

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

Scott Walker, Governor Laura Gutiérrez, Secretary

PHARMACY EXAMINING BOARD Contact: Dan Williams (608) 266-2112

Room 121A, 1400 East Washington Avenue, Madison, WI 53703 July 20, 2017

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 May 18, 2017 (5-7)
- 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. Terry Maves 7/1/2018
 - d. Thaddeus Schumacher 7/1/2019
 - e. Kristi Sullivan -7/1/2020 (reappointed, not yet confirmed)
 - f. Philip Trapskin 7/1/2017
 - g. Cathy Winters -7/1/2017
- D. Pilot Program Matters Discussion and Consideration
- E. Legislation/Administrative Rule Matters Discussion and Consideration (8-20)
 - 1) Scopes for Commencing Rule-Making for the Pilot Programs
 - a. Pharmacist to Technician Ratio (9-10)
 - b. Institutional Tech-Check-Tech (11-12)
 - c. Automated Final Check (13-14)
 - d. Community Tech-Check-Tech (15-16)
 - 2) Adoption of CR 16-079 Relating to Administration of Drug Products and Devices Other Than Vaccines (17-20)
 - 3) Update on Legislation and Pending or Possible Rulemaking Projects
- F. Speaking Engagements, Travel, or Public Relations Requests
- G. Informational Items Discussion and Consideration

H. Items Received After Preparation of the Agenda

- 1) Introductions, Announcements and Recognition
- 2) Election of Board Officers
- 3) Appointment of Board Liaisons
- 4) Administrative Updates
- 5) Education and Examination Matters
- 6) Credentialing Matters
- 7) Practice Matters
- 8) Legislation/Administrative Rule Matters
- 9) Informational Items
- 10) Disciplinary Matters
- 11) Presentations of Petitions for Summary Suspension
- 12) Petitions for Designation of Hearing Examiner
- 13) Presentation of Proposed Stipulations, Final Decisions and Orders
- 14) Presentation of Proposed Final Decision and Orders
- 15) Presentation of Interim Orders
- 16) Petitions for Re-Hearing
- 17) Petitions for Assessments
- 18) Petitions to Vacate Orders
- 19) Requests for Disciplinary Proceeding Presentations
- 20) Motions
- 21) Petitions
- 22) Appearances from Requests Received or Renewed
- 23) Speaking Engagement(s), Travel, or Public Relations Request(s)
- 24) Division of Legal Services and Compliance (DLSC) Matters
- 25) Prescription Drug Monitoring Program Information
- 26) Consulting with Legal Counsel
- 27) Liaison Report(s)
 - a. Appointed to Controlled Substances Board per Wis. Stats. §15.405(5g): Philip Trapskin
 - b. Continuing Education (CE) and Education and Examinations Liaison: Terry Maves
 - c. Credentialing Liaison(s): Terry Maves, Cathy Winters
 - d. Digest Liaison: Philip Trapskin
 - e. DLSC Liaison: Thaddeus Schumacher, Cathy Winters
 - f. Legislative Liaison: Philip Trapskin, Thaddeus Schumacher, Terry Maves
 - g. Monitoring Liaison(s): Franklin LaDien, Cathy Winters
 - 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 Liaison(s): Philip Trapskin, Cathy Winters

I. 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.).

J. Deliberation on Division of Legal Services and Compliance (DLSC) Matters

- 1) Administrative Warnings (21-22)
 - a. 16 PHM 051 (W.R.F.)
- 2) Stipulations, Final Decisions and Orders (23-28)
 - a. 16 PHM 135 (D.A.K.)
- 3) Stipulations and Interim Orders (29-33)
 - a. 16 PHM 199 (T.J.E.)
- 4) Case Closings (34-36)
 - a. 16 PHM 101
- 5) Monitoring
 - a. Michael Ivey, R.Ph., Requesting PIC hours, reduction in drug screens, and reduction in AA/NA attendance frequency (37-65)
 - b. Dirk Larson, R.Ph., Requesting increase in PIC hours (66-90)

K. Consulting with Legal Counsel

- L. Deliberation of Items Received After Preparation of Agenda
 - 1) Education and Examination Matters
 - 2) Credentialing Matters
 - 3) Disciplinary Matters
 - 4) Monitoring Matters
 - 5) Professional Assistance Procedure (PAP) Matters
 - 6) Petitions for Summary Suspension
 - 7) Petitions for Designation of Hearing Examiner
 - 8) Stipulations, Final Decisions and Orders
 - 9) Administrative Warnings
 - 10) Review of Administrative Warnings
 - 11) Proposed Final Decisions and Orders
 - 12) Orders Fixing Costs/Matters Related to Costs
 - 13) Case Closings
 - 14) Interim Orders
 - 15) Petitions for Assessments and Evaluations
 - 16) Petitions to Vacate Orders
 - 17) Remedial Education Cases
 - 18) Motions
 - 19) Petitions for Re-Hearing
 - 20) Appearances from Requests Received or Renewed

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

- M. Voting on Items Considered or Deliberated upon in Closed Session, if Voting is Appropriate
- N. Board Meeting Process (Time Allocation, Agenda Items) Discussion and Consideration
 - 1) Starting times for Rules Committee and Board meetings on September 21, 2017
- O. Board Strategic Planning and its Mission, Vision, and Values Discussion and Consideration

ADJOURNMENT

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 1400 East Washington Avenue, 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 MAY 18, 2017

PRESENT: Franklin LaDien, Terry Maves, Thaddeus Schumacher, Kristi Sullivan, Philip

Trapskin, Cathy Winters

EXCUSED: Grace Degner

STAFF: Dan Williams, Executive Director; Laura Smith, Bureau Assistant; Sharon Henes,

Administrative Rules Coordinator, and other Department staff

CALL TO ORDER

Thaddeus Schumacher, Chair, called the meeting to order at 11:02 a.m. A quorum of six (6) members was confirmed.

ADOPTION OF AGENDA

MOTION: Philip Trapskin moved, seconded by Terry Maves, to adopt the agenda as

published. Motion carried unanimously.

APPROVAL OF MINUTES OF APRIL 6 AND MARCH 31, 2017

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to approve the minutes of

April 6 and March 31, 2017 as published. Motion carried unanimously.

PILOT PROGRAM MATTERS

MOTION: Cathy Winters moved, seconded by Franklin LaDien, to request that the

Department draft four Scope Statements relating to preserving the substance of the current pilot programs to be approved at the next meeting. Motion

carried unanimously.

CLOSED SESSION

MOTION: Terry Maves moved, seconded by Kristi Sullivan, 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.). The Chair read the language of the motion. The vote of

each member was ascertained by voice vote. Roll Call Vote: Franklin LaDien-yes; Terry Maves-yes; Thaddeus Schumacher-yes; Kristi Sullivan-yes; Philip Trapskin-yes; Cathy Winters-yes. Motion carried unanimously.

At this time, all external communication contacts will be terminated for purposes of going into Closed Session.

The Board convened into Closed Session at 12:18 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 1:05 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to affirm all motions

made 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 DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Administrative Warning

15 PHM 035 – (T.J.L.)

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to rescind the

Administrative Warning previously issued on September 22, 2016. Motion

carried unanimously.

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to issue an amended

Administrative Warning on May 18, 2017 in the matter of DLSC case number

15 PHM 035. Motion carried unanimously.

(Franklin La Dien recused himself and left the room for deliberation and voting in the matter of 15 PHM 035.)

Proposed Stipulations, Final Decisions and Orders

<u>16 PHM 167 (S.V.H.)</u>

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to accept the Findings of Fact,

Conclusions of Law and Order in the matter of disciplinary proceedings against Steven V. Henningfield, DLSC case number 16 PHM 167. Motion carried

unanimously.

16 PHM 063 (A.C.P.)

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to accept the Findings of Fact,

Conclusions of Law and Order in the matter of disciplinary proceedings against Angela C. Paniagua, R.Ph., DLSC case number 16 PHM 063. Motion carried

unanimously.

16 PHM 160

MOTION: Cathy Winters moved, seconded by Terry Maves, to close DLSC case number

16 PHM 160, against D.A.S. and T.P. for Insufficient Evidence. Motion

carried unanimously.

16 PHM 126

MOTION: Philip Trapskin moved, seconded by Terry Maves, to close DLSC case

number 16 PHM 126, against J.B., for No Violation. Motion carried

unanimously.

MOTION: Cathy Winters moved, seconded by Terry Maves, to refer the matter of R.S.,

(16 PHM 126), to DLSC Intake for review. Motion carried unanimously.

MONITORING

Radix Laboratories, Inc.

MOTION: Cathy Winters moved, seconded by Philip Trapskin, to request that monitoring staff

obtain the most recent inspection report conducted by the FDA for Radix

Laboratories. Furthermore, the Monitoring Liaison is given delegated authority to act

upon Radix' request for full licensure. Motion carried unanimously.

Robin Block, R.Ph.

MOTION: Philip Trapskin moved, seconded by Terry Maves, to grant the request by Robin

Block, R.Ph., Inc. to be excused from testing for travel from July 5, 2017 until July

19, 2017. Motion carried unanimously.

ADJOURNMENT

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to adjourn the meeting.

Motion carried unanimously.

The meeting adjourned at 1:20 p.m.

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:			Request:	2) Date When Requ	est Submitted:
				10 I-1- 2017	
Sharon Henes Administrative Rules Coordinator				10 July 2017	red late if submitted after 12:00 p.m. on the deadline
Administrative Rules Coordinator				date:	red late it submitted diter 12.00 p.m. on the deddine
3) Name of Board, Committee, Council, Sections:			•	 8 business 	s days before the meeting
3) Name of Board, Com	mittee, Co	ouncii, Sect	ions:		
Pharmacy Examining					
4) Meeting Date:	1 <u>~</u>	hments:	,	the item be titled on	• • •
20 July 2017	Ye				Discussion and Consideration -making for the Pilot Programs
20 July 2017	□ N	ס		nacist to Technician	
				itional Tech-Check	
				nated Final Check	
				nunity Tech-Check	
				of CR 16-079 Rela	ting to Administration of Drug Products
					ending and Possible Rulemaking Projects
7) Place Item in:	I	8) Is an ap		the Board being	9) Name of Case Advisor(s), if required:
Open Session		scheduled	d?	_	
☐ Closed Session		_			
☐ Both		│	Fill out Board Ap	opearance Request)	
		☐ No			
10) Describe the issue a	and action	that shoul	d be addressed:		
11)			Authoriza	tion	
20	- 0				
Sharon I	Henes	•			
Signature of person ma	king this	request			Date
Supervisor (if required)					Date
Executive Director sign	ature (ind	icates appr	oval to add post	agenda deadline iten	n to agenda) Date
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Directions for including supporting documents:					
1. This form should be	attached	to any docu	ıments submitted		
					y Development Executive Director.
3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a					
meeting.					

PHARMACY EXAMINING BOARD

Rule No.:	Phar 7.01 (3)
Relating to:	Pharmaicst to Pharmacist Technician
Rule Type:	Permanent

- 1. Finding/nature of emergency (Emergency Rule only): N/A
- 2. Detailed description of the objective of the proposed rule:

The objective is to amend the pharmacist to technician ratio.

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

Under current pharmacy rules, a there is a 4 technicans per pharmacist ratio for staffing pharmacies. The Pharmacy Examining Board began a pilot program for Community Tech-Check-Tech on October 1, 2016 which will end on September 30, 2019 or the promulgation of rules. The purpose of the Ratio Pilot Program is to study the supervision and staffing of technicians in order to determine the minimum ratio necessary to ensure safety, quality and efficiency of the pharmacy and allow the availability of a pharmacist for involvement in other patient care activities.

The Pharmacy Examining Board will utilize the data obtained by the Board during the pilot program to create rules to determine the pharmacist to pharmacy technician ratio which has not been updated since March 2001.

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

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

450.02 (3) The board may promulgate rules:

- (a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
- (d) Necessary for the administration and enforcement of this chapter and ch. 961.
- (e) Establishing minimum standards for the practice of pharmacy.
- 5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

125 hours

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

Pharmacists, pharmacies, technicians and patients.

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

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have significant economic impact on small businesses):	а
None to minimal. It is not likely to have a significant economic impact on small businesses.	
Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377	
Authorized Signature	
Date Submitted	

PHARMACY EXAMINING BOARD

Rule No.:	Phar 7
Relating to:	Institutional Technician Check Technician
Rule Type:	Permanent

- 1. Finding/nature of emergency (Emergency Rule only): N/A
- 2. Detailed description of the objective of the proposed rule:

The objective is to create a process for technicians to check technicians filling prescriptions without a final check by the pharmacist.

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

Under current pharmacy rules, a final check of a prescription can only be performed by a pharmacist. The Pharmacy Examining Board began a pilot program for Institution Tech-Check-Tech on October 1, 2016 which will end on September 30, 2019 or the promulgation of rules. The purpose of the Institution Tech-Check-Tech Pilot Program is to study the accuracy of a pharmacy technician making a final check of another pharmacy technician filling the prescription in an institutional setting where a health care provider is administering the medication. The purpose is to increase the availability of a pharmacist for involvement in other patient care activities.

The Pharmacy Examining Board will utilize the data obtained by the Board during the pilot program to create rules which improve the safety, quality or efficiency of the practice of pharmacy.

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

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

450.02 (3) The board may promulgate rules:

- (a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
- (d) Necessary for the administration and enforcement of this chapter and ch. 961.
- (e) Establishing minimum standards for the practice of pharmacy.
- 5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

125 hours

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

Pharmacists, Pharmacies located in institutions, Technicians and Patients.

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

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):
None to minimal. It is not likely to have a significant economic impact on small businesses.
Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377
Department Head or Authorized Signature
Date Submitted

PHARMACY EXAMINING BOARD

Rule No.:	Phar 7
Relating to:	Automated Technology Final Check
Rule Type:	Permanent

- 1. Finding/nature of emergency (Emergency Rule only): N/A
- 2. Detailed description of the objective of the proposed rule:

The objective is to create a process for automated technology to complete the final check of a prescription instead of a pharmacist.

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

Under current pharmacy rules, a final check of a prescription can only be performed by a pharmacist. The Pharmacy Examining Board began a pilot program for automated technology final check on October 1, 2016 which will end on September 30, 2019 or the promulgation of rules. The purpose of the Automated Final Check Pilot Program is to study the accuracy of automated technology making a final check of the final dispensed medication. The purpose is to increase the availability of a pharmacist for involvement in other patient care activities.

The Pharmacy Examining Board will utilize the data obtained by the Board during the pilot program to create rules which improve the safety, quality or efficiency of the practice of pharmacy.

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

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

450.02 (3) The board may promulgate rules:

- (a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
- (d) Necessary for the administration and enforcement of this chapter and ch. 961.
- (e) Establishing minimum standards for the practice of pharmacy.
- 5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

125 hours

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

Pharmacists, Pharmacies, Technicians and Patients.

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

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):
None to minimal. It is not likely to have a significant economic impact on small businesses.
Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377
Authorized Signature
Date Submitted

PHARMACY EXAMINING BOARD

Rule No.:	Phar 7
Relating to:	Community Technician Check Technician
Rule Type:	Permanent

- 1. Finding/nature of emergency (Emergency Rule only): N/A
- 2. Detailed description of the objective of the proposed rule:

The objective is to create a process for technicians to check technicians filling prescriptions without a final check by the pharmacist.

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

Under current pharmacy rules, a final check of a prescription can only be performed by a pharmacist. The Pharmacy Examining Board began a pilot program for Community Tech-Check-Tech on November 1, 2016 which will end on October 31, 2019 or the promulgation of rules. The purpose of the Community Tech-Check-Tech Pilot Program is to study the accuracy of a pharmacy technician making a final check of another pharmacy technician of the final dispensed medication in a community pharmacy. The purpose is to increase the availability of a pharmacist for involvement in other patient care activities.

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

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

450.02 (3) The board may promulgate rules:

- (a) Relating to the manufacture of drugs and the distribution and dispensing of prescription rugs.
- (d) Necessary for the administration and enforcement of this chapter and ch. 961.
- (e) Establishing minimum standards for the practice of pharmacy.
- 5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

125 hours

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

Pharmacists, Pharmacies, Technicians and Patients.

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

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):
None to minimal. It is not likely to have a significant economic impact on small businesses.
Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377
Authorized Signature
Date Submitted

STATE OF WISCONSIN PHARMACY EXAMINING BOARD

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IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD

PHARMACY EXAMINING BOARD : ADOPTING RULES

: (CLEARINGHOUSE RULE 16-079)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate s. Phar 7.10 relating to administration of drug products and devices other than vaccines.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.035 (1r) and (1t), Stats.

Statutory authority: ss. 15.08 (5) (b) and 450.02 (2g) (b), Stats.

Explanation of agency authority:

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

The board shall promulgate rules that establish requirements and procedures for the administration of a drug product or device, as defined in s. 450.035(1g), by a pharmacist under s. 450.035(1r). [s. 450.02(2g)(b), Stats.]

Related statute or rule: N/A

Plain language analysis:

This proposed rule establishes requirements and procedures for a pharmacist or pharmacist intern to administer a prescribed drug product or device in order to implement 2015 Act 290. (A drug product or device does not include vaccinations.)

A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has completed a course of study and training in administration techniques.

A person who has successfully completed their second year and is enrolled in a school of pharmacy or a pharmacist licensed in another state who has applied for a Wisconsin pharmacist license may not administer a drug product or device unless they successfully complete a course

of study and training in administration technique and administers the drug product or device only under the direct supervision of a pharmacist who has successfully completed the course of study.

The course of study must be approved by the Accreditation Council for Pharmacy Education or the Board. The Board will evaluate programs using criteria substantially equivalent to the criteria used by the Accreditation Council or Pharmacy Education.

After the pharmacist administers a prescribed drug product or device, the pharmacist or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system the pharmacist shares with the prescribing practitioner.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not have rules relating to administration of drugs or devices other than vaccinations/immunizations.

Iowa: Iowa designates persons as qualified to administer drugs who are licensed pharmacists and have successfully completed a medication administration course. [657-8.32 Iowa Admin Code]

Michigan: Michigan does not have rules relating to administration of drugs or devices.

Minnesota: Minnesota does not have rules relating to administration of drugs or devices.

Summary of factual data and analytical methodologies:

The Board is implementing the language from 2015 Act 290. For the criteria for approving the course of study, the Board consulted with both the Medical Examining Board and Board of Nursing as is required pursuant to s. 450.02 (2g) (a).

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

This rule was posted for economic comments and none were received.

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 Kirsten.Reader@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, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 7.10 is repealed and recreated to read:

Phar 7.10 Administration of drug products and devices other than vaccines. (1) In this section, "course of study" means one or more classes, workshops, seminars or continuing education programs.

- (2) A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats. After the pharmacist administers a prescribed drug product or device, the pharmacist, a person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner.
- (3) A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board.
- (4) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats. may not administer a prescribed drug product or device unless the person satisfies all of the following:
 - (a) Successfully completes a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board
 - (b) Administers the prescribed drug product or device only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council of Pharmacy Education or the board.
 - (c) After administering the prescribed drug product or device, notifies the prescribing practitioner or enters the information in a patient record system shared by the prescribing practitioner.
- (5) The board may approve courses of study which meet criteria substantially equivalent to criteria used by the Accreditation Council for Pharmacy Education.
- (6) A course of study and training in administration technique shall include all of the following topics:
 - (a) Safe injection practices to prevent infections.
 - (b) Anatomy
 - (c) Proper injection techniques.
 - (d) The five rights of administration including right patient, right drug, right dose, right route and right time.

- (e) Patient reassessment after administration including signs and symptoms of adverse drug reactions.
- (f) Best practices in documentation of the medication administration.
- (7) This section does not apply to the administration of vaccines.

Note: To administer a vaccine a pharmacist must meet the requirements in s. 450.035, Stats.

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

This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Agency

Dated <u>March 31, 2017</u>

Chair of the Pharmacy Examining Board