.	Phar 6.075	Temperature; Humidity.
Phar 6.04	Floor design.	Phar 6.08	Security.
Phar 6.05	Sanitation.		

Note: Chapter Phar 6 as it existed on January 31, 1983, was repealed and a new chapter Phar 6 was created effective February 1, 1983.

Phar 6.01 Licenses; application. Requirements and procedures for applying for a pharmacy license are specified in s. 450.06, Stats. Approved application forms are available from the board. Appointments for the required pharmacy inspection may be made by contacting the board office. A license application and fee shall be on file with the board at least 30 days prior to the granting of the pharmacy license. A pharmacy may not operate unless a pharmacy license has been granted. Board action shall be taken within 60 business days of receipt of a completed pharmacy application, as provided in s. SPS 4.03.

Note: Applications are available upon request to the board office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; correction made under s. 13.93 (2m) (b) 7., Stats., Register, January, 1989, No. 397; am. Register, August, 1991, No. 428, eff. 9-1-91; am., Register, December, 1998, No. 516, eff. 1-1-99; correction made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.

Phar 6.02 Licenses; change of location or ownership. (1) A pharmacy license authorizes a pharmacy to operate only at the location designated on the license. Licenses may not be transferred to another location.

(1m) A hospital which has a pharmacy area providing outpatient pharmacy services which is physically separate from, and not contiguous to the area from which inpatient pharmacy services are provided, shall have a pharmacy license for the outpatient pharmacy in addition to a license for the inpatient pharmacy.

(2) Any change in pharmacy ownership shall be reported to the board office and the pharmacy license of the former owner returned. A pharmacy license shall be granted to the new pharmacy owner before the pharmacy may operate.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; cr. (1m), Register, February, 1996, No. 482, eff. 3-1-96.

Phar 6.03 Changes in managing pharmacist. The pharmacy owner shall report to the board any change of managing pharmacist within 5 days following the change.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83.

Phar 6.04 Floor design. (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 is open at any time solely as a non-prescription or sundry outlet, without a pharmacist present, 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 area plan varies from the requirement.

(2) PRESCRIPTION COUNTER SPACE. A pharmacy shall have a prescription counter with a free working surface of 18 or more inches in width and at least 12 square feet in area. This free-working surface must be used only for the compounding and dispensing of prescriptions.

(3) PROFESSIONAL SERVICE AREA REQUIREMENTS WHERE PHARMACIST IS ABSENT. (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 the following requirements are met:

1. A secured, physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by unlicensed 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.

3. A patient's telephone request to renew a certain prescription may be accepted, but a telephone message from a practitioner giving a new prescription order or renewal authority may not be accepted.

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.

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

7. The pharmacy examining board office is notified of the hours during which the establishment is operated as a sundry outlet.

(b) The managing pharmacist is responsible for compliance with all professional service area security requirements.

(c) Where no pharmacist is present in the professional service area a pharmacy is not required to convert to a non-prescription or sundry outlet if the following requirements are met:

1. The pharmacist is absent for a time period of one half hour or less.

2. The pharmacist must be accessible for communication with the remaining pharmacy staff by phone, pager or other device.

3. The pharmacy must indicate that the pharmacist is not available in the professional service area and indicate the period of absence and the time of the pharmacist's return.

4. Pharmacy technicians may only perform duties allowed by s. Phar 7.015 (2).

(4) PROFESSIONAL SERVICE AREA REMODELING. Any modifications of the approved floor plan shall be submitted to and approved by the board or its designee. Board action must be taken within 60 days.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; cr. (4), Register, August, 1991, No. 428, eff. 9-1-91; r. (3) (a) 4., Register, January, 1996, No. 481, eff. 2-1-96; CR 03-096: am. (3) (a) (intro.), cr. (3) (c) Register May 2004 No. 581, eff. 6-1-04.

Phar 6.05 Sanitation. The professional service area of a pharmacy shall have a sink convenient and suitable for cleaning

pharmaceutical equipment and supplied with hot and cold running water. Detergent and a waste disposal container also shall be provided in the professional service area.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83.

Phar 6.06 Laws and other references. The professional service area of a pharmacy shall have equipment of appropriate design and size for the intended pharmacy practice and shall have all of the following:

(1j) The latest available or immediately accessible version of federal and state pharmacy laws consisting of:

(a) Drug enforcement administration regulations, 21 CFR 1300 to end.

(b) Wisconsin pharmacy laws, ch. 450, Stats.

(c) Wisconsin controlled substances act, ch. 961, Stats.

(d) Wisconsin administrative code, rules of the pharmacy examining board.

(2k) References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(3L) The telephone number of a poison center. This number shall be conspicuously posted in the prescription department.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; r. and recr. Register, January, 1989, No. 397, eff. 2-1-89; correction in (2) made under 13.93 (2m) (b) 6., Stats., Register, January, 1989, No. 397; am. (1) (j) 3., Register, December, 1998, No. 516, eff. 1-1-99; CR 01-023: am. (1) (intro.) and (a) to (c), (j) (intro.) and (k), Register, August 2001 No. 548 eff. 9-1-01; 2017 Wis. Act 18: r. and recr. (title), renum. (1) (intro.) to (intro.) and am., r. (1) (a) to (i), renum. (1) (j), (k), (L) to (1j), (2k), (3L), r. (2) Register June 2017 No. 738, eff. 7-1-17.

Phar 6.07 Storage. (1) The professional service area shall have a refrigerator adequate for the storage of biological and other drugs requiring refrigeration.

(2) The professional service area shall have sufficient shelf, drawer or cabinet space for the proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment.

(3) Controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory of non-controlled substances in a manner that obstructs theft.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83.

Phar 6.075 Temperature; Humidity. (1) DEFINITIONS. In this section:

(a) "Business day" means a day the pharmacy is open for business.

(b) "Dry place" means a place that does not exceed 40% average relative humidity at 68 degrees Fahrenheit or the equivalent water vapor pressure at other temperatures.

(c) "Freezer" means a place in which the temperature is maintained between -13 and +14 degrees Fahrenheit.

(d) "Mean kinetic temperature" means the calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.

(e) "Refrigerator" means a place in which the temperature is maintained between 36 and 46 degrees Fahrenheit.

(2) STORAGE. Drugs shall be stored at appropriate temperature and under appropriate conditions, including in a dry place, according to the manufacturer recommendation or an official pharmaceutical compendium.

(3) RECORDING DEVICES. Manual, electromechanical or electronic temperature and humidity recording devices shall be placed within the storage space to accurately determine the area's temperature and humidity.

(4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy shall be monitored at least once during each business day. A minimum and maximum temperature over the course of the time a pharmacy is closed shall be obtained.

(5) RECORDS. Temperature and humidity records shall be maintained for a minimum of 5 years.

(6) DISPENSING OF SAFE DRUGS. The pharmacist shall use professional judgment, including consideration of the mean kinetic temperature, to determine whether a drug is safe to be dispensed.

History: CR 16-073: cr. Register November 2017 No. 743, eff. 12-1-17; corrections in (1) (b) and (c), (6) made under s. 35.17, Stats., Register November 2017 No. 743.

Phar 6.08 Security. A pharmacy shall have a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the board.

History: Cr. Register, December, 1998, No. 516, eff. 1-1-99; CR 05-001: am. Register August 2005 No. 596, eff. 9-1-05; CR 09-098: am. Register May 2010 No. 653, eff. 6-1-10.



April 15, 2020

Philip J. Trapskin
[redacted]
[redacted]

RE: Variance Request per Wis. Stat. § 450.02(3m)

Dear Mr. Trapskin,

On April 14, 2020, the Wisconsin Pharmacy Examining Board reviewed your variance request. You requested a variance of Wis. Admin. Code § Phar 7.01(1)(e) and (em), to **temporarily relax the consulting and delivery requirements when delivering medications or devices to a patient**. The stated purpose of the request is to allow flexibility regarding consultation and delivery to help compensate for workforce and personal protective equipment shortages during the COVID-19 emergency.

The effect of the variance would modify § Phar 7.01(1)(e) and (em) to read as follows:

(e) The pharmacist may use their professional judgment to determine if and how consultation is provided.

(em) Transfer the prescription to the patient or agent of the patient. Transfer may take place at any location that is appropriate under the circumstances and agreeable to the patient, and may be done by any appropriate delegate.

The Board considered the evidence presented and determined that the requirements of Wis. Stat. § 450.02(3m)(a) have been met. **Your variance, as requested, has been granted.** This variance shall apply to all persons legally permitted to practice pharmacy in the state of Wisconsin, and shall remain in effect for 90 days from today's date pursuant to Wis. Stat. § 450.02(3m)(b), unless modified or extended by further action of the Pharmacy Examining Board.

Please feel free to contact me if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jameson R. Whitney', is written over the typed name.

Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov



April 15, 2020

Philip Trapskin
[redacted]
[redacted]

RE: Variance Request per Wis. Stat. § 450.02(3m)

Dear Mr. Trapskin,

On April 14, 2020, the Wisconsin Pharmacy Examining Board reviewed your variance request. You requested a variance of Wis. Stat. § 450.07(1) and Phar 12.03(1) to **temporarily allow the manufacturing of needed personal protective equipment (PPE) without a license, an inspection, or compliance with FDA regulations**. The stated purpose of the request is to mirror similar actions taken by the federal government to allow manufacturers of other goods to manufacture masks during the COVID-19 emergency.

The effect of the variance would modify Wis. Stat. § 450.07(1) to read as follows:

(1) Except as provided under sub. (1m), no person may engage in manufacturing in this state unless the person obtains a manufacturer's license from the board, except that a person may engage in the manufacturing of personal protective equipment without a license during a period of declared emergency under Wis. Stat. § 323.10. For the issuance of a license under this subsection, the applicant shall pay the initial credential fee determined by the department under s. 440.03 (9) (a).


The variance would also modify Phar 12.03(1) to read as follows:

(1) No person may engage in the manufacturing of any drug or device in this state unless a license is granted to the person by the board under this chapter except that a person may engage in the manufacturing of personal protective equipment without a license during a period of declared emergency under Wis. Stat. § 323.10. The board shall not require any such person to comply with the federal regulations referenced in Phar 12.04 and 12.05 insofar as such regulations are relaxed or waived by the appropriate federal agencies during the declared emergency.

The Board considered the evidence presented and determined that the requirements of Wis. Stat. § 450.02(3m)(a) have been met. **Your variance, as requested, has been granted.** This variance shall apply to all persons seeking to manufacture PPE on a temporary basis in the state of Wisconsin, and shall remain in effect for 90 days from today's date pursuant to Wis. Stat. § 450.02(3m)(b), unless modified or extended by further action of the Pharmacy Examining Board.

Please feel free to contact me if you have any questions.

Sincerely,


Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov



June 23, 2020

Philip J. Trapskin
[redacted]
[redacted]

RE: Variance Request per Wis. Stat. §450.02(3m)

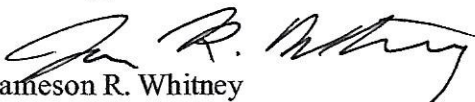
Dear Mr. Trapskin,

On March 25, 2020, the Wisconsin Pharmacy Examining Board granted a variance of Wis. Stat. § 450.06(1), to **allow pharmacists to dispense prescription medications and devices in locations that are not licensed pharmacies**. The stated purpose of the request was to compensate for rapidly changing conditions that may require flexibility for pharmacists to provide needed services during the COVID-19 emergency.

The Board considered whether to extend this variance on June 4, 2020, and determined that the requirements of Wis. Stat. §450.02(3m)(b) have been met. This variance is hereby **extended to August 1, 2020**, unless modified, rescinded, or extended by further action of the Pharmacy Examining Board pursuant to Wis. Stat. §450.02(3m)(b).

Please feel free to contact me if you have any questions.

Sincerely,


Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov



June 12, 2020

Philip J. Trapskin
[redacted]
[redacted]

RE: Variance Request per Wis. Stat. § 450.02(3m)

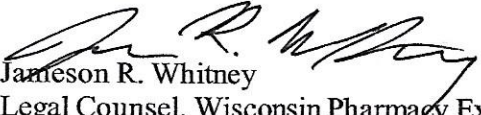
Dear Mr. Trapskin,

On March 17, 2020, the Wisconsin Pharmacy Examining Board granted a variance of Wis. Admin. Code § Phar 15.32(5), to **allow pharmacists and compounding personnel to re-use personal protective equipment (PPE) subject to the pharmacist's professional judgment regarding the condition of the equipment and suitability for re-use.** This included all PPE listed in Section Phar 15.32(5), specifically coveralls, shoe covers, hair and facial covers, face masks, eye shields, and gloves. The stated purpose of the request was to compensate for a shortage of PPE during the COVID-19 emergency.

The Board considered whether to extend this variance on June 4, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. This variance is hereby **extended to August 1, 2020**, unless modified, rescinded, or extended by further action of the Pharmacy Examining Board pursuant to Wis. Stat. § 450.02(3m)(b).

Please feel free to contact me if you have any questions.

Sincerely,


Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov



March 17, 2020

Sarah Sorum, Pharm. D.
Pharmacy Society of Wisconsin
701 Heartland Trail
Madison, WI 53717

RE: Variance Request per Wis. Stats. §450.02(3m)

Dear Ms. Sorum,

On March 15, 2020, the Wisconsin Pharmacy Examining Board reviewed your variance request and correspondence of March 6, 2020. You requested a variance of Wis. Admin. Code Phar 15.31(5), to **allow pharmacists and compounding personnel to re-use personal protective equipment (PPE) subject to the pharmacist's professional judgment regarding the condition of the equipment and suitability for re-use.** This would include all PPE listed in Phar 15.31(5), specifically coveralls, shoe covers, hair and facial covers, face masks, eye shields, and gloves. The stated purpose of the request is to compensate for a shortage of PPE during the COVID-19 emergency.

The Board considered the evidence presented and determined that the requirements of Wis. Stats. §450.02(3m)(a) have been met. **Your variance, as requested, has been granted.** This variance shall apply to all Wisconsin pharmacists and compounding personnel, and shall remain in effect for 90 days from today's date pursuant to Wis. Stats. §450.02(3m)(b), unless modified or extended by further action of the Pharmacy Examining Board.

Please feel free to contact me if you have any questions.

Sincerely,

Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov



April 16, 2020

Philip Trapskin
[redacted]
[redacted]

RE: Variance Request per Wis. Stat. § 450.02(3m)

Dear Mr. Trapskin,

On April 16, 2020, the Wisconsin Pharmacy Examining Board reviewed your variance request. You requested a variance of Wis. Stat. § 450.072(2)(b) to **temporarily allow wholesale distributors to deliver prescription drugs and devices to addresses approved by the board**. The stated purpose of the request is to enable the creation and use of “surge sites” to help respond to the COVID-19 emergency.

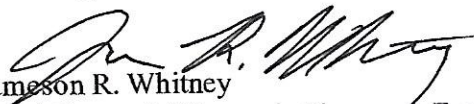
The effect of the variance would modify Wis. Stat. § 450.072(2)(b) to read as follows:

(b) A manufacturer or wholesale distributor may distribute a prescription drug only to the premises listed on the person's license or authorization, or to a facility or other site that has been approved by the Pharmacy Examining Board or its designee after written request to the board, and authorized by the Drug Enforcement Administration if the facility or other site is to receive controlled substances, except that a manufacturer or wholesale distributor may distribute the prescription drugs to an authorized agent of the person at the premises of the manufacturer or wholesale distributor if all of the following are true:

The Board considered the evidence presented and determined that the requirements of Wis. Stat. § 450.02(3m)(a) have been met. **Your variance, as requested, has been granted.** This variance shall apply to all persons legally permitted to engage in the wholesale distribution of prescription drugs or devices in the state of Wisconsin, and shall remain in effect for 90 days from today's date pursuant to Wis. Stat. § 450.02(3m)(b), unless modified or extended by further action of the Pharmacy Examining Board.

Please feel free to contact me if you have any questions.

Sincerely,


Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov



March 25, 2020

Danielle M. Womack, MPH
Pharmacy Society of Wisconsin
701 Heartland Trail
Madison, WI 53717

RE: Variance Request per Wis. Stats. § 450.02(3m)

Dear Ms. Womack,

On March 25, 2020, the Wisconsin Pharmacy Examining Board reviewed your variance request. You requested a variance of Wis. Stats. § 450.06(1), to **allow pharmacists to practice pharmacy in locations that are not licensed pharmacies**. The stated purpose of the request is to compensate for rapidly changing conditions that may require flexibility for pharmacists to provide needed services during the COVID-19 emergency.

The Board considered the evidence presented and determined that the requirements of Wis. Stat. § 450.02(3m)(a) have been met. **Your variance has been granted with the following modification: to allow pharmacists to dispense prescription medications and devices in locations that are not licensed pharmacies.** This variance shall apply to all persons legally permitted to practice pharmacy in the state of Wisconsin, and shall remain in effect for 90 days from today's date pursuant to Wis. Stat. § 450.02(3m)(b), unless modified or extended by further action of the Pharmacy Examining Board.

Please feel free to contact me if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jameson R. Whitney', is written over a horizontal line.

Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov



June 10, 2020

Philip J. Trapskin
[redacted]
[redacted]

RE: Variance Request per Wis. Stat. § 450.02(3m)

Dear Mr. Trapskin,

On March 25, 2020, the Wisconsin Pharmacy Examining Board granted a variance of Wis. Stat. § 450.03(1), 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 stated purpose of the request was to compensate for a shortage of pharmacy staff during the COVID-19 emergency. Subsequently, the provisions of that variance were superseded by Emergency Order #16, and it was rescinded on April 3, 2020. Subsequent to Emergency Order #16, 2019 Wis. Act 185 was signed into law. The state of emergency expired on May 11, 2020, and any temporary licenses issued pursuant to 2019 Wis. Act 185 expire on June 10, 2020.

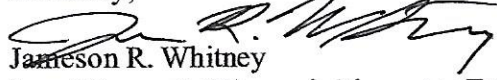
On June 4, 2020, the Wisconsin Pharmacy Examining Board reviewed this variance and your request to reissue the variance permitting out-of-state license holders to practice pharmacy in Wisconsin without a Wisconsin license. The Board considered the evidence presented and determined that the requirements of Wis. Stat. § 450.02(3m)(a) have been met. **The Board hereby reissues this variance subject to the following requirements:** *Any person with a valid and current license to practice pharmacy issued by another state may practice under that license and within the scope of that license in Wisconsin without first obtaining a temporary or permanent license from the Department of Safety and Professional Services (DPS), so long as the following conditions are met:*

- 1. The practice is necessary to ensure the continued and safe delivery of health care services;*
- 2. The pharmacist is not currently under investigation and does not currently have any restrictions or limitations placed on their license by their credentialing state or any other jurisdiction;*
- 3. The needs addressed reasonably prevented in-state credentialing in advance of practice;*
- 4. The pharmacist practicing under this section must apply for a temporary or permanent license within 30 days of first working in reliance on this variance; and*
- 5. A health care facility or pharmacy must notify DPS at dsps@wisconsin.gov within 10 days of a pharmacist practicing at its facility or pharmacy in reliance on this variance.*

This variance shall apply to all persons licensed in good standing to practice pharmacy in another state, United States territory, and the District of Columbia, and shall remain in effect from June 10, 2020 to August 1, 2020, pursuant to Wis. Stat. § 450.02(3m)(b), unless modified or extended by further action of the Pharmacy Examining Board.

Please feel free to contact me if you have any questions.

Sincerely,


Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov



July 1, 2020

Philip J. Trapskin
[redacted]
[redacted]

RE: Variance Request per Wis. Stat. § 450.02(3m)

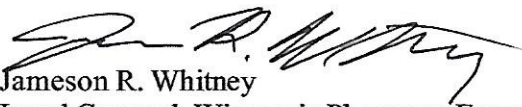
Dear Mr. Trapskin,

On April 3, 2020, the Wisconsin Pharmacy Examining Board granted a variance of Wis. Stat. § 450.065 to **temporarily allow pharmacies that are licensed in good standing in other states to deliver prescription drugs and devices to persons in Wisconsin without a Wisconsin license.** The stated purpose of the request was to compensate for supply disruptions during the COVID-19 emergency.

The Board considered whether to extend this variance on June 4, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. This variance is hereby **extended to August 1, 2020**, unless modified, rescinded, or extended by further action of the Pharmacy Examining Board pursuant to Wis. Stat. § 450.02(3m)(b).

Please feel free to contact me if you have any questions.

Sincerely,


Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov



April 1, 2020

Roxy Kozyckyj
Director, State Government Affairs – Midwest, Eastern Region
Healthcare Distribution Alliance
901 North Glebe Road, Suite 1000
Arlington, VA 22203

RE: Variance Request per Wis. Stats. § 450.02(3m)

Dear Ms. Kozyckyj,

On April 1, 2020, the Wisconsin Pharmacy Examining Board reviewed your variance request. You requested a variance of Wis. Stats. § 450.071 to **temporarily allow holders of wholesale distribution licenses to distribute prescription drugs from facilities that are not licensed in Wisconsin, but are licensed in other states, should the licensee's Wisconsin licensed facilities shut down.** The stated purpose of the request is to compensate for supply chain disruptions during the COVID-19 emergency.

The effect of the variance would modify Wis. Stats. § 450.071(1) to read as follows:

(1) No person may engage in the wholesale distribution of a prescription drug in this state without obtaining a license from the board for each facility from which the person distributes prescription drugs, except that a person licensed to engage in the wholesale distribution of prescription drugs may distribute from facilities that are licensed in good standing in other states, United States territories, or the District of Columbia, in the event of closure of the person's facilities that are licensed in Wisconsin. A licensee shall provide the board with the information required under subs (2) and (3) within 5 days of beginning distribution from an unlicensed facility. The board shall exempt a manufacturer that distributes prescription drugs or devices manufactured by the manufacturer from licensing and other requirements under this section to the extent the license or requirement is not required under federal law or regulation, unless the board determines that it is necessary to apply a requirement to a manufacturer.

The Board considered the evidence presented and determined that the requirements of Wis. Stats. § 450.02(3m)(a) have been met. **Your variance, as requested, has been granted.** This variance shall apply to all persons legally permitted to engage in the wholesale distribution of prescription drugs in the state of Wisconsin, and shall remain in effect for 90 days from today's date pursuant to Wis. Stats. § 450.02(3m)(b), unless modified or extended by further action of the Pharmacy Examining Board.

Please feel free to contact me if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jameson R. Whitney', is written over a white background.

Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov



June 29, 2020

Philip J. Trapskin
[redacted]
[redacted]

RE: Variance Request per Wis. Stat. §450.02(3m)

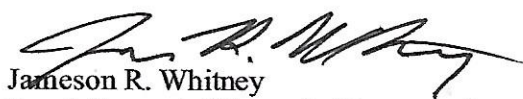
Dear Mr. Trapskin,

On April 1, 2020, the Wisconsin Pharmacy Examining Board granted a variance of Wis. Stat. § 450.071 to **temporarily allow holders of wholesale distribution licenses to distribute prescription drugs from facilities that are not licensed in Wisconsin, but are licensed in other states, should the licensee's Wisconsin licensed facilities shut down.** The stated purpose of the request was to compensate for supply chain disruptions during the COVID-19 emergency.

The Board considered whether to extend this variance on June 4, 2020, and determined that the requirements of Wis. Stat. §450.02(3m)(b) have been met. This variance is hereby **extended to August 1, 2020**, unless modified, rescinded, or extended by further action of the Pharmacy Examining Board pursuant to Wis. Stat. §450.02(3m)(b).

Please feel free to contact me if you have any questions.

Sincerely,


Jameson R. Whitney
Legal Counsel, Wisconsin Pharmacy Examining Board
608-266-8098 jameson.whitney@wisconsin.gov