



**TELECONFERENCE/VIRTUAL
PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
January 18, 2024**

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

9:00 A.M.

OPEN SESSION – CALL TO ORDER

- A. Approval of Agenda (1)**
- B. Approval of Minutes of December 7, 2023 (2)**
- C. Administrative Rule Matters – Discussion and Consideration (3-50)**
 - 1) Phar 8, Relating to Controlled Substances Requirements (4-12)
 - 2) Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing (13-50)
 - 3) Pending or Possible Rulemaking Projects
- D. Public Comments**

ADJOURNMENT

NEXT MEETING: FEBRUARY 29, 2023

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 virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at <https://dsps.wi.gov>. 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 hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, or reach the Meeting Staff by calling 608-267-7213.

**VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE
MEETING MINUTES
DECEMBER 7, 2023**

PRESENT: Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Brenda Taylor, Board Services Supervisor; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 9:01 a.m. A quorum was confirmed with four (4) members present.

ADOPTION OF AGENDA

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF OCTOBER 26, 2023

MOTION: Anthony Peterangelo moved, seconded by Susan Kleppin, to approve the Minutes of October 26, 2023, as published. Motion carried unanimously.


ADJOURNMENT

MOTION: Anthony Peterangelo moved, seconded by Susan Kleppin, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 10.55 a.m.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

| | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 1) Name and title of person submitting the request: Nilajah Hardin Administrative Rules Coordinator | | 2) Date when request submitted: 01/05/24 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: 01/18/24 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? Administrative Rule Matters – Discussion and Consideration 1. Phar 8, Relating to Controlled Substances Requirements 2. Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing 3. Pending or Possible Rulemaking Projects | |
| 7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session | 8) Is an appearance before the Board being scheduled? <i>(If yes, please complete Appearance Request for Non-DSPS Staff)</i> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | 9) Name of Case Advisor(s), if required: N/A | |
| 10) Describe the issue and action that should be addressed: Attachments: 1. Phar 8 Redlined Code Text 2. Phar 8 Emergency Rule Draft 3. Phar 1, 5, 6, 7, and 8 Redlined Code Text 4. Phar 1, 5, 6, 7, and 8 Final Rule Draft Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx | | | |
| 11) Authorization | | | |
|  Signature of person making this request | | 01/05/24 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. | | | |

Chapter Phar 8
REQUIREMENTS FOR CONTROLLED SUBSTANCES
(EFFECTIVE 09/01/22)

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>.

(4) EMERGENCY KITS IN LONG TERM CARE FACILITIES. Nothing in these rules shall prohibit long term care facilities from obtaining an emergency kit, from a DEA registered pharmacy, in compliance with federal law.

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) Pharmacists are to use professional judgement to contact prescribers for changes on controlled substances prescriptions as needed and in accordance with federal law and s. Phar 7.02 (5).

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. (1) Records shall be maintained as required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats.

(2) The managing pharmacist shall oversee quarterly 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) EXEMPTION. There shall be an exemption to the requirement for an identification card when the drug is lawfully delivered to the patient’s home, or any address requested by the patient, through mail, common carrier or delivery service. A valid signature is required upon delivery.

Phar 8.07 Partial Dispensing. Partial dispensing of controlled substances is allowed in accordance with federal law. ~~(1) A pharmacist may partially dispense a prescription containing a controlled substance listed in schedule III, IV and V.~~

~~(2) The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if one of the following conditions applies:~~

~~(a) If the pharmacist is unable to supply the full quantity called for in a written, electronic, or emergency oral prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written hard copy prescription order or written record of the electronic or emergency oral prescription order.~~

~~(b) If the patient requests partial dispensing.~~

~~(c) If the prescribing practitioner requests partial dispensing:~~

~~The remaining portion of any partially dispensed prescription under this section may be dispensed within 72 hours of the first partial dispensing. If the remaining portion is not dispensed within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.~~

~~(3) Prescription orders for schedule II controlled substances written for patients in long-term care facilities (LTCF) or for patients with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities to include individual dosage units. The prescribing practitioner may document a terminal illness by writing upon the face of the prescription order the phrase "terminal illness" or words of similar meaning. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescribing practitioner prior to partially dispensing the prescription. Documentation of a terminal illness, whether substantiated by the presence of an appropriate phrase written upon the face of the prescription order or through pharmacist contact with the prescribing practitioner, shall be placed within the individual medication profile record maintained under s. Phar 7.07. The pharmacist shall record on the prescription order whether the patient is "terminally ill" or an "LTCF patient." A prescription order that is partially dispensed and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been dispensed in violation of this section. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription order or on another appropriate record, uniformly maintained and readily retrievable, the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. Subsequent partial dispensing is not permitted under this section if the patient becomes deceased, or is no longer diagnosed as terminally ill, or no longer resides within an LTCF. The total quantity of a schedule II controlled substance dispensed by partial dispensing may not exceed the total quantity prescribed. Prescription orders for schedule II controlled substances for patients in an LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless terminated earlier by the discontinuance of medication.~~

~~(4) Information pertaining to current prescription orders for schedule II controlled substances for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:~~

~~(a) Display or printout of: the original prescription order designation; date of issue; identification of prescribing practitioner; identification of patient; name and address of the LTCF or name and address of the hospital or residence of the patient; identification of medication authorized, including dosage form, strength and quantity; listing of partial quantities that have been dispensed under each prescription order and the information required in sub. (3).~~

~~(b) Immediate (real time) updating of the prescription order record each time there is partial dispensing of the prescription.~~

~~(e) Retrieval of partially dispensed schedule II prescription information identical to that required by s. Phar 7.05 (2) for all prescription renewal information.~~

Phar 8.08 Controlled substances in emergency kits for long term care facilities. Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances:

- (1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.
- (2) The pharmaceutical services committee of the facility shall establish security safeguards for each emergency kit stored in the LTCF which shall include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.
- (3) A pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.
- (4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.
- (5) Noncompliance with this rule may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING EMERGENCY RULES

The statement of scope for this rule, SS 044-23, was approved by the Governor on June 22, 2023, published in Register 811A2 on July 10, 2023, and approved by the Pharmacy Examining Board on September 5, 2023. This emergency rule was approved by the Governor on (date).

ORDER

An order of the Pharmacy Examining Board to create Phar 8.03 (3), amend Phar 8.04, and repeal and recreate Phar 8.07, relating to controlled substances requirements.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

The Pharmacy Examining Board finds that an emergency exists and that this rule is necessary for the immediate preservation of the public peace, health, safety, or welfare. A statement of facts constituting the emergency is: Clearinghouse Rule 21-071 went into effect on October 1, 2022. This rule repealed and recreated all of Wisconsin Administrative Code Chapter Phar 8. Upon receiving feedback and completing an additional review, the Pharmacy Examining Board has determined that additional changes are needed to Phar 8 to address areas where requirements are no longer in effect or do not match federal regulations. Emergency rules are needed to ensure that these requirements can be updated to protect patient safety and allow effective regulation of the profession until permanent rules can be promulgated.

ANALYSIS

Statutes interpreted: ss. 450.09, 450.11, and 961.31, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (2), 450.02 (3) (a), (d), and (e), 961.31, Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats. states that “[t]he 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.”

Section 450.02 (2), Stats. provides that the board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

Section 450.02 (3) (a), Stats. provides that the board “may promulgate rules [r]elating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

Section 450.02 (3) (d), Stats. provides that the board “may promulgate rules [n]ecessary for the administration and enforcement of this chapter and ch. 961.”

Section 450.02 (3) (e), Stats. provides that the board “may promulgate rules [e]stablishing minimum standards for the practice of pharmacy.”

Section 961.31, Stats. provides that “[t]he pharmacy examining board may promulgate rules relating to the manufacture, distribution, and dispensing of controlled substances within this state.”

Related statute or rule: Wisconsin Administrative Code ch. Phar 7

Plain language analysis: This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. These revisions include the addition of language regarding changes to controlled substances prescriptions, amendments to remove language regarding suspicious controlled substances orders, and amendments to clarify that partial dispensing of controlled substances is allowed.

Summary of, and comparison with, existing or proposed federal regulation: The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

Comparison with rules in adjacent states:

Illinois: 225 Illinois Compiled Statutes 85 outlines Illinois’ Pharmacy Practice Act. These statutes are further described in the Illinois Administrative Code Title 68 Part 1330. Included in both are requirements for pharmacy standards and pharmacy operation [225 Illinois Compiled Statutes 85, Illinois Administrative Code Title 68 Chapter VII Subchapter b Part 1330 Sections 1330.600 to 1330.800]. Illinois law also requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA [Illinois Administrative Code Title 68 Chapter VII Subchapter b Part 1330 Sections 1330.710].

In the Illinois Controlled Substances Act, the rules require that inventory of controlled substances be done annually, with an exact count for Schedule II drugs and an approximation for Schedule III and IV. Illinois also requires that a record of all written prescription orders received and verbal prescriptions filled, compounded or dispensed for controlled substances be retained for at least 5 years [Illinois Administrative Code Title 77 Chapter XV Part 3100 Section 3100.360]. Illinois also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance in an emergency where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. There does not appear to be a requirement that the prescriber follow up with a written prescription [Illinois Administrative Code Title 77 Chapter XV Part 3100 Section 3100.400].

Iowa: The Iowa Pharmacy Board requires a pharmacy to maintain controlled substance records for at least 2 years and to segregate Schedule I and II drug records from other controlled substance records [657 Iowa Administrative Code Chapter 10 Section 10.36]. Iowa also requires that pharmacies keep a perpetual inventory of all Schedule II drugs on hand [657 Iowa Administrative Code Chapter 10 Section 10.18]. Iowa only requires a pharmacist to report theft or loss of controlled substances to the Pharmacy Board if there is reason to believe that the theft was committed by a pharmacy board licensee, otherwise it is sufficient to merely report to the DEA [657 Iowa Administrative Code Chapter 10 Section 10.21]. Iowa also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. The prescriber must then provide a written prescription within 7 days [657 Iowa Administrative Code Chapter 10 Section 10.26].

Michigan: Michigan requires theft or diversion of a controlled substance to be reported to the Michigan Department of Licensing and Regulatory Affairs within 15 days of completion of an investigation regarding a suspected theft or significant loss of a controlled substance, whether or not it is also reported to the DEA [Michigan Administrative Rules R 338.3141]. Inventory must be taken of all controlled substances at least annually and schedule II controlled substances must be stored separately [Michigan Administrative Rules R 338.3151]. Controlled substance records must be retained for at least 5 years. After two years from the date of dispensing, if the prescription is a hard copy and an electronic duplicate is made, the original hard copy may be destroyed [Michigan Administrative Rules R 338.3153]. Michigan also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. The prescriber must then provide a written prescription within 7 days [Michigan Administrative Rules R 338.3164 and 338.3165].

Minnesota: Minnesota requires a perpetual inventory of Schedule II substances which must be reconciled monthly [Minnesota Administrative Code Section 6800.4600]. Pharmacists, drug wholesalers, drug manufacturers, and controlled substance researchers must report loss or theft of controlled substances to the DEA immediately [Minnesota Administrative Code Section 6800.4800]. All prescription information must be maintained for at least 2 years [Minnesota Administrative Code Section 6800.3100].

Summary of factual data and analytical methodologies: The Pharmacy Examining Board completed a comprehensive review of ch. Phar 8, Requirements for Controlled Substances, in order to identify and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices. The board also evaluated ch. Phar 8 for ways to reduce the regulatory impact on pharmacies without negatively impacting public safety.

Fiscal Estimate: The Fiscal Estimate will be attached upon completion.

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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

Agency contact person:

Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 8.03 (3) is created to read:

Phar 8.03 (3) Pharmacists are to use professional judgement to contact prescribers for changes to controlled substances prescriptions as needed and in accordance with federal law and s. Phar 7.02 (5).

SECTION 2. Phar 8.04 is amended to read:

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 of the information required to be provided in the notification to the drug enforcement administration.

SECTION 3. Phar 8.07 is repealed and recreated to read:

Phar 8.07 Partial Dispensing. Partial dispensing of controlled substances is allowed in accordance with federal law.

SECTION 4. This emergency rule shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)

Dated _____ Agency _____
Chairperson
Pharmacy Examining Board

Chapter Phar 1 AUTHORITY AND DEFINITIONS

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

Phar 1.01 Authority. Rules in chs. Phar 1 to ~~4719~~ are adopted under authority of ss. 15.08 (5) (b), 227.11 (2), Stats, and ch. 450, Stats.

Commented [HND1]: Changes from Pharm Tech Rule

Phar 1.02 Definitions. As used in chs. Phar 1 to ~~4719~~:

Commented [HND2]: Changes from Pharm Tech Rule

(1) "Board" means the pharmacy examining board.

Note: The board office is located at ~~1400 East Washington Avenue~~ 4822 Madison Yards Way, Madison, Wisconsin ~~53702 53705~~.

Commented [HND3]: Changes from Pharm Tech Rule

(2) "Community pharmacy" means practice in a licensed pharmacy providing pharmaceutical services primarily on an outpatient basis.

(3) "DEA" means the drug enforcement administration.

~~(3m) "Direct supervision" means immediate, whether in person or real time video conferencing where all parties can communicate by simultaneous means of audio, video, or data communications, availability to continually coordinate, direct and inspect in real time the practice of another.~~

(4) "Institutional pharmacy" means practice in a licensed pharmacy providing pharmaceutical services primarily on an inpatient basis.

(4m) "Long term care facility" has the meaning given in 21 CFR 1300.01.

(5) "LTCF" means a long term care facility.

(6) "Managing pharmacist" means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

(6m) "NABP" means the National Association of Boards of Pharmacy.

(7) "NAPLEX" means the North American Pharmacy Licensing Examination.

(8) "Pharmacist" has the meaning given in s. 450.01 (15), Stats.

~~(9) "Pharmacist in charge" means a pharmacist who is physically present in the licensed facility and responsible for the routine operation of a pharmacy for the period of time specified by the managing pharmacist.~~

(10) "Pharmacy" means any place of practice licensed by the board under s. 450.06 or 450.065, Stats., unless otherwise provided for in s. 450.065, Stats.

~~(10m) "Pharmacy graduate" means a graduate of a school of pharmacy approved by the pharmacy examining board, who has submitted an application for pharmacist licensure or a qualified applicant awaiting examination for licensure approved by the board.~~

Commented [NH4]: Clearinghouse Comment #5b

(11) "Pharmacy owner" means a person or entity to whom a pharmacy license is issued.

~~(11m) "Pharmacy technician" means a person registered by the board under s. 450.068, Stats.~~

Commented [HND5]: Changes from Pharm Tech Rule

(12) "Practice of pharmacy" has the meaning under s. 450.01 (16), Stats.

(13) "PRN" means renew as needed.

(14) "Professional service area" means the area of a pharmacy in which prescriptions are compounded or dispensed, hypodermic needles, syringes, poisons and schedule V controlled substances as listed in s. 961.22, Stats., and ch. CSB 2 are available, or where patients are consulted.

Phar 1, 5, 6, 7, and 8: Remote Dispensing

Redlined Rule Text

(14m) "Remote dispensing site" has the meaning given in s. 450.01 (21c), Stats.

(15) "Terminal illness" means an incurable condition caused by injury or illness that reasonable medical judgment finds would cause death.

DRAFT

Chapter Phar 5

LICENSE RENEWAL

Phar 5.01 Requirements. (1) Pharmacists, pharmacies, manufacturers, distributors, and home medical oxygen providers licensed under ch. 450, Stats., and otherwise qualified for renewal, may continue to be licensed biennially by applying for renewal and paying the fee as determined by the department under s. 440.03 (9) (a), Stats.

(2) No one without a current renewal certificate may engage in the practice of pharmacy, nor hold himself or herself out to be a pharmacist nor use the title or letters “Pharmacist” or “Registered Pharmacist” or “R.Ph.”

(3) No pharmacy, manufacturer, distributor, or home medical oxygen provider may operate without a current license.

~~(3)~~(4) For the purposes of this chapter and pursuant to s. 450.09 (1) (a), stats., pharmacies shall include remote dispensing sites.

Phar 5.02 Change of name or address. (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.

Phar 5.04 Renewal prohibited. Any person whose license is currently suspended or revoked may not renew his or her license.

Phar 5.05 Renewal. (1) GENERAL. A person with an expired license may not reapply for a license using the initial application process.

(2) RENEWAL WITHIN 5 YEARS. A person renewing the license within 5 years shall do all of the following:

(a) Pay the renewal fee as determined by the department under s. 440.03 (9) (a), Stats., and any applicable late renewal fee.

(b) Certify the completion of 30 hours of continuing education during the last biennium.

(3) RENEWAL AFTER EXPIRATION DATE. Notwithstanding sub. (2), if a pharmacist fails to obtain renewal on or before the applicable renewal date, the board may suspend the pharmacist’s license and may require the pharmacist to pass an examination to the satisfaction of the board to restore that license.

(4) RENEWAL AFTER 5 YEARS. this subsection does not apply to license holders who have unmet disciplinary requirements. A person renewing the license after 5 years shall do all of the following:

(a) Pay the renewal fee as determined by the department under s. 440.03 (9) (a), Stats., and the renewal late fee.

(b) Evidence of having passed the multi-state pharmacy jurisprudence examination with Wisconsin designated as the primary state.

(c) If the person renewing the license does not have 2000 hours of practice as a pharmacist within last 24 months of submitting the application for renewal, the person shall meet one of the following requirements:

1. If the license has been expired for at least 5 years but not more than 10 years, the person shall submit evidence of all of the following:

a. Completion of 160 hours of internship for each year the pharmacist license was expired,

Commented [HN-D6]: Changes from CR 21-074 (Phar 5, 6, 7, 11, and 12 Clean Up Rule)

not to exceed 1000 hours.

b. Completion of 15 hours of continuing education for each year the pharmacist license was expired or within the last two years passing the NAPLEX.

2. If the license has been expired for more than 10 years, the person shall submit evidence of all of the following:

- a. Completion of 1000 hours of internship.
- b. Passing the NAPLEX.

Phar 5.06 Reinstatement. A licensee who has unmet disciplinary requirements and failed to renew the license within 5 years or whose license has been surrendered or revoked may apply to have the license reinstated in accordance with all of the following:

- (1) Evidence of completion of the requirements in s. [Phar 5.05 \(4\)](#) if the license has not been active within 5 years.
- (2) Evidence of completion of the disciplinary requirements, if applicable.
- (3) Evidence of rehabilitation or change in circumstances warranting reinstatement.

Phar 5.07 Pharmacy Technicians. (1) All requirements for renewal and reinstatement of a pharmacy technician registration are specified in chapter Phar 19.

(2) No pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes is eligible to be registered as a pharmacy technician.

Commented [HND7]: Changes from Pharm Tech Rule

Chapter Phar 6
PHARMACY LICENSES AND EQUIPMENT

Note: Chapter Phar 6 as it existed on January 31, 1983, was repealed and a new chapter Phar 6 was created effective February 1, 1983.

Phar 6.01 Licenses; application. Requirements and procedures for applying for a pharmacy license are specified in s. 450.06, Stats. Approved application forms are available from the board. Appointments for the required pharmacy inspection may be made by contacting the board office. A license application and fee shall be on file with the board at least 30 days prior to the granting of the pharmacy license. A pharmacy may not operate unless a pharmacy license has been granted. Board action shall be taken within 60 business days of receipt of a completed pharmacy application, as provided in s. SPS 4.03.

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

Phar 6.02 Licenses; change of location or ownership. (1) A pharmacy license authorizes a pharmacy to operate only at the location designated on the license. Licenses may not be transferred to another location.

(1m) A hospital which has a pharmacy area providing outpatient pharmacy services which is physically separate from, and not contiguous to the area from which inpatient pharmacy services are provided, shall have a pharmacy license for the outpatient pharmacy in addition to a license for the inpatient pharmacy.

(2) Any change in pharmacy ownership shall be reported to the board office and the pharmacy license of the former owner returned. A pharmacy license shall be granted to the new pharmacy owner before the pharmacy may operate.

Phar 6.025 Licenses; remote dispensing sites. A pharmacy may be subject to rules in this section that apply only to remote dispensing sites if a pharmacist remotely supervises the location for any period of time. The following conditions shall also be met:

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(1) The licensee provides notice to the Board of all of the information outlined in s. 450.06, Stats.

(2) The site meets all of the requirements listed in s. Phar 7.43.

(3) The site is any of the location types listed under s. 450.09 (2) (b) 1., Stats.

(4) A managing pharmacist shall report to the board if they are responsible for 5 or more remote dispensing sites. A managing pharmacist may not be responsible for more than 10 remote dispensing sites at any given time without approval from the board.

Phar 6.03 Changes in managing pharmacist. The pharmacy owner shall report to the board any change of managing pharmacist within 5 days following the change.

Phar 6.04 Floor design. (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~~

Commented [HN-D9]: Changes from CR 21-074 (Phar 5, 6, 7, 11, and 12 Clean Up Rule)

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 area plan varies from the requirement.

~~(2) PRESCRIPTION COUNTER SPACE. A pharmacy shall have a prescription counter with a free working surface of 18 or more inches in width and at least 12 square feet in area. This free working surface must be used only for the compounding and dispensing of prescriptions.~~

~~(3) PROFESSIONAL SERVICE AREA REQUIREMENTS WHERE PHARMACIST IS ABSENT REQUIREMENTS WHEN THE PROFESSIONAL SERVICE AREA IS CLOSED. (a) 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)1. A ~~secured~~ 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.~~

~~2. The barrier is locked in the absence of the pharmacist.~~

~~3. A patient's telephone request to renew a certain prescription may be accepted, but a telephone message from a practitioner giving a new prescription order or renewal authority may not be accepted.~~

~~(bm)5. 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.~~

~~(cm)6. 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.~~

~~7. The pharmacy examining board office is notified of the hours during which the establishment is operated as a sundry outlet.~~

~~(b) The managing pharmacist is responsible for compliance with all professional service area security requirements.~~

~~(c) Where no pharmacist is present in the professional service area a pharmacy is not required to convert to a non-prescription or sundry outlet if the following requirements are met:~~

~~1. The pharmacist is absent for a time period of one-half hour or less.~~

~~2. The pharmacist must be accessible for communication with the remaining pharmacy staff by phone, pager or other device.~~

~~3. The pharmacy must indicate that the pharmacist is not available in the professional service area and indicate the period of absence and the time of the pharmacist's return.~~

~~4. Pharmacy technicians may only perform duties allowed by s. Phar 7.015 (2).~~

~~(4) PROFESSIONAL SERVICE AREA REMODELING. Any modifications of the approved floor plan shall be submitted to and approved by the board or its designee. Board action must be taken within 60 days.~~

Phar 6.05 Sanitation. The professional service area of a pharmacy shall have a sink convenient and suitable for cleaning pharmaceutical equipment and supplied with hot and cold running water. Detergent and a waste disposal container also shall be provided in the professional service area.

Phar 6.06 Laws and other references. The professional service area of a pharmacy shall have equipment of appropriate design and size for the intended pharmacy practice and shall have all of the following:

(1j) The latest available or immediately accessible version of federal and state pharmacy laws consisting of:

- (a) Drug enforcement administration regulations, 21 CFR 1300 to end.
- (b) Wisconsin pharmacy laws, ch. 450, Stats.
- (c) Wisconsin controlled substances act, ch. 961, Stats.
- (d) Wisconsin administrative code, rules of the pharmacy examining board.

(2k) References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(3L) The telephone number of a poison center. This number shall be conspicuously posted in the prescription department.

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

(3) All controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory of non-controlled substances in a manner that obstructs theft or diversion.

Phar 6.075 Temperature; Humidity. (1) DEFINITIONS. In this section:

- (a) "Business day" means a day the pharmacy is open for business.
- (c) "Freezer" means a place in which the temperature is maintained between -13 and +14 degrees Fahrenheit.
- (d) "Mean kinetic temperature" means the calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.
- (e) "Refrigerator" means a place in which the temperature is maintained between 36 and 46 degrees Fahrenheit.

(2) STORAGE. Drugs shall be stored at appropriate conditions, including temperature and humidity, to prevent drug adulteration.

(3) RECORDING DEVICES. Manual, electromechanical or electronic temperature and humidity recording devices shall be placed within the storage space to accurately determine the area's temperature and humidity.

(4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy and the humidity of the pharmacy shall be continuously monitored. At least once each business day, the minimum and maximum temperature and humidity since the previous documented reading shall be recorded.

(5) RECORDS. Temperature and humidity records shall be maintained for a minimum of 5 years.

(6) DISPENSING OF SAFE DRUGS. The pharmacist shall use professional judgment, including consideration of the mean kinetic temperature, to determine whether a drug is safe to be dispensed.

Phar 6.08 **Security.** A pharmacy shall have a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the board.

Chapter Phar 7
PHARMACY PRACTICE

Note: Chapter Phar 7 as it existed on December 31, 2020, was repealed and a new chapter Phar 7 was created, effective January 1, 2021.

Subchapter I — General

Phar 7.01 Definitions. In this chapter:

(1) “Control number” means a unique number used to identify a repackaged drug or drug product in reference to a record that contains NDC, expiration date, and lot number.

(2) “Managing pharmacist” means a pharmacist who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, and who is personally in full and actual charge of the pharmacy and personnel.

(3) “NDC” means national drug code.

(4) “Repackaging for stock” means transferring a non-sterile drug product from the stock container in which it was distributed by the original manufacturer and placing it into a different stock container as a source for subsequent prescription dispensing without further manipulation of the drug.

(5) “Standing order” means an order transmitted electronically or in writing by a practitioner for a drug or device that does not identify a particular patient at the time it is issued for the purpose of drug or device dispensing or administration to individuals that meet criteria of the order.

Phar 7.02 Prescription. (1) REQUIREMENTS. A prescription drug order shall include all of the following:

(a) Date of issue.

(b) First and last name and address of the practitioner.

(c) Prescriptions ordered by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name and address of the practitioner.

(d) Name, strength, and quantity of the drug product or device.

(e) Directions for use of the drug product or device.

(f) Refills, if any.

(g) Symptom or purpose for which the drug is being prescribed if the patient indicates in writing to the practitioner that the patient wants the symptom or purpose for the prescription to be disclosed on the label.

(h) Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2) (a) 1., 448.035 (2) and 448.037 (2) (a) 1., Stats.

(i) If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.

(j) If prescription is issued under s. 255.07 (2), Stats., the name and address of the authorized entity or individual.

(k) Practitioner’s written signature, or electronic or digital signature.

(2) STANDING ORDER. (a) A prescription pursuant to a standing order shall include all of the following:

1. Date of issue.

2. First and last name and address of the practitioner.

3. Prescriptions ordered by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name and address of the practitioner.

4. Name, strength, and quantity of the drug product or device.

5. Directions for use of the drug product or device.

6. Refills, if any.

7. Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2) (a)1., 448.035 (2) and 448.037 (2) (a) 1., Stats.

8. If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.

9. If prescription is issued under s. 255.07 (2), Stats., the name and address of the authorized entity or individual.

10. An indication that the prescription is pursuant to a standing order.

(b) A copy of the standing order shall be retained under s. Phar 7.11 (1).

(3) ELECTRONIC PRESCRIPTION. (a) Except as provided in s. 89.068 (1) (c) 4., Stats., and as otherwise prohibited by law, a practitioner may transmit a prescription order electronically only if the patient approves the transmission and the prescription order is transmitted to a pharmacy designated by the patient. Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

(b) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided electronically with a prescription order.

(4) VERBAL PRESCRIPTION. Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. The verbal prescription shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

(5) ALTERATIONS. Any alterations that modify the original intent of a prescription shall be documented including the identification of the pharmacist responsible for the alteration and the practitioner or practitioner's delegate who authorized the alteration.

Phar 7.03 Drug utilization review. **(1)** A pharmacist shall complete a drug utilization review by reviewing the patient record prior to dispensing each prescription drug order for all of the following:

(a) Known allergies.

(b) Rational therapy.

(c) Contraindications.

(d) Reasonable dose, duration of use, and route of administration, considering the age and other patient factors.

(e) Reasonable directions for use.

(f) Potential or actual adverse drug reactions.

(g) Drug interactions with food, beverages, other drugs or medical conditions.

(h) Therapeutic duplication.

(i) Reasonable utilization and optimum therapeutic outcomes.

(j) Potential abuse or misuse.

(2) Upon recognizing a concern with any of the items in sub. (1) (a) to (j), the pharmacist shall take steps to mitigate or resolve the problem.

Phar 7.04 Transferring prescription order information. (1) GENERAL REQUIREMENTS. (a) A transfer of prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing of non-controlled substances and refills of controlled substances, may occur if all of the following conditions are satisfied:

1. The transfer of prescription order information is communicated in one of the following ways:
 - a. Verbal communication between two pharmacists.
 - b. Electronically or by facsimile machine between the two pharmacies.
2. A transfer of prescription information verbally shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

(b) A pharmacist shall transfer a prescription upon patient request pursuant to this section.

(2) NON-CONTROLLED SUBSTANCES. The transfer of prescription order information for non-controlled substances for the purposes of original or refill dispensing is permissible pursuant to the following requirements:

(a) The prescription record of the transferred prescription shall include the following information:

1. The word "VOID" is written on the face of the invalidated prescription order or recorded in a similar manner to "VOID" on a prescription order in a computer system meeting the requirements of s. Phar 7.11 (2) (a).

2. The name and address of the pharmacy to which it was transferred, the date and the first and last name of the pharmacist transferring the information are recorded on the invalidated prescription order or in a computer system meeting the requirements s. Phar 7.11 (2) (a).

(b) Unless a computer system meeting the requirements in sub. (4) is used, the transferred prescription order information shall include the following:

1. The word "TRANSFER" on the face of the transferred prescription order or recorded in a similar manner in a computer system.

2. The first and last name and address of the patient, the first and last name and address of the prescribing practitioner.

3. Name, strength, form and quantity of the drug product or device prescribed and the directions for use.

4. The date of issuance of the original prescription order, the original prescription order number, the original number of refills authorized on the original prescription order and the date of original dispensing if the prescription order has previously been dispensed.

5. The number of valid refills or total quantity remaining and the date of the last refill.

6. The pharmacy's name and address from which the prescription order information was transferred.

7. The first and last name of the pharmacist transferring and receiving the prescription order information.

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

(a) The transfer of prescription order information is permissible only on a one-time basis. Pharmacies electronically sharing a computer system meeting the requirements of sub. (4) may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(b) Notwithstanding sub. (1) (a), the transfer shall be communicated directly between 2 licensed pharmacists.

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(c) The transferring pharmacist shall do all of the following:

1. Write the word "VOID" on the face of the invalidated prescription. For electronic prescriptions, information that the prescription has been transferred shall be added to the prescription record.

2. Record on the reverse of the invalidated prescription or in the electronic prescription record all of the following:

- a. Name, address and DEA registration number of the pharmacy to which it was transferred.
- b. The first and last name of the pharmacist receiving the prescription order.
3. Record the date of the transfer.
4. Record the first and last name of the pharmacist transferring the information.

(d) For paper prescriptions and prescriptions received verbally and reduced to writing by the pharmacist, the pharmacist receiving the transferred prescription information shall write the word "TRANSFER" on the face of the transferred prescription and reduce to writing all information required to be on the prescription, including all of the following:

1. Date of issuance of the original prescription order.
2. Original number of refills authorized on the original prescription order.
3. Date of original dispensing.
4. Number of valid refills remaining and the dates and locations of previous refills.
5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
6. First and last name of the pharmacist making the transfer.
7. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

(e) For electronic prescriptions being transferred electronically, the transferring pharmacist shall provide the receiving pharmacist with the original electronic prescription data and all of the following:

1. The date of the original dispensing.
2. The number of refills remaining and the dates and locations of previous refills.
3. The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.
4. The first and last name of the pharmacist transferring the prescription.
5. The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.

(4) USE OF SHARED COMPUTER SYSTEM. A shared computer system used for transferring prescription order information shall, in addition to meeting the requirements of s. Phar 7.11 (2) (a), contain a shared real time electronic file database with a complete record of all prescriptions filled and dispensed.

Phar 7.05 Label requirements. (1) This section does not apply to institutional pharmacies as defined in s. Phar 7.50 (3).

(2) All prescribed drugs or devices shall have a label attached to the container disclosing all of the following:

(a) Identification of the patient by one of the following:

1. Except as provided in subds. 2. to 5., the first and last name of the patient.

2. For an antimicrobial drug dispensed under s. 450.11 (1g), Stats., the first and last name of the patient, if known, or the words, “expedited partner therapy” or the letters “EPT”.

3. For an opioid antagonist when delivered under s. 450.11 (1i), Stats., the first and last name of the person to whom the opioid antagonist is delivered.

4. For an epinephrine auto-injector prescribed under s. 118.2925 (3) or 255.07 (2), Stats., the name of the school, authorized entity, or other person specified under s. 255.07 (3), Stats.

5. If the patient is an animal, the last name of the owner, name of the animal and animal species.

(b) Symptom or purpose for which the drug is being prescribed if the prescription order specifies the symptom or purpose.

(c) Name and strength of the prescribed drug product or device dispensed, unless the prescribing practitioner requests omission of the name and strength of the drug product or device.

(d) The date for which the medication shall not be used after.

(e) Pharmacy name, address and telephone number.

(f) Prescriber name.

(g) Date the prescription was filled.

(h) Prescription order number.

(i) Quantity.

(j) Number of refills or quantity remaining.

(k) Directions for use of the prescribed drug or device as contained in the prescription order.

(3) A label for prescribed drugs or devices may include the following:

(a) Symptom or purpose for which the drug is being prescribed if requested by the patient.

(b) Both the generic name of the drug product equivalent and the brand name specified in the prescription order may be listed on the label if the brand name is listed on the prescription and the drug product equivalent is dispensed, unless the prescribing practitioner requests that the brand name be omitted from the label.

(c) Written or graphic product descriptions.

(d) Any cautions or other provisions.

(4) Subsection (2) does not apply to complimentary samples of drug products or devices dispensed in original packaging by a practitioner to his or her patients.

Phar 7.06 Repackaging for stock. A pharmacy repackaging for stock any non-sterile drugs shall do all of the following:

(1) The repackaging for stock process is conducted under conditions that ensure the integrity of the drug.

(2) Products repackaged for stock shall include a beyond use date that ensures the integrity of the drug.

(3) The repackaged container shall be selected to mitigate adulteration from light, temperature and humidity.

(4) The repackaged for stock drugs are labeled physically or electronically with all the following components:

(a) Drug name, strength, form and beyond use date.

(b) One of the following identifiers:

1. Pharmacy control number.

2. NDC number and manufacturer lot number.

3. Name of manufacturer or distributor of the drug product, and the manufacturer lot number.

- (5) Records of all repackaging for stock operations are maintained and include all the following:
- (a) Name, strength, form, quantity per container, and quantity of containers.
 - (b) NDC number or the name of the manufacturer or distributor of the drug product.
 - (c) Manufacturer lot number.
 - (d) Original container's expiration date and the beyond-use date for the new containers.
 - (e) First and last name of the pharmacist or delegate that repackaged the drug and the first and last name of the pharmacist that verified the accuracy of the repackaging.
 - (f) Date of repackaging.
 - (g) Any pharmacy control numbers.

Phar 7.07 Final check. (1) A final check of accuracy and correctness is required for any prescription drug product or device dispensed and shall include all of the following:

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- (a) Verifying label is correct and meets labeling requirements.
 - (b) Verifying the drug product or device is correct.
 - (c) Completion of the drug utilization review.
- (2) For all prescription drug ~~product~~products or ~~device dispensing~~devices dispensed by a pharmacist, the prescription record shall identify the pharmacist responsible for each part of the final check. If sub. (1) (a) or (b) is completed by ~~delegate check~~ delegate-a pharmacy product verification technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the ~~delegate~~ pharmacy product verification technician performing the check.

Phar 7.08 Patient consultation. (1) A pharmacist shall provide the patient or patient's agent consultation to optimize proper use of a prescription drug or device, that meets any of the following:

- (a) Has not been dispensed previously to the patient.
 - (b) Is a change in therapy.
 - (c) Upon request of a patient or patient's agent.
 - (d) Whenever deemed necessary based upon the professional judgement of the dispensing pharmacist.
- (2) Notwithstanding sub. (1), consultation is not required when one of the following occurs:
- (a) A drug or device will be administered, by ingestion, inhalation, injection, or any other route, by or in the presence of one of the following:
 1. An individual with a scope of practice that includes the administration of a drug or device.
 2. A delegate of an individual with authority to delegate the administration of a drug or device.
 - (b) A patient or patient's agent refuses consultation.
- (3) Consultation shall contain any of the following information that, in the pharmacist's professional judgment, serves the best interest of the patient:
- (a) Name and description of the drug.
 - (b) Form, dose, route of administration and duration for drug therapy.
 - (c) Intended use of the drug and expected action.
 - (d) Directions and precautions for the preparation, administration, and use.
 - (e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
 - (f) Techniques for self-monitoring drug therapy.

- (g) Action to be taken in the event of a missed dose.
- (h) Proper storage and appropriate disposal method of unwanted or unused medication.
- (4) The consultation required in this section shall be communicated verbally when in the pharmacist's professional judgment it is in the best interest of the patient.
- (5) A pharmacist shall provide the patient or patient's agent, for all consultations required under sub. (1), a written patient drug education monograph.
- (6) The consultation required in this section may occur before or after delivery of the prescription to the patient or patient's agent.
- (7) Every licensed pharmacy dispensing directly to a patient or patient's agent inside the pharmacy shall conspicuously post a board approved sign stating a patient's rights to pharmacist consultation and information on how to file a complaint to the board.
- (8) A prescription drug or device delivered by common carrier, mail, or delivery service or picked up at a drive through window shall include a copy of information which is board-approved stating a patient's rights to pharmacist consultation and information on how to file a complaint to the board.

Phar 7.085 Delivery by common carrier or delivery services. Utilization of common carrier or delivery services to deliver a prescription to a location of the patient's choice from the pharmacy which fills the prescription to the patient or patient's agent shall ensure all of the following:

- (1) The delivery method is appropriate to prevent drug adulteration.
- (2) The patient or patient's agent is provided a method by which the patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the prescription drug product or device, including all of the following:
 - (a) Timeliness of delivery.
 - (b) Condition of the prescription drug upon delivery.
 - (c) Failure to receive the proper prescription drug product or device.
- (3) Any prescription drug product or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, a pharmacist at the dispensing pharmacy shall take steps to mitigate patient harm.

Phar 7.09 Procurement, recall and out-of-date drugs and devices. (1) A pharmacy shall have a system for identifying a drug or device subjected to a product recall and for taking appropriate actions as required by the recall notice.

(2) A drug or device may not be dispensed after the drug's or device's expiration date or beyond use date. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed.

Phar 7.10 Return or exchange of health items. (1) In this section:

- (a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug product, or items of personal hygiene.
- (b) "Original container" means the container in which a health item was sold, distributed, or dispensed.

(c) “Tamper-evident package” means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.

(2) No health item after taken from a pharmacy where sold, distributed or dispensed, may be returned to that pharmacy, except for any of the following:

(a) Where the health item was dispensed in error, was defective, adulterated, or misbranded.

(b) When in the professional judgment of the pharmacist substantial harm could result to the public or patient if it were to remain in the possession of the patient, patient’s family or agent, or other person.

(c) A health item that is prepackaged for consumer use without a prescription when returned in compliance with all applicable state and federal laws.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

(3) A health item returned to a pharmacy pursuant to sub. (2) (a) and (b), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. A returned health item shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

(4) It is not a return of a health care item if a patient or agent of a patient delivers a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device is for the same patient’s use.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

(5) It is not a return of a health care item if a patient or agent of a patient delivers a previously dispensed drug or device to a pharmacy for the purpose of destruction at the pharmacy or other disposal by an authorized person or entity.

(6) This section does not prohibit participation in a drug repository program in accordance with ch. DHS 148.

Phar 7.11 Pharmacy records. (1) GENERAL. Pharmacy records shall be maintained for a minimum period of 5 years unless otherwise specified in state or federal law.

(2) **PRESCRIPTION RECORDS.** (a) A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of prescription order information for the purposes of original or refill dispensing if the system is:

1. Capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining.

2. Equipped with an auxiliary procedure which, during periods of down-time, shall be used for documentation of prescription dispensing. The auxiliary procedure shall ensure that prescription refills are authorized by the original prescription order, that the maximum number of prescription refills has not been exceeded and that all of the appropriate data are retained for on-line entry as soon as the computer system is again available for use.

(b) A record of all prescriptions dispensed shall be maintained for a minimum period of 5 years after the date of the last refill.

(c) All systems used for maintaining a record of any prescription dispensing shall contain all items required in the medical profile record system.

(d) A paper prescription for non-controlled substances may be scanned and stored electronically in the computer system under par. (a). For purposes of this chapter, the prescription becomes an electronic prescription.

(3) **MEDICATION PROFILE RECORD SYSTEM.** (a) An individual medication profile record system shall be maintained in all pharmacies for humans and non-humans for whom prescriptions, original or refill, are dispensed. The system shall be capable of permitting the retrieval of information.

(b) The following minimum information shall be retrievable:

1. Patient's first and last name, or if not human, name of pet, species and last name of owner.
2. Address of the patient.
3. Birth date of the patient or, if not human, birth date of the owner.
4. Name of the drug product or device dispensed.
5. Strength of the drug product or device dispensed.
6. Form of the drug product or device dispensed.
7. Quantity of the drug product or device prescribed, dispensed and remaining.
8. Number of refills prescribed.
9. Directions for use.
10. Prescription order number.
11. Original date of issue.
12. Dates of dispensing.
13. Prescriber's first and last name.

(c) The pharmacist shall be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy as communicated by the patient or agent of the patient. If none, this should be indicated.

(d) Medication profile records shall be maintained for a minimum period of 5 years following the date of the last dispensing.

Phar 7.12 Delegation by a physician. The pharmacist shall document the delegation by a physician under s. 450.033, Stats. The delegated act may not be started prior to the documentation. The documentation shall be maintained for a minimum of 5 years after the last delegated act under that delegation.

Phar 7.13 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), Stats., 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 5 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.

Phar 7.14 ~~Delegate check delegate Pharmacy Product Verification Technician-check-Pharmacy Technician.~~ (1) DEFINITIONS. In this section:

(a) "~~Delegate Pharmacy Product Verification Technician~~" means a ~~person~~ registered pharmacy technician to whom the pharmacist has delegated the task of product verification.

(b) "~~Delegate check delegate Pharmacy Product Verification Technician-check-Pharmacy Technician~~" means the process in which ~~one delegate pharmacy product verification technician~~ conducts the task of product verification of technical dispensing functions completed by ~~an unlicensed individual~~ a pharmacy technician. A ~~delegate pharmacy product verification technician~~ may not conduct product verification as part of the final check of their own product preparation.

(c) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, as part of the final check and ensure the product has not reached its expiration or beyond use date.

(d) "Supervising pharmacist" means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a ~~delegate pharmacy product verification technician~~ and ensuring for direct supervision of the ~~delegate pharmacy product verification technician~~.

(2) ~~DELEGATE PHARMACY PRODUCT VERIFICATION TECHNICIAN~~ QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a ~~delegate pharmacy technician~~ who meets all of the following:

~~(a) Is at least 18 years old.~~

Commented [HND12]: Changes from Pharm Tech rule

(b) Completed an accredited pharmacy technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(c) Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:

1. Elements of correct product including all of the following:

- a. Drug name.
- b. Strength.
- c. Formulation.
- d. Expiration date.
- e. Beyond use date.

2. Common dispensing medication errors and concepts including all of the following:

- a. Wrong medication.
- b. Wrong strength.
- c. Wrong formulation.
- d. Extra or insufficient quantity.
- e. Omitted medications if utilizing unit dose or compliance packaging.
- f. Expired medication.
- g. Look-alike or sound-alike errors.
- h. High-alert medications.

3. Eligible medications/products for delegate-check-delegateproduct verification by a technician.

4. Organizational policies and procedures on reporting of medication errors.

5. Overview of the medication use process including all of the following:

- a. Procurement.
- b. Ordering.
- c. Dispensing.
- d. Administration.
- e. Monitoring.

6. A practical training designed to assess the competency of the delegatepharmacy technician prior to starting the validation process. The practical training shall include simulation of at least 2 occurrences of each of the following:

- a. Wrong drug.
- b. Wrong strength.
- c. Wrong formulation.
- d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

1. The delegatepharmacy technician being validated shall make a product verification on the work of a pharmacist or unlicensed personanother pharmacy technician for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the delegatepharmacy technician during the validation process.

(e) Notwithstanding pars. ~~(a)(b)~~ to (d), a-delegatean individual who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the

~~delegation~~pharmacy product verification technician qualifications unless the ~~delegate~~individual fails to meet the quality assurance standards under sub. (4).

(3) ELIGIBLE PRODUCT. (a) *Institutional pharmacies.* The ~~delegate~~pharmacy product verification technician may do the product verification in an institutional pharmacy if all of the following requirements are met:

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.

2. A drug utilization review performed by a pharmacist prior to dispensing.

3. The drug product will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The ~~delegate~~pharmacy product verification technician may do the product verification in a community pharmacy if all of the following requirements are met:

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.

2. A drug utilization review performed by a pharmacist prior to dispensing.

3. A non-pharmacist shall be able to check the accuracy of the medication by one of the following:

a. The drug product or device is in the original packaging from a manufacturer.

b. The drug product or device includes a description of the drug product or device on the prescription label.

c. The pharmacist shows the patient or patient's agent the drug product or device and provides a monograph that includes a description of the drug product or device.

(4) QUALITY ASSURANCE. (a) A minimum of 5% of each ~~delegate's product~~ pharmacy product verification technicians's verifications shall be audited by a licensed pharmacist. The accuracy of each ~~delegate~~ pharmacy product verification technician shall be tracked individually.

(b) A record of each ~~delegate check~~ pharmacy product verification technician-check-pharmacy technician audit shall include all of the following:

1. Name of the pharmacy product verification ~~delegat~~technician.

2. Total number of product verifications performed.

3. Number of product verifications audited by the pharmacist.

4. Percentage of product verifications audited by pharmacist.

5. Percentage of accuracy.

6. Number of product verification errors identified.

7. Type of error under sub. (2) (c) 2. a. to c. and e.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each ~~delegate's~~ pharmacy product verification technician's previous 12 months accuracy and correctness of ~~delegate check~~ pharmacy product verifications including a review of the quality assurance log.

(d) A ~~delegate~~ pharmacy product verification technician shall be revalidated if the ~~delegate~~ individual fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed ~~delegate check~~ pharmacy product verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the ~~delegate-check-delegate~~ pharmacy product verification by technicians which shall be made available to the board upon request.

(6) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each ~~delegate~~ pharmacy product verification technician that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising ~~delegate-check-delegate~~ pharmacist, indicating the name of the supervising ~~delegate-check-delegate~~ pharmacist, and the dates the supervision responsibilities begin and end.

3. Quality assurance audits and quarterly assessments.

(b) Records shall be made available to the board upon request.

Subchapter II — Central Shared Services

Phar 7.30 Definitions. In this subchapter:

(1) “Central shared services pharmacy” means a pharmacy licensed in this state acting as an agent of an originating pharmacy.

(2) “Labeling pharmacy” means the central shared services pharmacy or originating pharmacy which is responsible for product verification under s. Phar 7.07 (1) (a) and (b).

(3) “Originating pharmacy” means a pharmacy licensed in this state that uses a central shared services pharmacy.

Phar 7.31 Requirements. An originating pharmacy may use a central shared services pharmacy only pursuant to the following requirements:

(1) The central shared services pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract.

(2) The central shared services pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number that it provides services to.

(3) The central shared services pharmacy and originating pharmacy maintain a written protocol delineating each pharmacy’s assumption of responsibility for compliance with state and federal law.

(4) Unless the central shared services pharmacy shares a computer system with the originating pharmacy meeting the requirements of s. Phar 7.04 (4) and contains the medication profile record under s. Phar 7.11 (3), it may not perform drug utilization review under s. Phar 7.03 to satisfy the final check requirement under s. Phar 7.07 (1) (c).

(5) The prescription label attached to the container shall contain the name and address of the labeling or originating pharmacy. The date on which the prescription was dispensed for purposes of s. 450.11 (4) (a) 2., Stats., shall be the date on which the labeling pharmacy filled the prescription order.

(6) The originating pharmacy or central shared services pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.

(7) In addition to meeting the other recordkeeping requirements required by state and federal law, the central shared services pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for the final check under s. Phar 7.07 (1).

Subchapter III — Delivery Systems and Remote Dispensing

Phar 7.40 Definitions. In this subchapter:

(1) “Delivery system” means a structure, controlled by a pharmacy licensed in this state, that a prescription is placed in for patient pick-up.

(2) “Supervising pharmacy” means a licensed pharmacy that oversees the operations and administration of remote dispensing.

Phar 7.41 Delivery system. (1) A prescription shall be stored in a secure delivery system immediately upon delivery to the location of the delivery system. Only the patient or patient’s agent shall be able to open the door or locker containing only the patient’s prescription.

(2) The delivery system shall be designed in a manner which does not disclose protected health information.

(3) The delivery system shall maintain appropriate environmental controls, including temperature and humidity, to prevent drug adulteration.

(4) The use of a delivery system does not create an exemption to s. 450.11 (1b), Stats.

(5) A log shall be maintained by the dispensing pharmacy of all prescriptions delivered to the delivery system.

(6) The delivery system shall be inventoried at least weekly and a list of unclaimed prescriptions shall be reviewed by a pharmacist.

(7) The managing pharmacist shall establish written policies and procedures for all of the following:

- (a) Stocking of the delivery system.
- (b) Determining access to the delivery system.
- (c) Detection and mitigation of diversion and theft.

Phar 7.42 Automated direct-to-patient dispensing system. (1) In this section “supervising practitioner” means the practitioner who is responsible for the operation of the automated direct-to-patient dispensing system and requirements of this section.

(2) An automated direct-to-patient dispensing system in a secure and professionally appropriate environment in any of the locations under s. 450.062 (1) to (4), Stats., may operate for purposes of practitioner dispensing. The supervising practitioner will ensure all of the following requirements are met:

(a) Individuals with access to the automated direct-to-patient dispensing system for the purpose of stocking, inventory, and monitoring shall be limited to the supervising practitioner or a delegate.

(b) The automated direct-to-patient dispensing system shall label the prescription in compliance with s. Phar 7.05.

(c) The automated direct-to-patient dispensing system shall maintain records of all prescription fills and dispenses in compliance with s. Phar 7.11 (1).

(d) The reporting of all monitored prescription drugs dispensed from the automated direct-to-patient dispensing system to the prescription drug monitoring program.

(3) The supervising practitioner or delegate shall establish written policies and procedures for automated direct-to-patient dispensing system for all of the following:

- (a) Stocking.
- (b) Determining access.
- (c) Detection and mitigation of diversion and theft.

Phar 7.43 Remote dispensing. ~~(1) In this section, "supervising pharmacist" means a Wisconsin licensed pharmacist, appointed by the managing pharmacist, who is responsible for the remote dispensing and compliance with this section.~~

(2) LOCATION. A ~~pharmacist or a~~ person engaged in the practice of pharmacy under s. 450.03 (1) (f) ~~or; (g) or (i),~~ Stats., ~~a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m)~~ may dispense at any of the locations under s. ~~450.062 (1) to (4)450.09 (2) (b) 1. a. to d.,~~ Stats.

~~(3) TITLE. No person may use or display the title "pharmacy", "drugstore," "apothecary," or any other title, symbol or insignia having the same or similar meanings in connection with remote dispensing.~~

(4) REQUIREMENTS. (a) A remote dispensing location shall display a sign, easily viewable by customers, that states all of the following:

- 1. Prescriptions may be filled at this location.
- 2. This remote dispensing location is being supervised by a pharmacist located at all of the following:
 - a. Name of pharmacy.
 - b. Address of pharmacy.
 - c. Telephone of pharmacy.
- 3. Patient has a right to pharmacist consultation and information on how to file a complaint to the board.

(b) Remote dispensing may not occur if ~~the supervising pharmacy is closed~~ **a pharmacist is not available remotely. A pharmacist shall provide direct supervision of pharmacist delegates at remote dispensing pharmacies. A pharmacist shall be available to the pharmacist delegate either in person or contact by telecommunication means.**

(c) A prescribed drug or device may not be dispensed in the absence of the ability of a patient and pharmacist's delegate to communicate with a pharmacist.

~~(d) Remote dispensing locations shall have a centrally monitored alarm. For all after hour entries, the personnel entering the location shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for a minimum of 5 years.~~

(5) DISPENSING REQUIREMENTS. Remote dispensing shall comply with all of the following:

- (a) Visually inspecting all prescription orders, labels and dispensed product.
- (b) Labeling requirements under s. Phar 7.05. The prescription label shall contain the name and address of the ~~supervising pharmacy remote dispensing site~~ as the licensed facility from which the prescribed drug or device was dispensed.
- (c) Final check under s. Phar 7.07.
- (d) Federal law if dispensing controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACIST ~~OR SUPERVISING PHARMACIST.~~ ~~(a) The managing pharmacist~~ **responsible for** ~~the remote dispensing~~ ~~supervising pharmacy or the supervising pharmacist~~ shall do all of the following:

- (a)+** Have written policies and procedures for system operation, safety, security, accuracy and access.

Commented [NH13]: Public Comment (DeBisschop): Clarify whether pharmacists who supervise a remote dispensing site also have to be at a pharmacy or if they can be at a non-pharmacy location.

Commented [NH14R13]: Changes highlighted in yellow

Commented [NH15]: Clearinghouse Comment #5e

Commented [NH16]: Public Comment (PSW): In 7.43 (6) (a) and (b), remove "supervising pharmacy"

Commented [NH17R16]: Changes highlighted in yellow

~~2(b).~~ Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.

~~(c)3.~~ Visit the remote dispensing location at least monthly to confirm delivery status of all drugs, to ensure written policies and procedures are being followed, and to ensure that remote dispensing personnel comply with all federal and state laws regulating the practice of pharmacy.

~~4(d).~~ Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.

~~5(c).~~ Documentation indicating accepting responsibility for compliance with this section, signed and dated by ~~both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist, and the dates the supervision responsibilities begin and end.~~

~~(b) The managing pharmacist at the supervising pharmacy or supervising pharmacist is responsible for all remote dispensing connected to the supervising pharmacy.~~

(7) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), ~~or (gm), or (i),~~ Stats., ~~a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m)~~ shall meet the following requirements to remote dispense:

- (a) Be 18 years of age or older.
- (b) Be a high school graduate or have equivalent education.

~~(c) Have completed 1500 hours of work as a pharmacist delegate within the 3 years prior to engaging in remote dispensing or completed an accredited pharmacy technician training program.~~

~~(d) A pharmacist shall provide direct supervision of pharmacist delegates. A pharmacist shall be available to the pharmacist delegate either in person or contact by telecommunication means.~~

Commented [HND18]: Changes from Pharm Tech rule

Commented [NH19]: Public Comment (DeBisschop): In 7.43 (7)(c), clarify whether 1,500 work requirement is paid time only or if it can include rotation/internship hours; Define "pharmacist delegate" or use a more descriptive term.

Commented [NH20R19]: Changes highlighted in yellow

Subchapter IV — Institutional Pharmacies

Phar 7.50 Definitions. In this subchapter:

(1) "Chart order" means an order entered on the chart or a medical record of an inpatient or resident of an institutional facility by a practitioner or practitioner's delegate for a drug product or device.

(2) "Institutional 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, 146.903 (1) (b), 233.40, 233.41, 233.42, or 252.10, Stats.; a hospice facility under s. 50.90 (1) (c), Stats.; a county jail; and a correctional facility operated under the authority of the department of corrections.

(3) "Institutional pharmacy" means a pharmacy that provides pharmacy services to an institutional facility. This definition is not for purposes under s. 450.09 (1) (a), Stats.

Phar 7.51 Chart orders. A chart order shall contain all of the following:

- (1) First and last name of the patient.
- (2) Patient's medical record number or date of birth.
- (3) Date of issuance.
- (4) Name, strength, and form of the drug product or device prescribed.
- (5) Directions for use.

- (6) The signature by one of the following methods:
 - (a) If handwritten, the practitioner's or delegate's signature.
 - (b) Electronic signature of the practitioner or delegate.
- (7) Chart orders prepared by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name of the practitioner.

Phar 7.52 Labels. All prescribed drug products and devices dispensed for administration by a health care provider at the institutional facility shall have a label attached to the container disclosing all of the following:

- (1) Drug name, strength and form.
- (2) Beyond use date or expiration date.
- (3) Special storage conditions, if required.

Phar 7.53 Security and access. (1) Arrangements shall be made in advance by the managing pharmacist for access of drugs by the health care staff of the institutional facility when dispensing by a pharmacist is not available.

- (2) In the absence of a pharmacist, drugs shall be stored in a manner in which only authorized personnel may obtain access and is sufficiently secure to deny access to unauthorized persons.
- (3) The managing pharmacist shall develop policies and procedures in place to mitigate and prevent theft and diversion.

Phar 7.54 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug product, or items of personal hygiene.

(b) "Original container" means the container in which a health item was sold, distributed, or dispensed.

(c) "Tamper-evident package" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.

(2) A health item which has been sold, distributed or dispensed, may be returned to the institutional pharmacy under s. Phar 7.10 (2) or if the health item has not left the control of the health care facility staff authorized to have access to prescription drug products.

(3) A health item returned to an institutional pharmacy may be sold, distributed, or dispensed to the institutional facility if all of the following apply:

- (a) The health item was never in the possession and control of the patient.
- (b) The health item was sold, distributed or dispensed in a tamper-evident package and, for a drug product, includes the beyond use date or expiration date and manufacturer's lot number.
- (c) The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

Phar 7.55 Automated technology product verification. (1) DEFINITIONS. In this section:

(a) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(b) "Supervising pharmacist" means the pharmacist licensed in this state who is responsible for the operations and outcomes of the product verification done by an automated technology.

(2) **AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS.** Product verification may be done only by an automated technology which meets all of the following:

- (a) Located within a licensed pharmacy.
- (b) Utilizing barcodes or another machine-readable technology to complete the product verification.
- (c) Validated by the following process:
 1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.
 2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.
- (d) Revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy and correctness of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations.
- (3) ELIGIBLE PRODUCT. The automated technology may do the product verification if the product meets all of the following:
 - (a) Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date.
 - (b) Has a drug utilization review performed by a pharmacist prior to delivery.
 - (c) Will be administered by an individual authorized to administer medications at the institution where the medication is administered.
- (4) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated technology product verification which shall be made available to the board upon request.
- (5) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:
 1. All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
 2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.
 3. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.
 4. Documentation of the dates of all software upgrades.
 5. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.
- (b) Records shall be made available to the board upon request.

Subchapter V — ~~Unlicensed Persons~~Uncredentialed Pharmacy Staff

Phar 7.60 Definition. ~~s. (1) "Direct supervision" means immediate availability to continually coordinate, direct and inspect in real time the practice of another. In this subchapter, "Uncredentialed pharmacy staff" means any staff practicing in the pharmacy area who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats.~~

~~(2) "General supervision" means to continually coordinate, direct and inspect the practice of another.~~

Commented [HND21]: Changes from Pharm Tech rule

~~Phar 7.61 Persons who have completed their second year of pharmacy school or pharmacists from another state applying for licensure. A person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats., is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board.~~

Phar 7.62 Unlicensed persons Uncredentialed pharmacy Staff. (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats. a pharmacy graduate as defined in s. Phar 1.02 (10m)

(2) A pharmacist shall provide ~~general~~ direct supervision of ~~unlicensed personnel~~ uncredentialed pharmacy staff. A pharmacist shall be available to the ~~unlicensed uncredentialed pharmacy staff~~ person for consultation either in person or contact by telecommunication means.

(3) An ~~unlicensed uncredentialed pharmacy staff~~ person may not ~~do any of the following~~ engage in the practice of pharmacy as defined in s. 450.01 (16), Stats., or the practice of a pharmacy technician as defined in s. Phar 19.02.

~~(a) Provide the final check on the accuracy and correctness of drug product or device dispensing under s. Phar 7.07 (1) (a) or (b), unless the person is validated for delegate check delegate under s. Phar 7.14.~~

~~(b) Complete the drug utilization review under s. Phar 7.03.~~

~~(c) Administer any prescribed drug products, devices or vaccines under s. 450.035, Stats.~~

~~(d) Provide patient specific counseling or consultation.~~

(4) The prohibitions in sub. (3), do not apply to a person completing an internship for purposes of meeting the internship requirement under s. 450.03 (2) (b), Stats.

(5) A managing pharmacist shall provide training to or verify competency of an ~~unlicensed uncredentialed pharmacy staff~~ person prior to the ~~unlicensed uncredentialed pharmacy staff~~ person performing a delegated act.

(6) The managing pharmacist shall determine which acts may be delegated in a pharmacy. The managing pharmacist has a duty to notify all pharmacists practicing in that pharmacy which acts may be delegated to specific unlicensed ~~persons~~ uncredentialed pharmacy staff. This record shall be provided to the board upon request.

(7) A pharmacist may delegate to an ~~unlicensed uncredentialed pharmacy staff~~ person any delegated act approved by the managing pharmacist pursuant to sub. (3).

Commented [NH22]: Public Comment (DeBisschop): Also include pharmacy graduates in s. Phar 7.61

Commented [NH23R22]: Changes highlighted in yellow; Definition of "direct supervision" moved to 7.01 and expanded.

Commented [NH24]: Remote Dispensing Rule Change Only

Chapter Phar 8
REQUIREMENTS FOR CONTROLLED SUBSTANCES
(EFFECTIVE 09/01/22)

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>.

(4) EMERGENCY KITS IN LONG TERM CARE FACILITIES. Nothing in these rules shall prohibit long term care facilities from obtaining an emergency kit, from a DEA registered pharmacy, in compliance with federal law.

(4)(5) REMOTE DISPENSING SITES. For the purposes of this chapter and pursuant to s. 450.09 (1) (a), Stats., pharmacies shall include remote dispensing sites.

Commented [NH25]: Clearinghouse Comment #2d
(Yellow highlight)

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.

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. (1) Records shall be maintained as required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats.

(2) The managing pharmacist shall oversee quarterly 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) EXEMPTION. There shall be an exemption to the requirement for an identification card when the drug is lawfully delivered to the patient’s home, or any address requested by the patient, through mail, common carrier or delivery service. A valid signature is required upon delivery.

Phar 8.07 Partial Dispensing. (1) A pharmacist may partially dispense a prescription containing a controlled substance listed in schedule III, IV and V.

(2) The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if one of the following conditions applies:

(a) If the pharmacist is unable to supply the full quantity called for in a written, electronic, or emergency oral prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written hard copy prescription order or written record of the electronic or emergency oral prescription order.

(b) If the patient requests partial dispensing.

(c) If the prescribing practitioner requests partial dispensing.

The remaining portion of any partially dispensed prescription under this section may be dispensed within 72 hours of the first partial dispensing. If the remaining portion is not dispensed within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.

(3) Prescription orders for schedule II controlled substances written for patients in long term care facilities (LTCF) or for patients with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities to include individual dosage units. The prescribing practitioner may document a terminal illness by writing upon the face of the prescription order the phrase "terminal illness" or words of similar meaning. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescribing practitioner prior to partially dispensing the prescription. Documentation of a terminal illness, whether substantiated by the presence of an appropriate phrase written upon the face of the prescription order or through pharmacist contact with the prescribing practitioner, shall be placed within the individual medication profile record maintained under s. Phar 7.07. The pharmacist shall record on the prescription order whether the patient is "terminally ill" or an "LTCF patient." A prescription order that is partially dispensed and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been dispensed in violation of this section. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription order or on another appropriate record, uniformly maintained and readily retrievable, the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. Subsequent partial dispensing is not permitted under this section if the patient becomes deceased, or is no longer diagnosed as terminally ill, or no longer resides within an LTCF. The total quantity of a schedule II controlled substance dispensed by partial dispensing may not exceed the total quantity prescribed. Prescription orders for schedule II controlled substances for patients in an LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless terminated earlier by the discontinuance of medication.

(4) Information pertaining to current prescription orders for schedule II controlled substances for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

(a) Display or printout of: the original prescription order designation; date of issue; identification of prescribing practitioner; identification of patient; name and address of the LTCF or name and address of the hospital or residence of the patient; identification of medication authorized, including dosage form, strength and quantity; listing of partial quantities that have been dispensed under each prescription order and the information required in sub. (3).

(b) Immediate (real time) updating of the prescription order record each time there is partial dispensing of the prescription.

(c) Retrieval of partially dispensed schedule II prescription information identical to that required by s. Phar 7.05 (2) for all prescription renewal information.

Phar 8.08 Controlled substances in emergency kits for long term care facilities. Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances:

- (1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.
- (2) The pharmaceutical services committee of the facility shall establish security safeguards for each emergency kit stored in the LTCF which shall include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.
- (3) A pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.
- (4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.
- (5) Noncompliance with this rule may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 23-054)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 1.02 (9), 7.43 (1), (3); and (4) (d), and 7.61; amend Phar 7.43 (2), (4) (b), (5) (b), and (7) (intro.), and 7.62 (1); create Phar 1.02 (3m), (10m), and (14m), 5.01 (4), 6.025, and 8.01 (5); and repeal and recreate Phar 7.43 (6) repeal Phar 1.02 (9), 7.43 (1), (3); and (4) (d); and amend Phar 7.43 (2), (4) (b), (5) (b), (6) (title), (6) (a), (6) (a) 5, (6) (b), and (7), and 7.62 (1), relating to remote dispensing.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.02 (5) and 450.09 (1) and (2) (b) 2, Stats.

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

Explanation of agency authority:

Section 15.08 (5) (b), Stats. states that “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.”

Section 450.02 (3) (a), Stats. allows the board to “promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

Section 450.02 (3) (d), Stats. says that the board “may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.”

Section 450.02 (3) (e), Stats. provides that the board “may promulgate rules establishing minimum standards for the practice of pharmacy.”

Section 450.02 (5), Stats. provides that “the board may promulgate rules governing pharmacies that are operated as remote dispensing sites. Rules promulgated under this subsection may exempt pharmacies operated as remote dispensing sites from requirements governing pharmacies that are not operated as remote dispensing sites.”

Related statute or rule: s. 961.31, Stats.

Plain language analysis: The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 101. These changes include the creation of s. Phar 6.025, which are rules that specifically apply to remote dispensing sites, as well as amendments to s. Phar 7.43 to allow for remote dispensing sites to operate without the presence of a pharmacist. Clarification was also added to ss. Phar 5.01 (4) and 8.01 (5) that pharmacies shall include remote dispensing sites. The Board also added a definition of pharmacy graduates to chapter Phar 1, and modified requirements in chapter Phar 7 to allow them to practice pharmacy while waiting for their license to be granted.

Summary of, and comparison with, existing or proposed federal regulation: The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

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: N/A

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains requirements for pharmacy licensure and dispensing. There is a provision that allows a pharmacy that is not in the same location as its home pharmacy, and services are being provided during an emergency situation, to operate as an emergency remote pharmacy. The Illinois Department of Financial and Professional Regulation may also waive the requirement for a pharmacist to be on duty at all times for state facilities that are not treating human ailments. Additionally, automated pharmacy systems operated from a remote site must be under continuous supervision of a pharmacist however, that pharmacist is not required to be physically present if they can monitor the system electronically [225 Illinois Compiled Statutes ch. 85 s. 15 and 22b]. The Illinois Department of Financial and Professional Regulation is also responsible for the promulgation of rules to implement certain sections of the Illinois Pharmacy Practice Act. These rules in the Illinois Administrative Code include definitions for “emergency situation” and what is required in order to operate an emergency remote temporary pharmacy [Illinois Administrative Code s. 1330.420].

In Illinois, graduate of a pharmacy program approved by the Illinois Department of Financial and Professional Regulation may be registered as a pharmacy technician

with the “student pharmacist” designation, if they have graduated from said program within the last 18 months. Student pharmacists are allowed to practice pharmacy under the supervision of a pharmacist [225 Illinois Compiled Statutes ch. 85 s. 9 (c)].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and include requirements for remote dispensing in hospital pharmacies. Additionally, a pharmacist is required to be onsite at a telepharmacy site for at least 16 hours per month and can otherwise monitor the site remotely. The telepharmacy site is a separate licensure category from a correctional, hospital, nuclear, or general pharmacy site. If the average number of prescriptions dispensed per day exceeds 150 at a telepharmacy site, the pharmacist is required to be on site 100 percent of the time and the site must apply for licensure as a general pharmacy [657 Iowa Administrative Code sections 7.7 and 13.9 (6)].

In Iowa, graduates of a college of pharmacy approved by the Iowa Board can register as a “pharmacist-intern.” Pharmacist-interns are required to practice under the supervision of a licensed pharmacist. This registration automatically terminates upon the pharmacist-intern receiving “licensure to practice pharmacy in any state, lapse in the pursuit of a degree in pharmacy, or one year following graduation from the college of pharmacy,” whichever happens sooner [657 Iowa Administrative Code sections 4.1 and 4.6 (3)].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for pharmacy in Michigan, among several other occupations. Unless at a mental health facility or hospital, remote pharmacies cannot be located within 10 miles of another pharmacy, unless a waiver is granted by the Michigan Board. A pharmacist is required to oversee a remote pharmacy; however, a qualified pharmacy technician must be on site at all times that the pharmacy is open if the pharmacist in charge is not physically present. A Pharmacist may not be responsible for more than three remote pharmacy sites at any one time [Michigan Compiled Laws s. 333.17742a and b].

In Michigan, pharmacy graduates can apply for an educational limited license if they are within 180 days of completing an approved educational program. Pharmacy graduates practicing under an educational limited license may only do so under the “personal charge of a pharmacist” [Michigan Administrative Code R 338.513].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Part 6800 of the Minnesota Administrative Code includes the regulations for pharmacy in Minnesota. [Minnesota Administrative Rules part 6800]. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes pharmacy regulations. According to Section 34 (10) of this chapter, it is unlawful to run a pharmacy without a pharmacist in charge. Operation of a pharmacy without a

pharmacist present and on duty is only allowed under an approved variance by the Board. [Minnesota Statutes 151.34 (10), 151.071 (2) (13)].

In Minnesota, pharmacy graduates can apply for a “pharmacist-intern” registration if they are a graduate of a pharmacy college approved by the Minnesota Board. Pharmacist interns must practice under the direct supervision of a licensed pharmacist [Minnesota Administrative Rules Chapter 6800 Parts 5100-5600].

Summary of factual data and analytical methodologies: The Board reviewed the statutory changes from 2021 Wisconsin Act 101 and updated Wisconsin Administrative Code Chapters Phar 1, 5, 6, 7, and 8 accordingly. While completing this review, the Board also identified a need to create a definition of a Pharmacy Graduate and include them in certain pharmacy practice circumstances.

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

The rule was posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens. No comments 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on October 26, 2023, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1 Phar 1.02 (9) is repealed.

SECTION 2 Phar 1.02 (3m), (10m), and (14m) are created to read:

Phar 1.02 (3m) “Direct supervision” means immediate, whether in person or real time video conferencing where all parties can communicate by simultaneous means of audio, video, or data communications, availability to continually coordinate, direct and inspect in real time the practice of another.

Phar 1.02 (10m) “Pharmacy graduate” means a graduate of a school of pharmacy approved by the ~~pharmacy examining~~ board, who has submitted an application for pharmacist licensure or a qualified applicant awaiting examination for licensure approved by the board.

Phar 1.02 (14m) “Remote dispensing site” has the meaning given in s. 450.01 (21c), Stats.

SECTION 3 Phar 5.01 (4) is created to read:

Phar 5.01 (4) For the purposes of this chapter and pursuant to s. 450.09 (1) (a), Stats., pharmacies shall include remote dispensing sites.

SECTION 4 Phar 6.025 is created to read:

Phar 6.025 Licenses; remote dispensing sites. A pharmacy may be subject to rules in this section that apply only to remote dispensing sites, if a pharmacist remotely supervises the location for any period of time. The following conditions shall also be met:

- (1) The ~~l~~icensee provides notice to the Board of all of the information outlined in s. 450.06, Stats.
- (2) The site meets all of the requirements listed in s. Phar 7.43.
- (3) The site is any of the location types listed under s. 450.09 (2) (b) 1., Stats.
- (4) A managing pharmacist shall report to the ~~b~~Board if they are responsible for 5 or more remote dispensing sites. A managing pharmacist ~~may shall~~ not be responsible for more than 10 remote dispensing sites at any given time without approval from the ~~b~~Board.

SECTION 5 Phar 7.43 (1) is repealed.

SECTION 6 Phar 7.43 (2) is amended to read:

Phar 7.43 (2) LOCATION. A ~~pharmacist or a person engaged in the practice of pharmacy~~ under s. 450.03 (1) (f); ~~or (g), or (i),~~ Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) may dispense at any of the locations under s. 450.62 (1) ~~to (4)~~ 450.09 (2) (b) 1. a. to d., Stats.

SECTION 7 Phar 7.43 (3) is repealed.

SECTION 8. Phar 7.43 (4) (b) is amended to read:

Phar 7.43 (4) (b) Remote dispensing may not occur if ~~the supervising pharmacy is closed~~ a pharmacist is not available remotely.

SECTION 9. Phar 7.43 (4) (d) is repealed.

SECTION 10. Phar 7.43 (5) (b); ~~(6) (title), (6) (a), (6) (a) 5, and (6) (b); and (7) are~~ is amended to read:

Phar 7.43 (5) (b) Labeling requirements under s. Phar 7.05. The prescription label shall contain the name and address of the ~~supervising pharmacy~~ remote dispensing site as the licensed facility from which the prescribed drug or device was dispensed.

~~(6) (title) RESPONSIBILITIES OF MANAGING PHARMACIST OR SUPERVISING PHARMACIST.~~

~~(6) (a) The managing pharmacist of the supervising pharmacy or the supervising pharmacist shall do all of the following:~~

~~(6) (a) 5. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist, and the dates the supervision responsibilities begin and end.~~

~~(6) (b) The managing pharmacist at the supervising pharmacy or supervising pharmacist is responsible for all remote dispensing connected to the supervising pharmacy.~~

SECTION 11. Phar 7.43 (6) is repealed and recreated to read:

Phar 7.43 (6) RESPONSIBILITIES OF MANAGING PHARMACIST. The managing pharmacist responsible for the remote dispensing pharmacy shall do all of the following:

(a) Have written policies and procedures for system operation, safety, security, accuracy and access.

(b) Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.

(c) Visit the remote dispensing location at least monthly to confirm delivery status of all drugs, to ensure written policies and procedures are being followed, and to ensure that remote dispensing personnel comply with all federal and state laws regulating the practice of pharmacy.

(d) Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.

(e) Documentation indicating accepting responsibility for compliance with this section, signed and dated by the managing pharmacist.

SECTION 12. Phar 7.43 (7) (intro.) is amended to read:

Phar 7.43 (7) (intro.) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) ~~or~~ (g), ~~or~~ (i), Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) shall meet the following requirements to remote dispense:

SECTION 14. Phar 7.61 is repealed.

SECTION ~~151~~. Phar 7.62 (1) is amended to read:

Phar 7.62 (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m).

SECTION ~~162~~. Phar 8.01 (5) is created to read:

Phar 8.01 (5) REMOTE DISPENSING SITES. For the purposes of this chapter and pursuant to s. 450.09 (1) (a), ~~s~~Stats., pharmacies shall include remote dispensing sites.

SECTION ~~173~~. 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)

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

Dated _____

Agency _____

Chairperson
Pharmacy Examining Board