Wisconsin Department of Safety and Professional Services Division of Policy Development 4822 Madison Yards Way, 2nd Floor PO Box 8366 Madison WI 53708-8366



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Scott Walker, Governor Laura Gutiérrez, Secretary

PHARMACY EXAMINING BOARD

Room N208, 4822 Madison Yards Way, 2nd Floor, Madison, WI 53705 Contact: Thomas Ryan (608) 266-2112 December 6, 2018

Notice: The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the action and deliberation of the Board.

AGENDA

11:00 A.M. OR IMMEDIATELY FOLLOWING THE RULES COMMITTEE MEETING

OPEN SESSION - CALL TO ORDER - ROLL CALL

- A. Adoption of Agenda (1-4)
- B. Approval of Minutes of October 25, 2018 (5-6)
- C. Administrative Updates Discussion and Consideration
 - 1) Staff Updates
 - 2) Board Member Term Expiration Date
 - a. Grace Degner 7/1/2018
 - b. Franklin LaDien 7/1/2020 (reappointed, not yet confirmed)
 - c. Thaddeus Schumacher 7/1/2019
 - d. Kristi Sullivan 7/1/2020 (reappointed, not yet confirmed)
 - e. Philip Trapskin 7/1/2021 (reappointed, not yet confirmed)
 - f. John Weitekamp 7/1/2022 (appointed, not yet confirmed)
 - g. Cathy Winters -7/1/2021 (reappointed, not yet confirmed)
- D. Legislative/Administrative Rule Matters Discussion and Consideration (7-10)
 - 1) Phar 6 Relating to Storage
 - 2) Phar 7 Relating to Tech-Check-Tech Pilot Programs
 - 3) Phar 7 Relating to Automated Technology Final Check Pilot Program
 - 4) Phar 17 Relating to Interns
 - 5) Updates on Legislation and Pending or Possible Rulemaking Projects
- E. Pilot Program Matters Discussion and Consideration
- F. Deliberation on Items Added After Preparation of Agenda:
 - 1) Introductions, Announcements and Recognition
 - 2) Election of Officers
 - 3) Appointment of Liaisons and Alternates
 - 4) Delegation of Authorities
 - 5) Administrative Updates

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

G. 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.).

H. Credentialing Matters

1) Application Reviews

a. Fisher Bioservices Inc. – Wholesale Distributor of Prescription Drug License Application (11-41)

I. Deliberation on DLSC Matters

- 1) Administrative Warnings
 - a. 17 PHM 095 K.L.G. (42-43)

- b. 17 PHM 095 W.P. **(44-45)**
- 2) Stipulations, Final Decisions and Orders
 - a. 16 PHM 199 Timothy J. Endres, R.Ph. (46-52)
- 3) Case Closings
 - a. 16 PHM 014 & 16 PHM 075 E.S.I. Pharmacy (**53-60**)
 - b. 16 PHM 186 Morton LTC (**61-67**)
 - c. 17 PHM 104 J.W., W #07536 (**68-72**)
 - d. 17 PHM 180 S.P. #2042 (**73-77**)
 - e. 17 PHM 180 T.R.S. (**78-82**)
- 4) **Monitoring (83-84)**
 - f. John Bosnjak, R.Ph. Requesting Full Licensure (85-119)
- J. Consulting with Legal Counsel
- K. Deliberation of Items Received After Preparation of Agenda
 - 1) Education and Examination Matters
 - 2) Credentialing Matters
 - 3) DLSC Matters
 - 4) Monitoring Matters
 - 5) Professional Assistance Procedure (PAP) Matters
 - 6) Petitions for Summary Suspension
 - 7) Petitions for Designation of Hearing Examiner
 - 8) Proposed Stipulations, Final Decisions and Orders
 - 9) Proposed Interim Orders
 - 10) Administrative Warnings
 - 11) Review of Administrative Warnings
 - 12) Proposed Final Decisions and Orders
 - 13) Orders Fixing Costs/Matters Related to Costs
 - 14) Case Closings
 - 15) Board Liaison Training
 - 16) Petitions for Assessments and Evaluations
 - 17) Petitions to Vacate Orders
 - 18) Remedial Education Cases
 - 19) Motions
 - 20) Petitions for Re-Hearing
 - 21) Appearances from Requests Received or Renewed

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

- L. Voting on Items Considered or Deliberated upon in Closed Session, if Voting is Appropriate
- M. Board Meeting Process (Time Allocation, Agenda Items) Discussion and Consideration
- N. Board Strategic Planning and its Mission, Vision, and Values Discussion and Consideration

ADJOURNMENT

NEXT SCHEDULED MEETING: JANUARY 23, 2019

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.

PHARMACY EXAMINING BOARD MEETING MINUTES OCTOBER 25, 2018

PRESENT: Grace Degner, Franklin LaDien, Thaddeus Schumacher, Kristi Sullivan, Philip

Trapskin

EXCUSED: John Weitekamp, Cathy Winters

STAFF: Brittany Lewin, Division Administrator; Kate Stolarzyk, Bureau Assistant;

Sharon Henes, Administrative Rules Coordinator, and other Department staff

CALL TO ORDER

Thaddeus Schumacher, Chair, called the meeting to order at 11:14 a.m. A quorum of five (5) members was confirmed.

ADOPTION OF AGENDA

Amendments to the Agenda:

• REMOVE: Item a. "17 PHM 135 – W. & G.W.H." under item I. Deliberation on DLSC Matters, 2) Case Closings

• ADD: Under item E. Legislative/Administrative Rule Matters, "1. Phar 17 Relating to Internships, 2. 2017 Act 108 Report"

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to adopt the agenda

as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF SEPTEMBER 27, 2018

MOTION: Philp Trapskin moved, seconded by Franklin LaDien, to approve the

minutes of September 27, 2018 as published. Motion carried unanimously.

CLOSED SESSION

MOTION: Kristi Sullivan moved, seconded by Franklin LaDien, to convene to closed

session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). Thaddeus Schumacher, Chair, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Grace Degner-yes; Franklin LaDien-yes; Thaddeus Schmacher-yes; Kristi Sullivan-yes; and Philip Trapskin-yes. Motion

carried unanimously.

The Board convened into Closed Session at 12:48 p.m.

RECONVENE TO OPEN SESSION

MOTION: Kristi Sullivan moved, seconded by Franklin LaDien, to reconvene into

open session. Motion carried unanimously.

The Board reconvened into Open Session at 12:53 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to affirm all motions

made and votes taken in closed session. Motion carried unanimously.

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

DELIBERATION ON DLSC MATTERS

Stipulations, Final Decisions and Orders

17 PHM 126 – Martha Truettner, R.Ph.

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to adopt the

Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Martha Truettner, R.Ph., DLSC Case

Number 17 PHM 126. Motion carried unanimously.

17 PHM 180 - Luke T. Mittelstaedt, R.Ph.

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to adopt the Findings

of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Luke T. Mittelstaedt, R.Ph., DLSC Case Number 17

PHM 180. Motion carried unanimously.

ADJOURNMENT

MOTION: Kristi Sullivan moved, seconded by Franklin LaDien, to adjourn the

meeting. Motion carried unanimously.

The meeting adjourned at 12:55 p.m.

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:				2) Date When Request Submitted:			
Sharon Henes				21 November 2018			
Administrative Rules Co	•		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, Co	uncil, Sections:					
Pharmacy Examining Bo	oard						
4) Meeting Date:	5) Attac	hments:	6) How	should the item be tit	tled on the agenda page?		
6 December 2018	☐ Yes ☐ No		Legislative and Administrative Rule Matters 1. Phar 6 Relating to Storage 2. Phar 7 Relating to Tech-Check-Tech Pilot Programs 3. Phar 7 Relating to Automated Technology Final Check Pilot Program 4. Phar 17 Relating to Interns				
					nd Pending or Possible Rulen		
7) Place Item in:		8) Is an appearant	ce before	the Board being	9) Name of Case Advisor(s), if required:	
Open Session		Scheduled?					
☐ Closed Session		☐ Yes					
10) Describe the issue a		No					
11)		Α	Authoriza	tion			
,					11/01/10		
Sharon Hene	<u>S</u>				11/21/18		
Signature of person making this request					Date		
Supervisor (if required)				Date			
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date							
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.							

TEXT OF RULE

SECTION 1. Phar 6.07 (1) is repealed and recreated to read:

Phar 6.07 (1) The storage of drugs shall be secure, neat, clean and orderly.

SECTION 2. Phar 6.07 (2) is repealed.

SECTION 3. Phar 6.07 (3) is amended to read:

Phar 6.07 (3) Controlled <u>All controlled</u> substances shall be stored in a securely locked, substantially-constructed cabinet or dispensed throughout the inventory of non-controlled substances in a manner that obstructs theft or diversion.

SECTION 4. Repeal Phar 6.075 (b).

SECTION 5. Phar 6.075 (2) is amended to read:

Phar 6.075 (2) STORAGE. Drugs shall be stored at appropriate temperature and under appropriate conditions, including in a dry place temperature and humidity, according to the manufacturer recommendation or an official pharmaceutical compendium prevent drug adulteration.

SECTION 6. Phar 6.075 (4) is amended to read:

Phar 6.075 (4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy <u>and the humidity of the pharmacy</u> shall be monitored at lest once during each business day. A minimum and maximum temperature <u>and the humidity</u> over the course of the time a pharmacy is closed shall be obtained.

SECTION 7. 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 17

PHARMACY INTERNSHIP

Phar 17.01	Authority.	Phar 17.05	Postgraduate internship.
Phar 17.02	Definitions.	Phar 17.06	Practical experience internship.
Phar 17.03	Academic internship.	Phar 17.07	Student non-academic internship
Phar 17.04	Foreign graduate internship.		_

Phar 17.01 Authority. The rules in this chapter are adopted pursuant to the authority in ss. 15.08 (5) (b), 227.11 (2), and 450.03 (1) (g) and (2) (b), Stats.

History: CR 01–134: cr. Register July 2002 No. 559, eff. 8–1–02; correction made under s. 13.92 (4) (b) 7., Stats., Register June 2015 No. 714.

Phar 17.02 Definitions. In this chapter:

- (1) "Academic internship" means a practical experience program consisting of the practice of pharmacy sponsored by a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.
- (2) "Direct supervision" means immediate on premises availability to continually coordinate, direct and inspect at first hand the practice of another.
- (3) "Foreign graduate internship" means the practice of pharmacy by a person who has first filed an application with the board for original licensure under s. Phar 2.02 and has not graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.
- **(4)** "Intern" means a person engaged in the practice of pharmacy pursuant to subs. (1), (3), (6) and (8) or s. 450.03 (1) (g), Stats.
- **(5)** "Internship in the practice of pharmacy" means the completion of a minimum of 1500 hours in aggregate in the practice of pharmacy under subs. (1), (3), (6), (7) or (8).
- **(6)** "Postgraduate internship" means the practice of pharmacy by a person who has first filed an application with the board for original licensure under s. Phar 2.02 and has graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.
- (7) "Practical experience internship" means practical experience acquired in another state which is comparable to an internship as described in subs. (1), (3), (6) and (8).
- (8) "Student non-academic internship" means the practice of pharmacy by a person which is not acquired in an academic internship.
- **(9)** "Supervising pharmacist" means a pharmacist who supervises and is responsible for the actions of an intern in the practice of pharmacy.

History: CR 01-134: cr. Register July 2002 No. 559, eff. 8-1-02.

Phar 17.03 Academic internship. A person participating in an academic internship is not required to register as an intern with the board. There is no restriction in the number of hours earned in an academic internship.

History: CR 01-134: cr. Register July 2002 No. 559, eff. 8-1-02.

Phar 17.04 Foreign graduate internship. (1) Prior to performing duties as an intern or to receiving credit for hours participating in a foreign graduate internship the person must file an application with the board for original licensure under s. Phar 2.02, and submit evidence satisfactory to the board of having obtained certification by the foreign pharmacy graduate examination committee.

- **(2)** A foreign graduate internship is limited to performing duties constituting the practice of pharmacy under the supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location worked by an intern under his or her supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request. Prior to performing duties as an intern or to receiving credit for hours in an internship in the practice of pharmacy under this section the supervising pharmacist shall be disclosed in the initial application and any change of a supervising pharmacist shall be disclosed to the board prior to further performing duties constituting the practice of pharmacy as an intern.
- **(4)** Upon completing a maximum of 2000 hours of the practice of pharmacy in a foreign graduate internship, the internship is terminated and the person shall not further engage in the practice of pharmacy until obtaining licensure from the board.

History: CR 01–134: cr. Register July 2002 No. 559, eff. 8–1–02; CR 06–050: am. (1), (2) and (4), r. (3) and (5) Register October 2006 No. 610, eff. 11–1–06.

- **Phar 17.05 Postgraduate internship. (1)** Prior to performing duties as an intern or to receiving credit for hours participating in a postgraduate internship, the person must file an application with the board for original licensure under s. Phar 2.02 and submit to the board evidence of having been graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.
- (2) A postgraduate internship is limited to performing duties constituting the practice of pharmacy under the supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location worked by an intern under his or her supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request.
- (3) Upon completing a maximum of 2000 hours of the practice of pharmacy in a postgraduate internship, the internship is terminated and the person shall not further engage in the practice of pharmacy until obtaining licensure from the board.

History: CR 01–134: cr. Register July 2002 No. 559, eff. 8–1–02; CR 06–050: am. (2) Register October 2006 No. 610, eff. 11–1–06.

Phar 17.06 Practical experience internship. There is no restriction in the number of hours earned in a practical experience internship. In determining comparable practical experience the board shall consider the duties performed constituting the practice of pharmacy as described in s. 450.01 (16), Stats.

History: CR 01–134: cr. Register July 2002 No. 559, eff. 8–1–02.

Phar 17.07 Student non-academic internship.

- (1) Prior to performing duties as an intern or to receiving credit for hours participating in a student non-academic internship the person must successfully complete his or her second year in and be enrolled at a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.
- (2) A student non-academic internship is limited to performing duties constituting the practice of pharmacy under the direct supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location

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Phar 17.07

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worked by an intern under his or her direct supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request.

History: CR 01-134: cr. Register July 2002 No. 559, eff. 8-1-02.