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

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

Tony Evers, Governor
Dawn B. Crim, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI 53705
Contact: Christine Poleski (608) 266-2112
January 28, 2021

Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. ***A quorum of the Board may be present during any committee meetings.***

AGENDA

8:30 A.M.

OPEN SESSION – CALL TO ORDER

A. Approval of Agenda (1)

B. Administrative Rule Matters – Discussion and Consideration (2)

1) Phar 2, Related to Endorsement Licensure (Emergency and Permanent) **(3)**
2) Phar 8, Relating to Controlled Substances Requirements **(4-5)**
3) 2021 Biennial Report Under s. 227.29 Wis Stats. **(6)**
4) Pending or Possible Rulemaking Projects

C. Public Comments

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 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 deaf or 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.

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:
Kassandra Walbrun	1/6/2021
	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Pharmacy Examining Board – Rules Committee

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
1/28/2021	☒ Yes ☐ No	Administrative Rule Matters – Discussion and Consideration 1. Phar 2, related to Endorsement Licensure (Emergency and Permanent) 2. Phar 8, related to Controlled Substances Requirements 3. 2021 Biennial Report under s. 227.29, Wis. Stats.

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	

10) Describe the issue and action that should be addressed:

1. Discuss status of emergency rule and potential for permanent rule

2. Review draft rule. Discuss follow up questions regarding state authority and federal rules (pdf)

3. Review of Pharmacy rules for report development

11) Authorization

Kassandra Walbrun *1/6/2021*

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

Chapter Phar 2

APPLICATION FOR PHARMACIST LICENSE

Note: Chapter Phar 2 as it existed on January 31, 1983, was repealed and a new chapter Phar 2 was created effective February 1, 1983.

Phar 2.02 Application procedure for original licensure. (1) Each applicant for original licensure as a pharmacist shall submit all of the following:

(a) Completed application form with the signature of the applicant.

(b) A statement from the dean of the school of pharmacy or the academic records office of the respective educational institution that the applicant has graduated from the pharmacy school.

(c) If the applicant was foreign educated, evidence satisfactory to the board that the applicant has obtained certification by the foreign pharmacy graduate examination committee.

(d) Evidence of having completed an internship in the practice of pharmacy, consisting of a minimum of 1,500 hours, which shall consist of one or more of the following:

1. A statement from the dean of the school of pharmacy or the academic records office certifying the number of hours that the applicant has successfully completed in a practical experience program of the respective educational institution.

2. A statement from a supervising pharmacist certifying the number of hours that the applicant was supervised by that supervising pharmacist in an internship in the practice of pharmacy described in ch. Phar 17.

3. Verification of practical experience acquired by the applicant in another state, which is approved and verified by the board or by the agency which is the equivalent of the board in the state in which the practical experience was acquired.

(e) The fees required under s. 440.05 (1), Stats.

(f) Evidence of having passed the NAPLEX.

(g) Evidence of having passed the multi−state pharmacy jurisprudence examination with Wisconsin as primary state.

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

(2) Any change of name made prior to admission to examination shall be supported by an affidavit satisfactory to the board.

History: Cr. Register, January, 1983, No. 325, eff. 2−1−83; am. (1) (intro.) and (d), Register, December, 1998, No. 516, eff. 1−1−99; emerg. renum. (1) (d) to be (1) (e), cr. (1) (d), eff. 1−1−02; CR 01−134: renum. (1) (d) to be (1) (e), cr. (1) (d), Register July 2002 No. 559, eff. 8−1−02; CR 02−140: am. (1) (intro.) Register May 2003 No. 569, eff. 6−1−03; CR 02−150: r. (1) (c) Register May 2003 No. 569, eff. 6−1−03; CR 06−050: cr. (1) (c) Register October 2006 No. 610, eff. 11−1−06; CR 09−019: am. (1) (intro.) Register October 2009 No. 646, eff. 11−1−09; CR 16−017: am. (1) (intro.), (a), cr. (1) (f), (g) Register September 2016 No. 729, eff. 10−1−16; **CR 19−164: am. 2.02 (1) (c), (d) (intro.), 1., 3. Register July 2020 No. 775, eff. 8−1−20.**

Phar 2.05 Application procedure for persons licensed in another state. Each applicant licensed as a pharmacist in another state shall submit all of the following:

(1) Completed application form with the signature of the applicant and fee as determined by the department under s. 440.05, Stats.

(2) NABP Clearinghouse license transfer application.

(3) Evidence of having passed the multi−state pharmacy jurisprudence examination with Wisconsin as primary state.

History: Renum. from Phar 3.02 and am. (1) (intro.), Register, December, 1998, No. 516, eff. 1−1−99; CR 09−019: am. (1) (intro.) Register October 2009 No. 646, eff. 11−1−09; CR 16−017: r. and recr. Register September 2016 No. 729, eff. 10−1−16.

Chapter Phar 8
REQUIREMENTS FOR CONTROLLED SUBSTANCES

Phar 8.01 Federal registration and compliance with federal, state, and local laws and regulations. (1) FEDERAL REGISTRATION REQUIRED. In order to possess, manufacture, distribute, dispense, or conduct research with controlled substances in this state, pharmacies and pharmacists shall register with the drug enforcement administration as required under federal law.

(2) CONTROLLED SUBSTANCES AUTHORIZATION UNDER FEDERAL REGISTRATION. As provided under s. 961.32 (1m) (a), Stats., a pharmacy or pharmacist registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances in this state to the extent authorized by their federal registration and in conformity with the provisions of ch. 961, Stats.

(3) COMPLIANCE WITH LAWS AND REGULATIONS. Failure to register or otherwise comply with applicable federal, state, and local laws and regulations relating to possessing, manufacturing, distributing, dispensing, or conducting research with controlled substances constitutes unprofessional conduct for purposes of s. 450.10, Stats.

Phar 8.02 Notification of suspicious orders of controlled substances. A pharmacy shall, at the time of providing required notification to the drug enforcement administration of a suspicious order or series of orders for controlled substances, provide notification to the board. The notification to the board shall include all information provided in the notification to the drug enforcement administration.

Phar 8.03 Identification card requirements under s. 450.11 (1b), Stats. (1) DEFINITION. In s. 450.11 (1b) (e) 3., Stats., "health care facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community−based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.

(2) RECORDKEEPING. Records required under s. 450.11 (1b) (bm), Stats., shall be maintained for at least 5 years from the date the drug was dispensed, or, for a record that is subject to s. 961.385, Stats., until the name of a person to whom a drug is dispensed is delivered to the controlled substances board under s. 961.385, Stats., whichever is sooner.

Phar 8.04 Dispensing schedule II controlled substances in emergency situations under s. 961.38 (2), Stats. (1) DEFINITION. For purposes of dispensing a schedule II controlled substance under s. 961.38 (2), Stats., "emergency situation" means a situation in which the prescribing practitioner determines all of the following:

(a) Immediate administration of the schedule II controlled substance is necessary for proper treatment of the patient.

(b) No appropriate alternative treatment is available, including the administration of a drug that is not a schedule II controlled substance.

(c) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing.

(2) RECORDKEEPING. Records of prescriptions for schedule II controlled substances dispensed under s. 961.38 (2), Stats., shall be retained and available for inspection by authorized persons for at least 5 years from the date of such records.

(3) REQUIRED NOTIFICATION. A dispensing pharmacist shall, at the time of providing required notification to the drug enforcement administration of the failure of a prescribing practitioner to deliver a written prescription within 7 days after authorizing an emergency oral prescription for a schedule II controlled substance, provide notification to the board. The notification to the board shall include all information provided in the notification to the drug enforcement administration.

Philip Trapskin
Chairperson

Franklin LaDien
Vice Chairperson

Cathy Winters
Secretary

PHARMACY EXAMINING BOARD

4822 Madison Yards Way
PO Box 8366
Madison WI 53708-8366

Email: dsps@wisconsin.gov
Voice: 608-266-2112
FAX: 608-251-3032

March 22, 2019

Senator Stephen Nass, Senate Co-Chairperson
Joint Committee for Review of Administrative Rules
Room 10 South, State Capitol
Madison, WI 53702

Representative Joan Ballweg, Assembly Co-Chairperson
Joint Committee for Review of Administrative Rules
Room 210 North, State Capitol
Madison, WI 53702

RE: Report Submitted in Compliance with s. 227.29 (1), Stats.

Dear Senator Nass and Representative Ballweg:

This report has been prepared and submitted in compliance with s. 227.29 (1), Stats.

I. Unauthorized rules, as defined in s. 227.26 (4) (a):

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules are unauthorized.

II. Rules for which the authority to promulgate has been restricted:

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules have restricted authority.

III. Rules that are obsolete or that have been rendered unnecessary:

Rule	**Description of why the rule is obsolete or has been rendered unnecessary.**	**Action taken to address or reason for not taking an action**
Phar 5.02	It is no longer necessary for a pharmacist to notify the Board in writing of a name or address change. The change is typically done electronically.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.
Ch. Phar 7	This chapter has not had a comprehensive review in over 15 years. There are several obsolete and unnecessary provisions, particularly in the areas of technology.	The Board is currently working on an entire rewrite of this chapter to reflect current pharmacy standards and practice, and reduce the regulatory impact on pharmacies without negatively impacting public safety.

IV. Rules that are duplicative of, superseded by, or in conflict with another rule, a state statute, a federal statute or regulation, or a ruling of a court of competent jurisdiction:

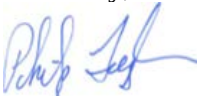
Rule	Citation or the text of the statute, regulation, or ruling.	Action taken to address or reason for not taking an action
Phar 11.01	Procedures for disciplinary proceedings. Procedures for disciplinary proceedings before the board are set forth in ch. SPS 2. This provision is unnecessary.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.
Phar 12.04	Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets the standards in 21 USC 351 and 352 (1984) and 21 CFR 210 and 211 (1985). The referenced federal statute has been superseded.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.

V. Rules that are economically burdensome:

Rule		**Action taken to address or reason for not taking an action**
Phar 6.04	Floor design, professional service area, and prescription counter space are economically burdensome and do not correspond with the evolving types of pharmacies.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.
Phar 6.07	Storage requirements are economically burdensome and do not correspond with the evolving types of pharmacies.	The Board is currently drafting a rule to update this section.
Phar 6.075	Temperature and humidity requirements were based upon nationally accepted standards. Stakeholders informed the Board of challenges and burdens in meeting these provisions.	The Board is currently drafting a rule to update this section.
Ch. Phar 7	This chapter has not had a comprehensive review in over 15 years. There are several provisions which are economically burdensome.	The Board is currently working on an entire rewrite of this chapter to reflect current pharmacy standards and practice, and reduce the regulatory impact on pharmacies without negatively impacting public safety.

Thank you.

Cordially,



Philip Trapskin
Chairperson