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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
April 29, 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 8, Related to Controlled Substances Requirements **(3-5)**
2) Phar 5, 6, 7, 11, 12, Related to Changes Identified in the 2019 Legislative Report **(6-10)**
3) Pending or Possible Rulemaking Projects

C. Public Comments

ADJOURNMENT

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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	4/20/2021
	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?
4/29/2021	☒ Yes ☐ No	Administrative Rule Matters – Discussion and Consideration 1. Phar 8, related to Controlled Substances Requirements 2. Phar 5, 6, 7, 11, 12, related to changes identified in the 2019 Legislative Report. 3. Other Pending/Possible Rule Projects.

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. Review draft rule. (pdfs)

2. Review draft rule. (pdf)

11) Authorization

Kassandra Walbrun — Signature of person making this request

4/20/2021 — Date

Supervisor (if required) — Date

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — Date

DRAFT 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. 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., pharmacies and pharmacists registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, and 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 with the drug enforcement administration 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.

> **Note:** The United States Department of Justice Drug Enforcement Administration has published a pharmacist's manual, which provides an informational outline of the federal Controlled Substances Act. It can be found online at: https://www.deadiversion.usdoj.gov/pubs/manuals/index.html.

Phar 8.02 Purpose of issue of prescription order. Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

Phar 8.03 Valid prescription requirements. (1) A pharmacist may not dispense controlled substances for a prescription the pharmacist knows, or reasonably should know, is not a valid prescription under applicable federal, state, and local laws and regulations.

(2) An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid. A pharmacist knowingly dispensing pursuant to such a purported order, as well as the practitioner issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

(3) As provided under s. 961.38 (4r), Stats., a pharmacist is immune from any civil or criminal liability and from discipline under s. 450.10, Stats., for any act taken by the pharmacist in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.

Phar 8.04 Notification of suspicious orders for and theft or loss of controlled substances. A pharmacy or pharmacist shall notify the board of a suspicious order or series of orders for controlled substances or the theft or loss of controlled substances on the same day notification is required to be provided to the drug enforcement administration. Notification to the board shall include all information required to be provided in the notification to the drug enforcement administration.

Phar 8.05 Recordkeeping. Records required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats., shall be maintained for at least 5 years from the date the drug was received, manufactured, distributed, or 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. Records shall be readily retrievable, easily readable, and available for inspection by authorized persons for at least 5 years from the date of such record. An electronic recordkeeping system shall have the capability of producing a printout of records as required under this section. The pharmacist-in-charge shall oversee monthly inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.

Phar 8.06 Identification card requirement under s. 450.11 (1b), Stats. (1) DEFINITION. In this section and 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) IDENTIFICATION CARD REQUIREMENT. As provided under s. 450.11 (1b) (b) and (e), Stats., a controlled substance included in schedule II or III of ch. 961, Stats., may not be dispensed, and may not be delivered to a representative of the ultimate user, without an identification card belonging to the person to whom the drug is being dispensed or delivered. An identification card is not required if any of the following applies:

(a) The drug is administered or dispensed directly to the ultimate user by a practitioner.

(b) The pharmacist or other person dispensing or delivering the drug has personal knowledge of the person to whom the drug is dispensed or delivered, and that the person is the ultimate user or the ultimate user's authorized representative.

(c) The drug is delivered to a health care facility to be administered in the health care facility.

Phar 8.07 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) REQUIRED NOTIFICATION. A dispensing pharmacist shall notify the board 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. The notification shall be provided to the board on the same day notification is required to be provided to the drug enforcement administration and shall include all information required to be provided in the notification to the drug enforcement administration.

Phar 8.08 Dispensing and sale of pseudoephedrine products. The dispensing and sale of pseudoephedrine products shall meet all applicable federal, state, and local laws and regulations relating to schedule V controlled substances, including all the following requirements:

(1) The requirements under ss. 961.23 and 961.38 (4), Stats., for dispensing schedule V controlled substances.

(2) The requirements under s. 961.235, Stats., for records relating to sales of pseudoephedrine products.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 6.04 (2) and (3) (a) 2. and 3., Phar 6.04 (3) (a) 7. (b) and (c) and (4), and Phar 11; to renumber and amend Phar 6.04 (3) (a) (intro.), 1., 5., and 6.; and to amend s. Phar 5.02 (1) and (2), Phar 6.04 (1), Phar 7.04 (3) (intro.), and Phar 12.04, relating to obsolete and unnecessary provisions for pharmacists and pharmacies.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.06 (1) and 450.09 (4), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), (b), (d), and 450.06 (1), 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 may promulgate rules relating to the distribution and dispensing of prescription drug and establishing security standards for pharmacies. [s. 450.02 (3) (a) and (b), Stats.]

The Board may promulgate rules necessary for the administration and enforcement of this chapters 450 and 961, Stats. [s. 450.02 (3) (d), Stats.]

No pharmacist may dispense at any location in this state that is not licensed as a pharmacy by the board. No person in this state may use or display the title “pharmacy," “drugstore," “apothecary," or any other title, symbol, or insignia having the same or similar meanings, except for a place of practice which is licensed under this section as a pharmacy by the board. [s. 450.06 (1), Stats.]

Related statute or rule: N/A

Plain language analysis:

The Pharmacy Examining Board identified the following rules in its 2019 report filed with the Joint Committee for Review of Administrative Rules pursuant to s. 227.29, Stats.

Phar 5.02 is revised to delete obsolete or unnecessary provisions to require the notification to the Board regarding name or address change to be submitted in writing.

Phar 6.04 is revised to delete economically burdensome requirements and requirements which do not correspond with the evolving types of pharmacies.

Phar 7.04 (3) is revised to correct a typographical error occurring in CR 19-145 related to which should refer to Schedule III – V drugs instead of Schedule III – IV drugs. The omission of Schedule V creates inconsistency with the federal law and confusion for pharmacists.

Ch. Phar 11 is repealed as it is duplicative and unnecessary.

Phar 12.04 is revised as the federal standards referenced have been superseded.

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

Comparison with rules in adjacent states:

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.610 outlines the standards for pharmacy structure/equipment standards. The section does require a locked area for drugs. However, Illinois does not identify professional service area square footage requirements or signage requirements.

Iowa: The complete Iowa Board of Pharmacy rules are contained in 657 Iowa Administrative Code. The Iowa Pharmacy Practice Act is codified under administrative code chapter 155A, specifically related to licensed pharmacies under s. 155A.13. Rules do require a locked area for drugs. However, there are no comparable requirements for professional service area square footage or signage.

Michigan: Michigan administrative code MCL 338.536 for housing of pharmacies specifically requires pharmacies to have a prescription department that is devoted primarily to the practice of pharmacy that occupies not less than 150 square feet of space, and that it includes a prescription counter that provides not less than 10 square feet of free working surface. For each additional pharmacist on duty, workspace must be increased by not less than 4 square feet and pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee must be permanently enclosed by partitions from the floor to the ceiling of substantial construction and must be securely lockable. There do not appear to be requirements for signage.

Minnesota: The Minnesota Administrative Code chapter 6800 related to pharmacies and pharmacists, provides the rules for the standards for pharmacies. Specifically, Minnesota Administrative Code section 6800.0700 provides minimum requirements for pharmacies. The pharmacy space requirements include the pharmacy must: contain more than 250 square feet in the dispensing and drug storage area; maintain a prescription dispensing counter at least 18 inches deep that provides 2 linear feet; maintain an aisle behind the prescription dispensing

counter at least 36 inches wide, extending the full length of the counter; be surrounded by a continuous partition or wall extending from the floor to the permanent ceiling; and contain doors capable of being securely locked. There do not appear to be requirements for signage.

Summary of factual data and analytical methodologies:

The Board conducted a full review of its administrative codes in compliance with the Legislative Report to the Joint Committee of Review of Administrative Rules under s. 227.29, Stats. The items in this rule project are a result of that review.

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

This rule will be posted for economic comments for 14 days.

Fiscal Estimate and Economic Impact Analysis:

The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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:

Kassandra Walbrun, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8306; phone (608) 261-4463; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 5.02 (1) and (2) are amended to read:

Phar 5.02 (1) A pharmacist shall notify the board ~~in writing~~ when ~~his or her~~ a pharmacist's name has been legally changed, within 30 days of the change.
(2) A pharmacist shall notify the board ~~in writing~~ when ~~his or her~~ a pharmacist's address has been changed, within 30 days of the change.

SECTION 2. Phar 6.04 (1) is amended to read:

Phar 6.04 (1) PROFESSIONAL SERVICE AREA. ~~The professional service area of a pharmacy shall not be less than 250 sq. ft. No more than 20% of the space may be used for storage of bulk~~

~~pharmaceuticals.~~ If the ~~pharmacy~~ building is open at any time ~~solely as a non-prescription or sundry outlet, without a pharmacist present~~ while the professional service area is closed, the professional service area shall be secured as specified in sub. (3). ~~A variance to the 250 sq. ft. professional service area requirement may be authorized by the board upon submission of a specific plan describing the manner in which the proposed professional service plan varies from the requirement~~.

SECTION 2. Phar 6.04 (2) is repealed.

SECTION 3. Phar 6.04 (3) (a) (intro.), and 1. are renumbered Phar 6.04 (3) (intro.) and (am) and are amended to read:

Phar 6.04 (3) (intro.) ~~PROFESSIONAL SERVICE AREA REQUIREMENTS WHERE PHARMACIST IS ABSENT~~ REQUIREMENTS WHEN THE PROFESSIONAL SERVICE AREA IS CLOSED

~~Except as provided in par. (c), if no pharmacist is present in the professional service area, a pharmacy may convert to a non-prescription or sundry outlet if~~ When the pharmacy professional service area is closed, the pharmacy shall meet all of the following requirements ~~are met~~:

(am) A locked, secure physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by ~~unlicensed~~ unauthorized personnel. A secured barrier may be constructed of other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

SECTION 4. Phar 6.04 (3) (a) 2. and 3. are repealed.

SECTION 5. Phar 6.04 (3) (a) 5. and 6. are renumbered Phar 6.04 (3) (bm) and (cm) and amended to read:

Phar 6.04 (3) ~~(a) 5.~~(bm) Signs of reasonable size are posted at ~~the entrance of the building and~~ the professional service area which prominently ~~displaying~~ display the hours the ~~pharmacist will be on duty~~ professional services are available.

~~6.~~(cm) The manner in which the telephone is answered does not imply that the ~~location is, at that time, operating as a pharmacy~~ professional services are available.

SECTION 6. Phar 6.04 (3) (a) 7., (b) and (c) and (4) are repealed.

SECTION 7. Phar 7.04 (3) (intro.) is amended to read:

7.04 (3) (intro.) The transfer of original prescription information for a controlled substance listed in Schedule III – ~~IV~~V shall meet the following requirements:

SECTION 8. Chapter Phar 11 is repealed.

SECTION 9. Phar 12.04 is amended to read:

Phar 12.04 Inspections. 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)~~ federal and state laws and regulations.

SECTION 10. 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)
