

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

Tony Evers, Governor Dawn B. Crim, Secretary

### VIRTUAL/TELECONFERENCE PHARMACY EXAMINING BOARD

Virtual, 4822 Madison Yards Way, Madison, WI Contact: Christine Poleski (608) 266-2112 September 24, 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 AFTER THE PHARMACY RULES COMMITTEE)

### OPEN SESSION - CALL TO ORDER - ROLL CALL

- A. Adoption of Agenda (1-4)
- B. Approval of Minutes of July 23, 2020 (5-8)
- **C.** Conflicts of Interest
- **D.** Introductions, Announcements and Recognition
- E. Administrative Matters Discussion and Consideration (9)
  - 1) Department, Staff and Board Updates
  - 2) Appointment of Liaisons and Alternates
  - 3) Board Members Term Expiration Dates
- **F.** Legislative and Policy Matters Discussion and Consideration
- G. Administrative Rule Matters Discussion and Consideration (10)
  - 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Phar 5, 6, 7, 11, and 12, Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References and Technical Correction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) Pending or Possible Rulemaking Projects
- H. Position Statement Review Discussion and Consideration (11-17)
- I. Pharmacy Patient Consultation Signs Discussion and Consideration (18-19)
- J. Variances Discussion and Consideration (20)
  - 1) Review, Discussion and Consideration of All Current Variances (21-28)
  - 2) Review, Discussion and Consideration of Any Proposed Variances
    - a. Pharmacy Society of Wisconsin Variance Request (29-33)
    - b. Variance Requests Received After Preparation of the Agenda
- K. COVID-19 Discussion and Consideration

- L. Pilot Program Matters Discussion and Consideration
- M. Email Blast Planning Discussion and Consideration

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

- Consider Attendance at the Virtual National Association of Boards of Pharmacy (NABP)-American College of Clinical Pharmacy (ACCP) District IV Annual Meeting on October 8, 2020
- 2) National Association of Boards of Pharmacy NABP/ACCP District IV 2022 Annual Meeting Planning
- O. 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

#### P. 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.).

### Q. Deliberation on Division of Legal Services and Compliance Matters

- 1) Administrative Warnings
  - a. 18 PHM 167 S.J.G. (**34-35**)
  - b. 18 PHM 167 S.W.K. (**36-37**)
  - c. 19 PHM 074 C.L.T. (**38-40**)
- 2) Case Closings
  - a. 18 PHM 059 W. & A.N. (**40-47**)
  - b. 18 PHM 167 W. (48-52)
  - c. 18 PHM 195 C. (**53-58**)
  - d. 19 PHM 016 A.A.T. (**59-64**)
  - e. 19 PHM 030 P.N.S.P. (**65-68**)
  - f. 19 PHM 074 C. & R.F.L. (**69-73**)
  - g. 19 PHM 139 C. (**74-78**)
  - h. 19 PHM 291 C. (**79-82**)
  - i. 20 PHM 012 H.P. (**83-87**)
  - j. 20 PHM 013 L.C.P. (**88-91**)
  - k. 20 PHM 015 P.I. (**92-65**)
  - 1. 20 PHM 016 R.A.P. (**96-99**)
  - m. 20 PHM 058 O.C.P. (**100-102**)
  - n. 20 PHM 063 S.Y.R., B.H.P.L., & B.P.P. (**103-109**)
  - o. 20 PHM 083 A.H.G. (110-112)

### 3) Stipulations and Final Decisions and Orders

- a. 18 PHM 192 Ryan J. Nelson, R.Ph. (113-125)
- b. 18 PHM 195 Paul D. Ford, R.Ph. (126-131)
- c. 19 PHM 035 Kevin O'Brien, R.Ph. (132-137)
- d. 19 PHM 139 Chelsea L. Wilson, R.Ph. (138-143)
- e. 19 PHM 139 Stacey L. McDonald, R.Ph. (**144-149**)
- f. 19 PHM 161, 19 PHM 273, & 19 PHM 276 Huevepharma, Inc. (**150-155**)
- g. 20 PHM 115 Kelly Fausek, R.Ph. (**156-164**)

### 4) Monitoring Matters

a. Kathryn Lindemann, R.Ph. – Requesting Review of Draft of Order Reinstating Stay of Suspension and Imposing Limitations (165-198)

### R. Deliberation of Items Added After Preparation of the Agenda

- 1) Education and Examination Matters
- 2) Credentialing Matters
- 3) Application Reviews
- 4) DLSC Matters
- 5) Monitoring Matters
- 6) Professional Assistance Procedure (PAP) Matters
- 7) Petitions for Summary Suspensions
- 8) Petitions for Designation of Hearing Examiner
- 9) Proposed Stipulations, Final Decisions and Orders
- 10) Proposed Interim Orders
- 11) Administrative Warnings
- 12) Review of Administrative Warnings
- 13) Proposed Final Decisions and Orders
- 14) Matters Relating to Costs/Orders Fixing Costs
- 15) Case Closings
- 16) Board Liaison Training
- 17) Petitions for Assessments and Evaluations

- 18) Petitions to Vacate Orders
- 19) Remedial Education Cases
- 20) Motions
- 21) Petitions for Re-Hearing
- 22) Appearances from Requests Received or Renewed
- S. Consulting with Legal Counsel

### RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

### **ADJOURNMENT**

**NEXT MEETING: OCTOBER 22, 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. Requests for interpreters for the 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.

# TELECONFERENCE/VIRTUAL PHARMACY EXAMINING BOARD MEETING MINUTES JULY 23, 2020

**PRESENT:** Tiffany O'Hagan, Anthony Peterangelo (arrived at 11:27 a.m.), Philip Trapskin,

John Weitekamp, Cathy Winters, Michael Walsh

**EXCUSED:** Shana Weiss

**STAFF:** Christine Poleski, Executive Director; Christian Albouras, Executive Director;

Jameson Whitney, Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Megan Glaeser, Bureau Assistant; Daniel Betekhtin, 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 five (5) board members present.

#### ADOPTION OF AGENDA

**MOTION:** Michael Walsh moved, seconded by Cathy Winters, to adopt the Agenda

as published. Motion carried unanimously.

#### APPROVAL OF MINUTES

**MOTION:** Cathy Winters moved, seconded by Michael Walsh, to approve the

Minutes of June 4, 2020 as published. Motion carried unanimously.

(Anthony Peterangelo arrived at 11:27: a.m.)

### **ADMINISTRATIVE RULE MATTERS**

### Scope to Amend Phar 1, 6, 7, 8, 12, 13 Relating to Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers and Distributors

**MOTION:** Cathy Winters moved, seconded by John Weitekamp, to approve the

Scope Statement revising Phar 1, 6, 7, 8, 12, 13, relating to electronic track and trace pedigree system, drug supply chain security, manufacturers and distributors, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion carried

unanimously.

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### <u>Phar 2 Relating to Reciprocal Credentials for Service Members, Former Service Members</u> and their Spouses

**MOTION:** 

Anthony Peterangelo moved, seconded by Michael Walsh, to authorize the Chairperson to approve the preliminary rule draft of Phar 2, relating to reciprocal credentials for service members, former service members and their spouses, for posting of economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

### <u>Designation of Gabapentin as a Monitored Drug in the Prescription Drug Monitoring Program</u>

**MOTION:** 

Anthony Peterangelo moved, seconded by Cathy Winters, to indicate that the Pharmacy Examining Board supports the designation of Gabapentin as a monitored drug in the Prescription Drug Monitoring Program. Motion carried unanimously.

#### COVID-19

### Review, Discussion and Consideration of All Current Variances

**MOTION:** Cathy Winters moved, seconded by Michael Walsh, upon due

consideration of the requirements for renewal of variances under  $\S$  450.02(3m)b, and considering each of the current variances individually, to find that the requirements of  $\S$  450.02(3m)b have been met with regard to all active variances, and to extend all variances active as of July 23,

2020 by 90 days. Motion carried unanimously.

**MOTION:** John Weitekamp moved, seconded by Cathy Winters, to revise the

variance originally issued on April 15, 2020, regarding the manufacturing of PPE to clarify that manufacturers must be in compliance with current

FDA regulations. Motion carried unanimously.

#### CLOSED SESSION

**MOTION:** 

Michael Walsh moved, seconded by Cathy Winters, 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; and Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 3:23 p.m.

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

### **Administrative Warnings**

### 18 PHM 057 - K.M.H.

**MOTION:** Michael Walsh moved, seconded by Cathy Winters, to issue an

Administrative Warning in the matter of K.M.H., DLSC Case Number 18

PHM 057. Motion carried unanimously.

### **Case Closings**

**MOTION:** Anthony Peterangelo moved, seconded by Cathy Winters, to close the following DLSC Cases for the reasons outlined below:

- 1. 18 PHM 057 H.A. Prosecutorial Discretion (P5)
- 2. 18 PHM 121 E.P. No Violation
- 3. 19 PHM 035 B.P.I. No Violation
- 4. 19 PHM 043 L.D. Prosecutorial Discretion (P5)
- 5. 19 PHM 076 C.C.P. Prosecutorial Discretion (P5)
- 6. 19 PHM 077 M.R.C. Prosecutorial Discretion (P5)
- 7. 19 PHM 112 A.R.X. Prosecutorial Discretion (P5)
- 8. 19 PHM 146 R.D.M. & C. Prosecutorial Discretion (P2)
- 9. 19 PHM 176 A.P. No Violation
- 10. 19 PHM 193 I.P. No Violation
- 11. 19 PHM 202 B.B.P.L. Prosecutorial Discretion (P5)
- 12. 19 PHM 207 C. Prosecutorial Discretion (P2)
- 13. 19 PHM 208 D.P. Prosecutorial Discretion (P5)
- 14. 19 PHM 210 E.P.L. Prosecutorial Discretion (P5)
- 15. 19 PHM 213 F.R.C.P. Prosecutorial Discretion (P5)
- 16. 19 PHM 216 G.G.P. Prosecutorial Discretion (P5)
- 17. 19 PHM 222 M.D.E.P. Prosecutorial Discretion (P2)
- 18. 19 PHM 225 P.D.S. Prosecutorial Discretion (P5)
- 19. 19 PHM 227 P.D. Prosecutorial Discretion (P5)
- 20. 20 PHM 045 M.P. No Violation

Motion carried unanimously.

### 18 PHM 147 - M.R.S. & W.

MOTION: Michael Walsh moved, seconded by John Weitekamp, to close DLSC Case Number 18 PHM 147 against M.R.S. & W. for Insufficient Evidence. Motion carried.

(Tiffany O'Hagan recused herself and disconnected for deliberation and voting in the matter concerning 18 PHM 147, DLSC Case Number M.R.S. & W.)

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### **Stipulations, Final Decisions and Orders**

### 20 PHM 043 – ImprimisRx

**MOTION:** Anthony moved, seconded by John Weitekamp, to adopt the Findings of

Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against ImprimisRx, DLSC Case Number 20 PHM 043.

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 4:11 p.m.

### VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

**MOTION:** Anthony Peterangelo 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 4:15 p.m.

### **AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:				st:	2) Date When Request Submitted:		
Kimberly Wood, Program Assistant Supervisor-Adv.				<i>I</i> .	9/8/2020		
					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) N	3) Name of Board, Committee, Council, Sections:						
Pha	armacy Examining Bo	oard					
4) N	Meeting Date:	5) Attac	hments:	6) How	should the item be tit	led on the agenda page?	
9/24/2020		Administrative Matters – Appointment of Liaisons and Alternates					
			nce before the Board being 9) Name of Case Advisor(s), if required:				
$\boxtimes$	scheduled?		N/A		N/A		
	Closed Session		☐ Yes				
			⊠ No				
10)	Describe the issue a	nd action	that should be ac	ldressed:			
	The Chairperson show cancies created by the				sons and Alternates	due to new member onboarding and to fill	
	Credentia	aling Liais	on(s)	Anthony Peterangelo, Philip Trapskin, John Weitekamp			
	Office of Education and Examinations Liaison(s)		Cathy Winters; Alternate: John Weitekamp				
	Monitori	ing Liaiso	n(s)	Franklin LaDien; Alternate: Cathy Winters			
	Professional Assistance Procedure (PAP) Liaison(s)		Franklin LaDien; Alternate: Anthony Peterangelo				
•	Travel Liaison		Chairperson; Alternate: Vice Chairperson				
	Legislative Liaison(s)		Cathy Winters, Philip Trapskin, John Weitekamp				
	Pilot Program Liaison(s)		Philip Trapskin, Cathy Winters				
	Digest Liaison(s)		s)	Cathy Winters; Alternate: Philip Trapskin			
	Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g)		John Weitekamp				
	PHARM Rep to SCAODA		John Weitekamp; Alternate: Anthony Peterangelo				
	Screening Panel: January – December 2019		John Weitekamp, Franklin LaDien, Michael Walsh; Alternate: Cathy Winters				
	Pharmacy Rules Committee Cathy Winters, Philip Trapskin, John Weitekamp			Philip Trapskin, John Weitekamp			
11)	11) Authorization						
Kímberly Wood			9/18/2020				
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.

### AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:				2) Date When Request Submitted:		
Sharon Henes				15 September 2020	)	
Administrative Rules Coordinator				Items will be conside	ered late if submitted after 12:00 p.m. on the deadline	
2) Name of Board Comm	nittoo Co	unail Castions		date which is 8 busin	ness days before the meeting	
3) Name of Board, Comn		ouncii, Sections:				
Pharmacy Examining Bo						
4) Meeting Date:	5) Attac	hments:	6) How	should the item be ti	tled on the agenda page?	
24 September 2020	⊠ Y€			strative Rule Matters		
	☐ No	)		. Phar 5, 6, 7, 11, and 12 Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References		
				d Technical Correction		
			-		Possible Rulemaking Projects	
7) Place Item in:			ce before	the Board being	9) Name of Case Advisor(s), if required:	
		scheduled?				
☐ Closed Session		☐ Yes				
		☐ No				
10) Describe the issue a	nd actior	that should be add	dressed:			
11)		ı	Authoriza	tion		
Sharon Henes					9/15/2020	
					Date	
Signature of person making this request Date						
Supervisor (if required)						
Supervisor (if required)					Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date						
Directions for including supporting documents:						
<ol> <li>This form should be attached to any documents submitted to the agenda.</li> <li>Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.</li> </ol>						
2. Post Agenda Deadlin	e items n	nust be authorized	by a Supe	ervisor and the Polic	ry Development Executive Director.	
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.						

### AGENDA REQUEST FORM

1) Name and Title of Pe	rson Submitting the Request:	: 2) Date When Requ	2) Date When Request Submitted:			
Sharon Henes			17 September 2020			
Administrative Rules Co	oordinator		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, Com	mittee, Council, Sections:	date which is o bush	less days before the incetting			
Pharmacy Examining B						
4) Meeting Date:	5) Attachments:	6) How should the item be ti	tled on the agenda page?			
24 Sept 2020	⊠ Yes	Deand Desition Otatomen	to Discussion and Consideration			
•	Board Position Statements – Discussion and Consideration					
7) Place Item in:	9) Name of Case Advisor(s), if required:					
	scheduled?					
☐ Closed Session	Yes					
40) Deceribe the issue of	No No	lvooodi				
10) Describe the issue a	and action that should be add	nesseu.				
11)	A	Authorization				
Sharon Henes 9/17/2020						
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:						
This form should be attached to any documents submitted to the agenda.						
<ol> <li>Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.</li> <li>If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a</li> </ol>						
meeting.						

# Pharmacy Examining Board Position Statements

Position Statements Related to Pharmacies Issued by the Pharmacy Examining Board

### 1. Does the Pharmacist Have to Talk to a Patient About Prescription Medication Being Dispensed?

Yes. Consultation is required as per <a href="Phar 7.01(1)(e)">Phar 7.01(1)(e)</a>.

Revised: 04/15/2013

### 2. Can the Pharmacy Refuse to Take Back Prescription Medication?

Yes. A pharmacy is only permitted to take back prescriptions that have been dispensed in limited circumstances, see Phar 7.04(2).

Revised: 04/15/2013

### 3. Can the Pharmacist Give out a Patient's Personal Health Care Records or Information?

A pharmacist is a "health care provider" as defined in Wis. Stats. s146.81(1). As such, a pharmacist is required to comply with state laws regarding confidentiality of patient health care records. For Wisconsin's confidentiality of patient health care record requirements, see <u>Wis. Stat. § 146.82</u>.

Revised: 04/15/2013

#### 4. Can a Patient Receive More Than a 30 day Supply of a Controlled Substance?

Yes. Often a patient will need to discuss this issue with their insurance provider who may have limits regarding the amount that can be dispensed at any one time. However, Wisconsin law does not restrict the amount that may be dispensed.

Revised: 05/22/2013

### 5. Where can a Pharmacist Find Information Concerning the Sale and Purchase of Pseudoephedrine Products?

In 2005, <u>Wisconsin Act 14</u> took effect, regulating the sale and purchase of pseudoephedrine. The relevant provisions can be found in Wis. Stat. ch. 961, Uniform Controlled Substances Act. In 2006, the United States Congress passed the Combat Methamphetamine Epidemic Act of 2005, which requires any product containing ephedrine or pseudoephedrine, to be strictly regulated to help prevent the production of methamphetamine, an illegal street drug. Pseudoephedrine is a common ingredient in many cold and allergy relief products. The sale and purchase of pseudoephedrine is

regulated by federal and state law which is, at times, inconsistent with each other. A pharmacist is required to comply with both laws. Therefore, if federal and state laws are inconsistent, a pharmacist is required to comply with the more stringent provision. Both laws provide for buying restrictions based upon amount, as well as requirements for storage and record keeping. Further information concerning federal law may be found at <a href="http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm072423.htm">http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm072423.htm</a>. Wisconsin Stat. ch. 961 can be found at <a href="https://docs.legis.wisconsin.gov/statutes/statutes/961">https://docs.legis.wisconsin.gov/statutes/statutes/961</a>.

Revised12/11/2013

# 6. Can a Patient Receive Assistance From a Pharmacist in Repackaging Medications to Better Allow the Patient or a Caregiver to Manage Their Medication Administration? Even if That Pharmacist Never Dispensed the Medication Originally?

Yes. Wis. Stats. ch. 450 and Wis. Admin. Code s. Phar 7.04 permit a pharmacist to assist a patient or an agent of a patient in having a previously dispensed drug or device repackaged, relabeled and subsequently returned to the patient or the patient's agent for the same patient's use, even if the pharmacist did not dispense the drug or device originally. See <u>Wis. Admin. Code § Phar 7.04(4)</u>.

Note, however, there may be other statutory and/or code provisions not governed by the Pharmacy Examining Board that may limit or restrict the practice of repackaging, specifically as it relates to certain patients in long term care facilities and community based residential facilities. For more information, you may wish to refer to applicable rules of the Wisconsin Department of Health Services.

Revised: 09/11/2013

### 7. Does Wisconsin Require Out-Of-State Pharmacies to be Licensed to Dispense in Wisconsin?

Yes. A Wisconsin pharmacy license must be obtained by pharmacies licensed in another state which dispense prescription medications, including schedule II controlled substances, by mail or other delivery to patients in this state.

Revised: 05/22/2013

### 8. How Many Days Supply of a Controlled Substance may be Dispensed at one Time?

As of August 1, 2002, the PEB revised Wis. Admin. Code § Phar 8.05, the dispensing requirements for controlled substances, removing the 7-day date limitation on schedule II controlled substances prescriptions and eliminating the 34-day dispensing quantity limitation on all controlled substances. The repeal of these sections of Phar 8.05 is intended to allow practitioners and pharmacists to more fully exercise their professional judgment in prescribing and dispensing controlled substances. This is consistent with federal controlled substances prescription rules which have no date or days supply restrictions.

The state requirement that a schedule II controlled substance prescription may not be dispensed more than 60 days after the date of issue still remains.

Revised: 05/22/2013

### 9. Can a Pharmacist Dispense a Prescription Order for Methadone?

Neither Chapter 450 of the Wisconsin Statutes nor Chapter Phar of the Wisconsin Administrative Code specifically prohibits Wisconsin-licensed pharmacists from dispensing a prescription order for methadone. However, there may be applicable federal regulations which contain prohibitions and/or limitations that Wisconsin-licensed pharmacists may be subject to. For applicable federal law, see 21 CFR 1306.04 et seq, (<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1306">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1306</a>).

Revised: 09/11/2013

### 10. Can a Pharmacist Fill or Refill a Prescription Order for an Out-Of-State Prescriber?

Yes, Wisconsin pharmacies may legally fill or refill prescription orders from practitioners practicing in another state, if they are licensed in another state and recognized by Wisconsin as a person authorized to prescribe and administer drugs. This includes prescription orders for controlled substances. However, prescription orders for controlled substances are only valid for practitioners having a current federal drug enforcement registration number. A pharmacist should inquire further regarding a practitioner's authority to prescribe if the pharmacist, using professional judgment, is concerned that the prescription order might not be valid.

Revised: 05/22/2013

# 11. Are There Differences Between Federal Scheduling and Wisconsin Scheduling of Controlled Substances? How do I find out if a Substance is Controlled, and What Schedule it is?

The State follows Federal regulations for scheduled drugs, but may also have additional scheduled drugs that are regulated. You will want to consult <u>Chapter 961 of the Wisconsin Statutes</u> and the additions to the schedules through Administrative Rule. Those added in the administrative code can be found in <u>ch. CSB 2</u>. These may be updated periodically, so please check back often.

Revised: 05/22/2013

### 12. If an Out-Of-State Mail Order Pharmacy is Licensed in Wisconsin, do the Pharmacists Working There Need Wisconsin Credentials as Well?

No, the pharmacists do not need to be licensed in Wisconsin but they must be licensed in the state where the pharmacy is located.

Revised: 05/16/2013

### 13. Does an Out-Of-State Distributor Need a License to Ship Medication or Devices to Wisconsin Facilities?

As of June 1, 2008, distributors of medical devices no longer need a wholesale distributor of prescription drug license to ship medical devices into Wisconsin. Distributors of prescription drugs need to obtain a wholesale distribution license from the Board.

Revised: 07/17/2013

### 14. Do Out-Of-State Drug Manufacturers Need to be Licensed in Wisconsin?

Only those manufacturers physically located within Wisconsin need to obtain a drug manufacturer license.

Revised: 07/17/2013

# 15. Can a Distributor Ship Prescription Medications to a Storage Facility at a Different Location Than the Licensed Pharmacy Where they Will be Dispensed, or do the Medications Need to be Shipped Directly to the Licensed Pharamcy?

<u>Wis. Stat. § 450.072</u> regulate the distribution of prescription drugs. Distributors are only allowed to ship prescription medications to a licensed pharmacist. These restrictions apply to delivery of drugs to the premises listed on the pharmacist's license. A distributor may be able to apply for a delivery variance to ship medications to another location.

Revised: 07/17/2013

### 16. Can one Pharmacy Transfer a Prescription to Another Pharmacy via fax?

Yes, if certain enumerated conditions are met, including verbal verification by both pharmacists. See <u>Wis. Admin. Code ch. Phar 7.055</u> for the specific requirements.

Revised: 09/11/2013

### 17. Can a Pharmacist Administer Vaccines? Can Vaccines be Administered to Minors?

Under <u>Wis. Stats. § 450.035(2)</u>, a pharmacist may administer vaccines if they have completed 12 hours of approved education and fulfills the requirements under 450.035(2t). Under no circumstances may a pharmacist or person engaged in the practice of pharmacy administer vaccines to persons under the age of six (6).

Revised: 09/11/2013

### **18. Where do I Find Answers to Questions Related to EPT (Expedited Partner Therapy)?**

- **a. What is EPT?** Expedited Partner Therapy, or EPT, is a general term for the practice of treating the sex partner(s) of patients diagnosed with Sexually Transmitted Diseases (STDs) without an intervening medical evaluation of the partner(s).
- b. What changes were made in the new law? 2009 Wisconsin Act 280 went into

effect on May 26, 2010. The new law: 1) explicitly allows physicians, physician assistants, and certified nurse prescribers to furnish or prescribe medication for EPT and pharmacists to dispense medication for EPT; 2) limits civil liability for medical providers and pharmacists as long as EPT is provided in accordance with the Act; 3) allows the prescription to be written in the partner's name (preferred) or with "Expedited Partner Therapy" or "EPT" in place of a name when the patient does not know or is unwilling to give the partner's name; and 4) requires written materials be developed by the Department of Health Services (DHS) and be distributed to the patient by the medical provider, for use by the partner(s) receiving EPT.

- **c. Who is eligible/ineligible for EPT?** The Act specifies that EPT can only be used for partners of patients infected with Chlamydia trachomatis , Neisseria gonorrhoeae or trichomoniasis infections.
- **d.** Is there a limit to the number of partners that can receive EPT for a given patient? No. EPT allows for the treatment of all of a patient's partners. Treatment of all affected partners will reduce the risk of transmission and re-infection.
- **e. Is EPT limited to specific medications?** Only Antimicrobial drugs used to treat Chlamydia trachomatis, Neisseria gonorrhoeae or trichomoniasis can be prescribed using EPT. The Act specifically excludes all controlled substances.
- **f. How is EPT delivered to the partner(s)?** Medication may be dispensed to the patient by the medical provider to take to his/her partner(s), or separate prescriptions may be written for the patient and his/her partner(s).
- **g.** Is a pharmacist liable if an adverse event occurs? The Act exempts medical prescribers and pharmacists from civil liability for injury to, or death of, the sexual partner unless an act or omission of the provider involves reckless, wanton, or intentional misconduct.
- **h. Who will pay for the partner's medication?** The patient's insurance cannot be billed for the partner's medication (unless the partner is covered on the patient's insurance and the partner information is known). There is currently no state funding to pay for EPT medication. The patient may elect to pay the full cost of the medication for the partner(s).
- **i. Are pharmacists required to participate?** The Act does not require pharmacists to participate.
- **j.** Are pharmacists required to give information regarding STDs when consulting a person receiving EPT? The Act requires that the medical provider provide written information to the patient for use by the partner(s) that has information on STDs, their treatment and the risk of drug allergies. The Act also requires that a pharmacist provide consultation in accordance with the rules promulgated by the Pharmacy Examining Board, and also ask whether the partner is allergic to the prescribed medication and advise discontinuing the medication if the person has a known allergy or develops signs of an allergic reaction after taking the medication.
- k. How do pharmacists fill prescriptions for EPT? Pharmacists must meet all of the

requirements of the Pharmacy Examining Board for filling prescriptions. Prescriptions must also be labeled according to <u>Wis. Stat. § 450.11(4)</u> which includes the full name of the patient if known or the words Expedited Partner Therapy or EPT. Consultation is required on each prescription per <u>Phar 7.01(1)(e)</u>. The patient may act as the agent of the partner(s) for purposes of fulfilling the consultation requirement.

**I.** How do pharmacists label a prescription without the partner's full name? Pharmacies that choose to dispense EPT prescriptions will likely need to establish a profile for a patient named Expedited Partner Therapy or EPT.

Revised: 10/30/2013

#### m. Where can I find more information about EPT?

The Wisconsin EPT Act, Frequently Asked Questions documents, provider guidance, and patient information sheets will be available

at <a href="https://www.dhs.wisconsin.gov/std/index.htm">https://www.dhs.wisconsin.gov/std/index.htm</a>. Questions about EPT in Wisconsin can be directed to the Wisconsin Department of Health STD Section at (608) 266-7365. EPT information and resources from the CDC are available at <a href="http://www.cdc.gov/std/ept">http://www.cdc.gov/std/ept</a>.

Revised: 10/30/2013

### AGENDA REQUEST FORM

1) Name and Title of Person Su	bmitting the Request	t: 2) Date When Req	2) Date When Request Submitted:				
Sharon Henes Administrative Rules Coordinat	or	Items will be conside	15 September 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, (	3) Name of Board, Committee, Council, Sections:						
Pharmacy Examining Board							
4) Meeting Date: 5) Atta	achments:	6) How should the item be t	itled on the agenda page?				
24 September 2020		Pharmacy Patient Consultation Sign					
		dressed:					
11) Authorization							
Sharon Henes 9/15/20							
Signature of person making this	s 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.							



# Illinois law requires the pharmacist talk to you about any new or changed prescriptions.

Education ensures safe and effective use of your medications, reducing the chances of a serious interaction.

If you receive prescriptions by mail, you may contact the pharmacist at the number provided on your order.

If the pharmacist fails to discuss any new or changed prescriptions with you, please contact the state regulatory authority.

# Department of Financial and Professional Regulation Division of Professional Regulation

Complaint Intake Unit 100 West Randolph Street, Suite 9-300 Chicago, IL 60601 Phone: (312) 814-6910

www.idfpr.com

### AGENDA REQUEST FORM

1) Name and Title of Per	rson Submitting the Reques	t:	2) Date When Request Submitted:				
In the same of the same of	Deard Coursel		09/14/2020				
Jameson Whitney,	Board Counsel		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, Com	mittee, Council, Sections:						
Pharmacy							
9/24/2020			should the item be tit	tled on the agenda page?			
No Variances—review, discussion, and action as appropriate							
7) Place Item in:		nce befor	e the Board being	9) Name of Case Advisor(s), if required:			
Open Session	scheduled?						
☐ Closed Session	☐ Yes (Fill out	Board A	ppearance Request)				
10) Describe the issue a	and action that should be ad	ldressed:					
10) 20001120 110 10000	and dotton that Should be du	0000U1					
				9, 2020, and consider what action should be			
taken. The Board shou	ld also consider delegating a	a ilaison i	to work with Board Co	ounsel on tuture variances.			
11)		Authoriza	ation	Data 0/14/20			
Signature of person ma Jameson Whitney	king this request			Date 9/14/20			
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Supervisor (if required)				Date			
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3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a							
meeting.							



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

Tony Evers, Governor Dawn B. Crim, Secretary

July 31, 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 later extended this variance to August 1, 2020.

The Board considered whether to extend this variance on July 23, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. This variance is hereby extended 90 days, 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



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

Tony Evers, Governor Dawn B. Crim, Secretary

July 31, 2020

Philip J. Trapskin [redacted] [redacted]

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

Dear Mr. Trapskin,

On April 16, 2020, the Wisconsin Pharmacy Examining Board granted 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 was to enable the creation and use of "surge sites" to help respond to the COVID-19 emergency. The Board later extended this variance to August 1, 2020.

The Board considered whether to extend this variance on July 23, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. This variance is hereby extended 90 days, 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



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

Tony Evers, Governor Dawn B. Crim, Secretary

July 31, 2020

Philip J. Trapskin [redacted] [redacted]

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

Dear Mr. Trapskin,

On April 15, 2020, the Wisconsin Pharmacy Examining Board granted a variance of Wis. Stat. § 450.07(1) and Wis. Admin. Code § 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 was to mirror similar actions taken by the federal government to allow manufacturers of other goods to manufacture masks during the COVID-19 emergency. The Board later extended this variance to August 1,2020. The Board considered whether to extend this variance on July 23, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. The Board modifies the variance as follows:

The variance of Wis. Stat. § 450.07(1) now reads 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 or following a period of declared emergency and for 90 days following the end of the 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 of Phar 12.03(1) now reads 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 or following a period of declared emergency and for 90 days following the end of the 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.

The Board reminds any persons who are engaged in manufacturing in reliance on this variance that the Board is only relaxing requirements pertaining to federal regulations referenced in Phar 12.04 and 12.05 to the extent that the appropriate federal agencies relax or waive such regulations. This variance is hereby **extended 90 days**, 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



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

Tony Evers, Governor Dawn B. Crim, Secretary

July 31, 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 later extended this variance to August 1, 2020.

The Board considered whether to extend this variance on July 23, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. This variance is hereby extended 90 days, 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



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

Tony Evers, Governor Dawn B. Crim, Secretary

July 31, 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 expired on June 10, 2020.

On June 4, 2020, the Wisconsin Pharmacy Examining Board reviewed and reissued this variance subject to requirements as stated in the June 10 letter. The Board considered whether to extend this variance on July 23, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. This variance is hereby **extended 90 days**, 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



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

Tony Evers, Governor Dawn B. Crim, Secretary

July 31, 2020

Philip J. Trapskin [redacted] [redacted]

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

Dear Mr. Trapskin,

On April 15, 2020, the Wisconsin Pharmacy Examining Board granted 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 was to allow flexibility regarding consultation and delivery to help compensate for workforce and personal protective equipment shortages during the COVID-19 emergency. The Board later extended this variance to August 1, 2020.

The Board considered whether to extend this variance on July 23, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. This variance is hereby extended 90 days, 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



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

Tony Evers, Governor Dawn B. Crim, Secretary

July 31, 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 later extended this variance to August 1, 2020.

The Board considered whether to extend this variance on July 23, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. This variance is hereby extended 90 days, 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



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

Tony Evers, Governor Dawn B. Crim, Secretary

July 31, 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 later extended this variance to August 1, 2020.

The Board considered whether to extend this variance on July 23, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. This variance is hereby extended 90 days, 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



TO: Wisconsin Pharmacy Examining Board

FROM: Sarah Sorum, PharmD

CEO / Executive Vice President Pharmacy Society of Wisconsin

DATE: July 15, 2020

SUBJECT: Variance Request per 450.02(3m)

Wis. Stat. § 450.02(3m) grants the Pharmacy Examining Board the right to grant a variance to any requirement of Chapter 450 or to any rule promulgated by the Pharmacy Examining Board if three conditions are met:

- 1. The board or its designee determines that a natural or manmade disaster or emergency exists or has occurred.
- 2. A pharmacist has requested the variance.
- 3. The board or its designee determines that the variance is necessary to protect the public health, safety, or welfare.

Due to the COVID-19 pandemic, many health care facilities have limited the number of non-essential or non-emergency visits for patients. Unfortunately, this has led to a decrease in the number of patients receiving necessary vaccines as recommended by the Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP). Per the CDC, a notable decrease in orders for vaccines between January and April 2020 as compared to January and April 2019 has been observed and is particularly notable for patients over the age of 2.

#### Per the CDC:

The ongoing COVID-19 pandemic is a reminder of the importance of vaccination. The identified declines in routine pediatric vaccine ordering and doses administered might indicate that U.S. children and their communities face increased risks for outbreaks of vaccine-preventable diseases.

As social distancing requirements are relaxed, children who are not protected by vaccines will be more vulnerable to diseases such as measles. In response, continued coordinated efforts between health care providers and public health officials at the local, state, and federal levels will be necessary to achieve rapid catch-up vaccination.

Even before the COVID-19 pandemic, as demonstrated by America's Health Rankings, Wisconsin's immunization rates have room to improve: Wisconsin ranks 41<sup>st</sup> in number of pertussis cases, a vaccine-preventable disease and outside the top ten best states for adolescent vaccinations, including meningococcal, HPV, and Tdap vaccines.<sup>1</sup> In 2016, all 72 Wisconsin counties fell below Healthy People 2020's influenza vaccination rate goal of 70% for children, adolescents, and adults under age 65.

<sup>&</sup>lt;sup>1</sup> America's Health Rankings. Wisconsin. America's Health Rankings. https://www.americashealthrankings.org/learn/reports/2017-annual-report/state-summaries-wisconsin. Published 2018. Accessed May 17, 2018.

A state-level comparison study found that pharmacy-based immunization statutes led to higher per capita influenza immunization rates.<sup>2</sup> In a decade long study, states with immunizing pharmacists increased rates 8.1%, preventing 81,000-134,000 flu cases in one year.<sup>3</sup> Eliminating cases of vaccine-preventable diseases can eliminate long-term costs to the healthcare system by eliminating the need for treatment costs.

In Wisconsin, pharmacists and pharmacy students who have completed two years of pharmacy school and are under the supervision of a licensed pharmacist have the authority to immunize patients six years and older when following ACIP recommendations. Additionally, pharmacists may immunize patients under the age of 6 with additional training and a patient-specific prescription order. Pharmacies are uniquely positioned to serve as an additional access point for patients – many pharmacies are open late (or 24 hours) and do not require immunization appointments. Additionally, 90% of Americans live within 5 miles of a pharmacy, which can make pharmacies a convenient option for many individuals, especially those with limited access to transportation.<sup>4</sup>

Unfortunately, due to staffing levels in busy pharmacies, it can be challenging for pharmacists to administer vaccines. Multiple states, including Idaho, Utah and Rhode Island, allow pharmacy technicians, under the delegation and supervision of a licensed pharmacist, to administer immunizations as an additional trained immunizer. Pharmacy technicians are jointly referred to as "delegates" in Wisconsin Statutes and "pharmacy technicians" in the Wisconsin Administrative Code. Allowing pharmacy technicians to also administer immunizations patients, when trained and under the supervision of a pharmacist, will increase pharmacies abilities and capacities to provide immunizations to patients, thereby assisting with the public health need to achieve the necessary vaccine catch-up.

Based upon the CDC's stated need to increase immunizations, we request that the Pharmacy Examining Board issue a variance to Wis. Stat. § 450.035(2m) and Phar 7.015(3)(1)(5).

Under our request, screening for contraindications and vaccine appropriateness would still be completed by the pharmacist, but the actual act of immunization could be completed by a technician if delegated by a pharmacist.

Thank you very much for your consideration of this variance request. Please do not hesitate to reach out with any questions.

Sincerely,

Sarah Sorum, PharmD

CEO / Executive Vice President Pharmacy Society of Wisconsin

Sarah Exorum

<sup>&</sup>lt;sup>2</sup> McConeghy KW, Wing C. A national examination of pharmacy-based immunization statutes and their association with influenza vaccinations and preventive health. Vaccine. 2016;34(30):3463–3468.

<sup>&</sup>lt;sup>3</sup> Hamm, N. (2017, August 22). *Pharmacists Increase Vaccination Rates*. Retrieved from http://drugtopics.modernmedicine.com/drugtopics/news/pharmacists-increase-vaccination-rates

<sup>&</sup>lt;sup>4</sup> National Association of Chain Drug Stores. RE: Health Care Workshop, Project No. P131207.



TO: Wisconsin Pharmacy Examining Board

FROM: Sarah Sorum, PharmD

CEO / Executive Vice President Pharmacy Society of Wisconsin

DATE: September 2, 2020

SUBJECT: Response to PEB Questions Regarding Delegate Immunization

On behalf of the Pharmacy Society of Wisconsin, we greatly appreciate the Pharmacy Examining Board (PEB)'s willingness to consider our variance request that would allow unlicensed delegates of a pharmacist to perform immunization services. During the PEB's July 23 call, a number of questions were raised regarding the variance request; it is our intent to have those questions answered below.

#### 1. Which specific statute or rules would be waived under the variance?

Per our original variance request, based upon the CDC's stated need to increase immunizations, we request that the Pharmacy Examining Board issue a variance to Wis. Stat. § 450.035(2m) and Phar 7.015(3)(1)(5). We are certainly open to PEB discussion with legal counsel regarding any additional waivers that would be necessary.

### 2. Exactly what would unlicensed delegates be doing?

Under our request, screening for contraindications and vaccine appropriateness would still be completed by the pharmacist, but the actual act of immunization could be completed by a technician if delegated by a pharmacist.

### 3. Would unlicensed delegates be required to administer vaccines? Would a pharmacist be required to allow any technician s/he works with to immunize under their delegated authority?

PSW supports voluntary participation by an unlicensed delegate in the training and provision of immunization administration. Furthermore, PSW supports a pharmacist's discretion in delegating immunization administration to an immunizing unlicensed delegate.

### 4. Would an unlicensed delegate require liability insurance in order to administer a vaccine?

It is our understanding that, similar to a student pharmacist intern who immunizes, only the delegating pharmacist's liability insurance would be required (per Wis. Stat. §450.035(2t)). Pharmacists should, however, confirm with their liability policy that delegates are covered under their policy.

### 5. Do other states allow pharmacy technicians to administer vaccines?

Yes! Rhode Island, Idaho, and Utah all allow pharmacy technicians to administer vaccines. A number of other states are considering this allowance to address gaps in vaccination coverage that have been exacerbated by the COVID-19 pandemic.

### 6. What would a training program for unlicensed delegates include?

The PSW immunization training course is a comprehensive course accredited by the Accreditation Council for Pharmacy Education (ACPE). The below table includes objectives that could be modified for a pharmacy technician audience.

Objective	Included in existing	Would be included in new
	pharmacists' training	technician training
Discuss the principles, scheduling, precautions, and	Yes	No
contraindications for vaccination		
Describe the epidemiology and clinical presentation	Yes	No
of vaccine-preventable diseases		
Develop a screening technique to identify patients	Yes	Screening procedures would be
needing immunization or who may have		covered and practiced
precautions or contraindications for immunization		
Develop policies and procedures for pharmacy-	Yes	Procedures for vaccination and
based immunization services that are in compliance		emergencies would be
with Wisconsin state law, including record keeping,		covered; Record keeping and
emergency procedures, and reporting		reporting requirements would
requirements		be covered
Evaluate vaccine information resources	Yes	No
Discuss the various safety procedures required of a	Yes	Yes
pharmacy delivering immunization services,		
including emergency procedure preparedness		
Use appropriate methods of reimbursement and	Yes	Yes
recordkeeping for immunization services		
Devise a strategy for the proper storage and	Yes	Yes
handling of vaccines		
Demonstrate techniques for vaccine and injectable	Yes	Administration technique (IM,
medication administration for adults and children		Sub-Q, nasal) of vaccines would
		be covered

Each participant will complete the online modules (including associated exams) and a vaccine administration lab. Participants are expected to complete the online modules and lab in their entirety and to have a current BLS/CPR certification (with documentation) before receiving certification.

The American Pharmacists Association (APhA) also offers a training course titled *Pharmacy-Based Immunization Administration by Pharmacy Technicians* which offers similar learning objectives and also contains both online and live components.

### 7. Given that conferences and trainings are not occurring in person, what would a practical/lab training component look like? How will training ensure that unlicensed delegates can correctly administer a vaccine?

The usual in-person presentation on the technique of giving immunizations has been adapted into a video presentation. Participants will be mailed a kit with all the necessary vaccine administration supplies and an injection training pad. Time slots will be made available to participants to sign up for a virtual meeting with either one of our immunization trainers and demonstrate their technique. Once the trainer has signed off that participants have shown acceptable technique, and all other elements of the training have been completed, participants will receive their certification.

Thank you very much for your consideration of this variance request. I hope that this letter has served to answer the questions raised on the July 23 PEB call. Please do not hesitate to reach out with any additional questions.

Sincerely,

Sarah Sorum, PharmD

CEO / Executive Vice President

Sarah Syorum

Pharmacy Society of Wisconsin