

Tony Evers, Governor Dawn B. Crim, Secretary

## PHARMACY EXAMINING BOARD Room N208, 4822 Madison Yards Way, 2<sup>nd</sup> Floor, Madison Contact: Debra Sybell (608) 266-2112 September 25, 2019

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 THE RULES COMMITTEE MEETING

# **OPEN SESSION – CALL TO ORDER – ROLL CALL**

- A. Adoption of Agenda (1-4)
- B. Approval of Minutes of July 17, 2019 (5-9)

# C. Administrative Matters – Discussion and Consideration

- 1) Department, Staff and Board Updates
- 2) Board Members Term Expiration Dates

# D. Credentialing Matters – Discussion and Consideration

1) APPEARANCE – Samantha Lange and Carmell Listenbee, Division of Professional Credential Processing: Review of Pharmacist Licensure Process

# E. Legislative and Administrative Rule Matters – Discussion and Consideration (10-18)

- 1) Phar 7 Emergency Rule Relating to Delegate Check Delegate
- 2) Phar 7 Emergency Rule Relating to Ratio
- 3) Phar 7 Emergency Rule Relating to Automated Technology Final Verification Check
- 4) Phar 6 Relating to Storage
- 5) Phar 17 Relating to Internships
- 6) Phar 15 Relating to Compounding
- 7) Legislation and Pending or Possible Rulemaking Projects

# F. Newsletter Planning – Discussion and Consideration (19-21)

- G. Pilot Program Matters Discussion and Consideration
- H. Education and Examination Matters Discussion and Consideration
  - 1) Multistate Pharmacy Jurisprudence Examination (MPJE) Question Writing and Review Update
- I. Speaking Engagements, Travel, or Public Relation Requests, and Reports Discussion and Consideration

- 1) Concordia University Wisconsin School of Pharmacy Speaking Engagement Invite
- J. 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 Administrative Rule Matters
  - 11) Liaison Reports
  - 12) Board Liaison Training and Appointment of Mentors
  - 13) Informational Items
  - 14) Division of Legal Services and Compliance (DLSC) Matters
  - 15) Presentations of Petitions for Summary Suspension
  - 16) Petitions for Designation of Hearing Examiner
  - 17) Presentation of Stipulations, Final Decisions and Orders
  - 18) Presentation of Proposed Final Decisions and Orders
  - 19) Presentation of Interim Orders
  - 20) Pilot Program Matters
  - 21) Petitions for Re-Hearing
  - 22) Petitions for Assessments
  - 23) Petitions to Vacate Orders
  - 24) Requests for Disciplinary Proceeding Presentations
  - 25) Motions
  - 26) Petitions
  - 27) Appearances from Requests Received or Renewed
  - 28) Speaking Engagements, Travel, or Public Relation Requests, and Reports
- K. 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.).

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

- 1) Administrative Warnings (22-25)
  - a. 17 PHM 112 S.P.S.
  - b. 17 PHM 136 K.A.S.
- 2) Proposed Stipulations, Final Decisions, and Orders (26-37)
  - a. 17 PHM 112 Ai K. Nguyen, R.Ph.
  - b. 17 PHM 112 Pick 'N Save Pharmacy #6879
- 3) Case Closings (38-96)
  - a. 17 PHM 090 S.
  - b. 17 PHM 136 W., M.H.P.
  - c. 17 PHM 159 P.A. & W.

- d. 18 PHM 024 C.M.Y., M.A.D., A.P., & A.P.
- e. 18 PHM 027 A.P.S.P.
- f. 18 PHM 032 V.H.P.
- g. 18 PHM 063 M.P.
- h. 18 PHM 091 M.D.L. & W.
- i. 18 PHM 213 B.P.
- j. 19 PHM 013 N.E.V., W.
- k. 19 PHM 044 A.M.K., C.

# 4) Monitoring Matters (97-120)

- a. Angela Lane, R.Ph. Compliance Review
- M. 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
- N. Consulting with Legal Counsel

# RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

# ADJOURNMENT

# NEXT MEETING: OCTOBER 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 JULY 17, 2019

**PRESENT:** Franklin LaDien, Thaddeus Schumacher, Philip Trapskin, John Weitekamp, Cathy Winters

#### **EXCUSED:**

**STAFF:** Debra Sybell, Executive Director; Jameson Whitney, Legal Counsel; Brice McCluskey, Operations Program Associate; Kimberly Wood, Program Assistant Supervisor-Adv.; Sharon Henes, Administrative Rules Coordinator, and other Department staff

## CALL TO ORDER

Philip Trapksin, Chairperson, called the meeting to order at 11:00 a.m. A quorum of five (5) members was confirmed.

## **ADOPTION OF AGENDA**

#### Amendments to the Agenda:

- Closed Session: Under item "J. Division of Legal Services and Compliance; 3) Case Closings" **REMOVE**:
  - "b. 17 PHM 106 A.K.S. & M.P."
  - **MOTION:** Thaddeus Schumacher moved, seconded by Cathy Winters, to adopt the Agenda as amended. Motion carried unanimously.

#### **APPROVAL OF MINUTES OF MAY 22, 2019**

#### Amendments to the Minutes:

**MOTION:** Thaddeus Schumacher moved, seconded by Cathy Winters, to approve the Minutes of May 22, 2019 as published. Motion carried unanimously.

# **ADMINISTRATIVE MATTERS**

#### **Board, Staff and Department Updates**

**MOTION:** Cathy Winters moved, seconded by John Weitekamp, to commend and thank Thaddeus Schumacher for his years of service and leadership to the Pharmacy Examining Board and the profession. Motion carried unanimously.

## LEGISLATIVE AND ADMINISTRATIVE RULE MATTERS

#### Scope for Emergency Rule Phar 7, Relating to Delegate Check Delegate

- **MOTION:** Cathy Winters moved, seconded by Thaddeus Schumacher, to approve the Emergency Scope Statement revising Phar 7, relating to delegate-check-delegate, 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.
- **MOTION:** Thaddeus Schumacher moved, seconded by Franklin LaDien, to designate the Chairperson to approve the emergency rule draft revising Phar 7, relating to delegate-check-delegate for submission to the Governor's Office and for publication in the official newspaper. Motion carried unanimously.

#### Scope for Emergency Rule Phar 7, Relating to Pharmacist to Delegate Ratio

- **MOTION:** Cathy Winters moved, seconded by Thaddeus Schumacher, to approve the Emergency Scope Statement revising Phar 7, relating to pharmacist to delegate ratio, 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.
- **MOTION:** Thaddeus Schumacher moved, seconded by John Weitekamp, to designate the Chairperson to approve the emergency rule draft revising Phar 7, relating to pharmacist to delegate ratio for submission to the Governor's Office and for publication in the official newspaper. Motion carried unanimously.

#### Scope for Emergency Rule Phar 7, Relating to Automated Technology Product Verification

- **MOTION:** Cathy Winters moved, seconded by Thaddeus Schumacher, to approve the Emergency Scope Statement revising Phar 7, relating to automated technology product verification, 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.
- **MOTION:** Thaddeus Schumacher moved, seconded by Franklin LaDien, to designate the Chairperson to approve the emergency rule draft revising Phar 7, relating to automated technology product verification, for submission to the Governor's Office and for publication in the official newspaper. Motion carried unanimously.

#### SPEAKING ENGAGEMENTS, TRAVEL, OR PUBLIC RELATION REQUESTS, AND REPORTS

## <u>Consideration of Attendance at the 2019 NABP/AACP District IV Meeting on October 16-</u> 18, 2019 in Indianapolis, IN

MOTION: Cathy Winters moved, seconded by Thaddeus Schumacher, to designate Franklin LaDien as the Board's delegate to attend the 2019 NABP/AACP District IV Meeting on October 16-18, 2019 in Indianapolis, IN. Motion carried unanimously.

# **CLOSED SESSION**

**MOTION:** John Weitekamp 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: Franklin LaDien-yes; Thaddeus Schumacheryes; Philip Trapskin-yes; John Weitekamp-yes; and Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 12:36 p.m.

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

#### Administrative Warnings

#### 18 PHM 033 – J.A.S.

**MOTION:** Thaddeus Schumacher moved, seconded by Cathy Winters, to issue an Administrative Warning in the matter of J.A.S., DLSC Case Number 18 PHM 33. Motion carried unanimously.

(Franklin LaDien recused himself and left the room for deliberation and voting in the matter concerning J.A.S., DLSC Case Number 18 PHM 33.)

#### 17 PHM 089 - T.W.F.B.

**MOTION:** Franklin LaDien moved, seconded by Cathy Winters, to issue an Administrative Warning in the matter of T.W.F.B., DLSC Case Number 17 PHM 89. Motion carried unanimously.

(John Weitekamp recused himself and left the room for deliberation and voting in the matter concerning Thomas W.F. Bull, R.Ph, DLSC Case Number 17 PHM 089.)

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#### 17 PHM 089 – Thomas W.F. Bull, R.Ph.

**MOTION:** Franklin LaDien moved, seconded by Cathy Winters, to reject the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Thomas W.F. Bull, R.Ph, DLSC Case Number 17 PHM 089. Motion carried unanimously.

(John Weitekamp recused himself and left the room for deliberation and voting in the matter concerning Thomas W.F. Bull, R.Ph, DLSC Case Number 17 PHM 089.)

#### **Case Closings**

- **MOTION:** Cathy Winters moved, seconded by Thaddeus Schumacher, to close the DLSC cases for the reasons outlined below:
  - 1. 17 PHM 150 B.C.L. Prosecutorial Discretion (P5)
  - 2. 17 PHM 188 S.J.R., A.R.H., and H.H.C.P. Insufficient Evidence (IE)
  - 3. 19 PHM 003 H.P.1, H.P.2, and C.D.S. Insufficient Evidence (IE) Motion carried unanimously.

#### 17 PHM 089 – A.P. and K.K.N.

**MOTION:** Cathy Winters moved, seconded by Franklin LaDien, to close DLSC Case Number 17 PHM 089, against A.P. and K.K.N., for no violation. Motion carried unanimously.

(John Weitekamp recused himself and left the room for deliberation and voting in the matter concerning A.P. and K.K.N., DLSC Case Number 17 PHM 089.)

#### 17 PHM 141 – S.G.H.P.

**MOTION:** Cathy Winters moved, seconded by Franklin LaDien, to close DLSC Case Number 17 PHM 141, against S.G.H.P., for no violation. Motion carried unanimously.

#### 18 PHM 033 – W.

**MOTION:** Cathy Winters moved, seconded by Thaddeus Schumacher, to close DLSC Case Number 18 PHM 033, against W., for no violation. Motion carried.

(Franklin LaDien recused himself and left the room for deliberation and voting in the matter concerning W., DLSC Case Number 18 PHM 033.)

#### **Monitoring Matters**

## Kathryn Lindemann, R.Ph. Requesting Review of Evaluation Results

**MOTION:** Franklin LaDien moved, seconded by Thaddeus Schumacher, to remove the stay of the suspension of respondent's license to practice pharmacy until the respondent undergoes a comprehensive neuropsychological evaluation, as recommended by her evaluator in the May 24, 2019 psychological evaluation report, and the Board has considered the results and any appropriate limitations on the respondent's license. Reference paragraph C(1)(e) and C(1)(f) of the final decision and order in case 17 PHM 083. Motion carried unanimously.

# **RECONVENE TO OPEN SESSION**

**MOTION:** Thaddeus Schumacher moved, seconded by Cathy Winters, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 1:32 p.m.

# VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

**MOTION:** Thaddeus Schumacher 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.)

# OPEN SESSION ITEMS NOTICED ABOVE NOT COMPLETED IN THE INITIAL OPEN SESSION

# ADJOURNMENT

**MOTION:** Thaddeus Schumacher moved, seconded by Cathy Winters, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 1:35 p.m.

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# State of Wisconsin Department of Safety & Professional Services

1) Name and Title of De	reen Cubmittin			uset Submitted			
1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator			2) Date When Req				
			16 September 2019				
			date which is 8 busi	ered late if submitted after 12:00 p.m. on the deadline ness days before the meeting			
3) Name of Board, Com	mittee, Council	, Sections:					
Pharmacy Examining B	oard						
4) Meeting Date:	5) Attachments:		6) How should the item be titled on the agenda page?				
25 September 2019	Yes Legislative and Administrative Rule Matters						
-	□ No		1. Phar 7 Emergency Rule Relating to Delegate Check Delegate				
			2. Phar 7 Emergency Rule Relating to Ratio				
			<ol> <li>Phar 7 Emergency Rule Relating to Automated Technology Final Verification Check</li> </ol>				
			Phar 6 Relating to Stora	ace			
			Phar 17 Relating to Inte				
			Phar 15 Relating to Con				
				or Possible Rulemaking Projects			
7) Place Item in:		an appearance befo	ore the Board being	9) Name of Case Advisor(s), if required:			
Open Session	sch	eduled?					
Closed Session		Yes					
		No					
10) Describe the issue a	and action that	should be addressed	:				
11)		Authori	zation				
Sharon Hene	S			9/16/19			
		at		, ,			
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

# STATE OF WISCONSIN PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	PROPOSED ORDER OF THE	
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD	1
PHARMACY EXAMINING BOARD	:	ADOPTING RULES	
	:	(CLEARINGHOUSE RULE )	

#### PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 6.07 (2) and 6.075 (1) (b); to amend Phar 6.07 (3), 6.075 (2) and 6.075 (4); and to repeal and recreate Phar 6.07 (1) relating to storage.

Analysis prepared by the Department of Safety and Professional Services.

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#### <u>ANALYSIS</u>

Statutes interpreted: s. 450.09 (4), Stats.

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

#### **Explanation of agency authority:**

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

The Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs. [s. 450.02 (3) (a), Stats.]

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

The Board may promulgate rules establishing minimum standards for the practice of pharmacy. [s. 450.02 (3) (e), Stats.]

#### Related statute or rule: N/A

#### Plain language analysis:

Section 1 and 2 repeals the specific requirement that a pharmacy have a refrigerator, sufficient shelf, drawer or cabinet space for prescription labels, prescription containers and adequate stock

of prescription drugs, chemicals and pharmacy equipment. This is replaced with the storage of drugs shall be secure, neat, clean and orderly.

Section 3 clarifies that all controlled substances are to be stored securely or dispersed in a way which obstructs theft or diversion.

Section 4 repeals the definition of "dry place" as it is no longer being used.

Section 5 amends the manner in which drugs are to be stored. Drugs are to be stored at appropriate conditions including, temperature and humidity, to prevent drug adulteration. It also adds the pharmacy's humidity will be monitored at least once during each business days and when the pharmacy is closed.

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

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule:  $\rm N/A$ 

# Comparison with rules in adjacent states:

**Illinois**: Illinois requires all pharmacies and equipment in the pharmacy to be maintained in a clean condition and in good repair. Illinois does require a sink to be required in all pharmacies that maintain drug inventory. Refrigeration shall be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

**Iowa**: Iowa requires effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program.

**Michigan**: Michigan requires all prescription drugs to be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings. Michigan requires a pharmacy to have necessary drawers, shelves, storage cabinets, prescription files, a sink with hot and cold running water and a refrigerator of reasonable capacity. In Michigan, controlled substances are required to be stored in a securely locked, substantially constructed cabinet, room, or cart or they may be dispersed throughout the stock of noncontrolled substances in a manner to obstruct the theft or diversion of controlled substances.

**Minnesota:** Minnesota requires a refrigerator and a sink with hot and cold running water. The refrigerator designated for drug storage shall have a manual, electromechanical, or electronic temperature recording equipment, devices, or logs to document proper storage of legend drugs every business day.

# Summary of factual data and analytical methodologies:

The Pharmacy Examining Board reviewed the storage requirements in light of health care evolving and recognizing that there are different types of pharmacies which may not require the specific items required in the current rule.

In addition, stakeholders raised concerns regarding the implementation of CR 16-073 and the Pharmacy Examining Board made clarifications to the temperature and humidity provisions as a result of the concerns raised.

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

# **Fiscal Estimate and Economic Impact Analysis:**

The Fiscal Estimate and Economic Impact Analysis is attached.

#### **Effect on small business**:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

#### Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

#### Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on \* to be included in the record of rule-making proceedings.

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

SECTION 4. Repeal Phar 6.075 (1) (b) is repealed.

SECTION 5. Phar 6.075 (2) and (4) are 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.

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 least 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)

# STATE OF WISCONSIN PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	PROPOSED ORDER OF THE	
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD	
PHARMACY EXAMINING BOARD	:	ADOPTING RULES	
	:	(CLEARINGHOUSE RULE )	

#### PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 17.02(1), (3), (5), (6), (7) and (8), 17.03, 17.04, 17.05, 17.06 and 17.07; to amend Phar 17.02(4); and to create Phar 17.035 relating to pharmacy internships.

Analysis prepared by the Department of Safety and Professional Services.

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#### ANALYSIS

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

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

#### **Explanation of agency authority:**

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

The board may promulgate rules necessary for the administration of chs. 450 and 961. [s. 450.02 (3) (d), Stats.]

The board may promulgate rules establishing minimum standards for the practice of pharmacy. [s. 450.02 (3) (e), Stats.]

Related statute or rule: Ch. Phar 2

#### Plain language analysis:

This rule simplifies and brings into statutory compliance ch. Phar 17.

SECTION 1 amends the statutory citations to correctly reflect the statutory authority.

SECTIONS 2 and 4 repeal unnecessary definitions due to the simplification of the rules.

SECTION 3 amends the definition for "intern" to mean a person who is completing an internship. It does not include a person who is allowed an exemption to practice pharmacy without a license under direct supervision (a person who has successfully completed two years of pharmacy school or a pharmacist from another state while waiting for the Wisconsin license application to be processed).

SECTIONS 5 and 7 repeal the different types (academic, foreign graduate, practical experience, and student non-academic).

SECTION 6 creates general requirements for an internship. The intern may only perform duties under the direct supervision of a supervising pharmacist. The supervising pharmacist shall keep track of the hours and locations worked by the intern. This documentation will be signed by the intern and the pharmacist and disclosed to the Board upon request.

# Summary of, and comparison with, existing or proposed federal regulation:

There are no federal regulations relating to pharmacist interns.

# Comparison with rules in adjacent states:

**Illinois**: Illinois requires approved pharmacy programs to contain a minimum of 400 hours of direct contact hours in clerkship and externship experience including supervised training in inpatient environments providing for interdisciplinary experiences with other health professionals and distributive aspects of pharmacy practice.

**Iowa**: In Iowa an intern is a person who is enrolled in a college of pharmacy or actively pursuing a pharmacy degree, or as otherwise provided by the board is registered for the purpose of obtaining instruction in the practice of pharmacy from a preceptor pursuant to Iowa Code section 155A.6. A licensed pharmacist must be on duty and responsible for intern during all periods of training and tasks usually restricted to a pharmacist may be delegated to interns at the discretion of the supervising pharmacist.

**Michigan**: Michigan requires an intern to obtain an intern license Before training an intern, a licensed pharmacist must obtain board approval. The preceptor is responsible for the overall internship program at the pharmacy.

**Minnesota:** Minnesota requires a person to register with the board before beginning an internship. Pharmacists intending to act as preceptors for interns must also register with the board. An intern performing tasks associated with dispensing or compounding shall be immediately and directly supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the actions of the intern. Immediate and direct supervision by a licensed pharmacist is not required when the intern performs tasks that do not involve dispensing and compounding. However, all drug therapy and related recommendations that an intern proposes to make to other health professionals and patients must be reviewed and approved by a licensed pharmacist before they are made.

## Summary of factual data and analytical methodologies:

The Pharmacy Examining Board did a comprehensive review of chapter Phar 17 to ensure the chapter is statutorily compliant and current with professional standards and practices.

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

## **Fiscal Estimate and Economic Impact Analysis:**

The Fiscal Estimate and Economic Impact Analysis is attached.

#### **Effect on small business**:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Dan.Hereth@wisconsin.gov, or by calling (608) 267-2435.

#### Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

#### Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on \* to be included in the record of rule-making proceedings.

\_\_\_\_\_

#### TEXT OF RULE

SECTION 1. Phar 17.01 is amended to read:

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) 450.02 (3) (d) and (e), Stats.

SECTION 2. Phar 17.02 (1) and (3) are repealed.

SECTION 3. Phar 17.02 (4) is amended to read:

Phar 17.02 (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 completing an internship in order to meet the

requirement under s. 450.03 (2) (b), Stats. It does not include a person practicing pharmacy pursuant to s. 450.03 (1) (f) or (g), Stats.

SECTION 4. Phar 17.02 (5), (6), (7) and (8) are repealed.

SECTION 5. Phar 17.03 is repealed.

SECTION 6. Phar 17.035 is created to read:

Phar 17.035 Internship. (1) The intern shall be limited to performing duties constituting the practice of pharmacy under the direct supervision of a supervising pharmacist.(2) The supervising pharmacist shall keep a written record of the hours and location worked by an intern under the pharmacist's supervision, signed by the intern and the supervising pharmacist. The written record shall be disclosed to the board upon request.

SECTION 7. Phar 17.04, 17.05, 17.06 and 17.07 are repealed.

SECTION 8. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

# State of Wisconsin Department of Safety & Professional Services

1) Name and Title of Person Submitting the Request:			2) Date When Request Submitted:			
Kimberly Wood, Program Assistant Supervisor-Adv.			9/13/19			
			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, Co	uncil, Sections:				
Pharmacy Examin	ning Board					
4) Meeting Date:	5) Attachment	s: 6) How should the ite	em be titled on the ag	jenda page?		
9/25/19	⊠ Yes □ No	Newsletter Planning	Newsletter Planning – Discussion and Consideration			
7) Place Item in:		,	8) Is an appearance before the Board being 9) Name of Case Advisor(s), if required:			
🖂 Open Sessio	on	scheduled?				
Closed Sess	sion	∐ Yes				
10) Describe the i	ssue and action	No that should be addressed	•			
,						
Review and discu	ss the example	email newsletter format.				
11)		Authoriz	ation			
Kimberly	Wood			9/13/19		
Signature of perso		request		Date		
	•	•				
Supervisor (if requ	uired)			Date		
Executive Directo	r signature (ind	icates approval to add pos	t agenda deadline ite	m 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>						
	3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a					
meeting.	-	-		·		

# AGENDA REQUEST FORM

# Wood, Kimberly - DSPS

From:	Wisconsin Department of Safety and Professional Services <widsps@public.govdelivery.com></widsps@public.govdelivery.com>
Sent:	Friday, August 23, 2019 11:15 AM
То:	Wood, Kimberly - DSPS; Cathy Winters
Subject:	Wisconsin Pharmacy Examining Board Update : TEST

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DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

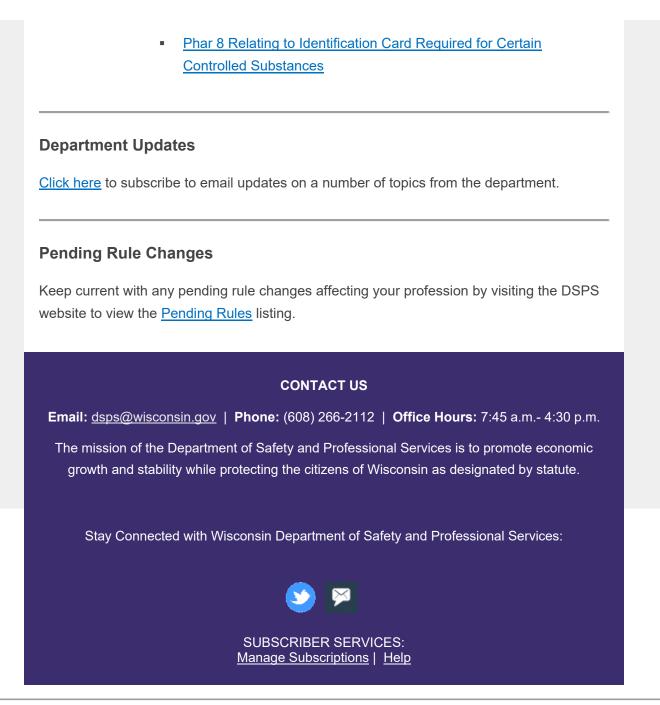
DATE: Month D, YYYY

# **Wisconsin Pharmacy Examining Board Updates**

You are receiving this update as a licensee of the Wisconsin Pharmacy Examining Board.

# Important Information Regarding Recent Changes to Administrative Rules

- Effective November 1, 2017, Phar 6 has been updated pursuant to 2017 Wisconsin Act 18:
  - o Phar 6 Pharmacy Licenses and Equipment
  - o 2017 Wisconsin Act 18
- Effective November 1, 2017, Phar 14 has been updated:
  - o Phar 14 Home Medical Oxygen Providers
- Effective September 1, 2017, Phar 7.10 has been updated:
  - Phar 7.10 Administration of drug products and devices other than vaccines
- On October 1, 2016 the following Pharmacy Chapters were updated:
  - o Rules:
    - Phar 1
    - Phar 2
    - <u>Ph</u>ar 4
    - Phar 5
    - Phar 8
  - o Orders
    - Phar 1, 8 Relating to Definitions and Controlled Substances
    - Phar 1, 2 and 4 Relating to Application and Examination
    - Phar 5 Relating to Renewal and Reinstatement



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