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**VIRTUAL/TELECONFERENCE**  
**PHARMACY RULES COMMITTEE of the**  
**PHARMACY EXAMINING BOARD**  
**Virtual, 4822 Madison Yards Way, Madison**  
**Contact: Brad Wojciechowski (608) 266-2112**  
**August 21, 2025**

*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 (1-2)**

**B. Approval of Minutes of June 19, 2025 (3)**

**C. Administrative Rule Matters – Discussion and Consideration (4-48)**

1. Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check **(4-12)**
2. Phar 1, 6, 7 and 10, Relating to Pharmacy Workplace Conditions **(13-48)**
3. Pending or Possible Rulemaking Projects

**D. Public Comments**

**ADJOURNMENT**

**NEXT MEETING: OCTOBER 16, 2025**

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held 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 any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. 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 of the  
PHARMACY EXAMINING BOARD  
MEETING MINUTES  
JUNE 19, 2025**

**PRESENT:** Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp

**ABSENT:** Susan Kleppin

**STAFF:** Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Tracy Drinkwater, Board Administration Specialist; and other Department staff

**CALL TO ORDER**

John Weitekamp, Chairperson, called the meeting to order at 9:02 a.m. A quorum was confirmed with three (3) members present.

**ADOPTION OF AGENDA**

**MOTION:** Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to adopt the Agenda as published. Motion carried unanimously.

**APPROVAL OF MINUTES OF APRIL 17, 2025**

**MOTION:** Tiffany O'Hagan moved, seconded by Anthony Peterangelo, to approve the Minutes of April 17, 2025, as published. Motion carried unanimously.

**ADJOURNMENT**

**MOTION:** Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 10:33 a.m.

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

**AGENDA REQUEST FORM**

<b>1) Name and title of person submitting the request:</b> Nilajah Hardin Administrative Rules Coordinator		<b>2) Date when request submitted:</b> 08/11/25 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>																
<b>3) Name of Board, Committee, Council, Sections:</b> Pharmacy Examining Board Rules Committee																		
<b>4) Meeting Date:</b> 08/21/25	<b>5) Attachments:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<b>6) How should the item be titled on the agenda page?</b> Administrative Rule Matters – Discussion and Consideration 1. Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check 2. Phar 1, 6, 7 and 10, Relating to Pharmacy Workplace Conditions 3. Pending or Possible Rulemaking Projects																
<b>7) Place Item in:</b> <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	<b>8) Is an appearance before the Board being scheduled?</b> <i>(If yes, please complete <a href="#">Appearance Request</a> for Non-DSPS Staff)</i> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>9) Name of Case Advisor(s), if required:</b> N/A																
<b>10) Describe the issue and action that should be addressed:</b> Attachments: 1. Phar 7 Preliminary Rule Draft 2. Letter from WMC 3. Phar 1, 6, 7, 10 Redlined Code Text 4. Virginia Language Copies of current Board Rule Projects Can be Viewed Here: <a href="https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx">https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx</a>																		
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;"><b>11)</b></td> <td style="width: 50%; text-align: center;"><b>Authorization</b></td> <td style="width: 40%;"></td> </tr> <tr> <td></td> <td style="text-align: center;"> </td> <td style="text-align: center;">08/11/25</td> </tr> <tr> <td></td> <td style="text-align: center;"><b>Signature of person making this request</b></td> <td style="text-align: center;"><b>Date</b></td> </tr> <tr> <td></td> <td style="text-align: center;"><b>Supervisor (if required)</b></td> <td style="text-align: center;"><b>Date</b></td> </tr> <tr> <td></td> <td colspan="2" style="text-align: center;"> <b>Executive Director signature (indicates approval to add post agenda deadline item to agenda)</b>    <b>Date</b> </td> </tr> </table>				<b>11)</b>	<b>Authorization</b>				08/11/25		<b>Signature of person making this request</b>	<b>Date</b>		<b>Supervisor (if required)</b>	<b>Date</b>		<b>Executive Director signature (indicates approval to add post agenda deadline item to agenda)</b> <b>Date</b>	
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<b>Directions for including supporting documents:</b> 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.																		

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD

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

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PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 7.01 (2) and 7.40 (2); renumber and amend Phar 7.02 (5); amend Phar 7.02 (4), 7.05 (2) (a) 4., 7.07 (2), 7.08 (1) (a), and 7.42 (2) (intro); to repeal and recreate Phar 7.04 (3); and to create Phar 7.01 (1a), 7.02 (5) (a) to (c), 7.05 (5), 7.16, and 7.43 (4) (d) , relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** ss. 450.02 (2) and (5); 450.09 (1) and (2) (b) 2; 450.10; and 450.11 Stats.

**Statutory authority:** ss. 15.08 (5) (b); 450.02 (2); 450.02 (3) (a), (b), (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 (2), Stats., states that “the Board shall promulgate rules that do all of the following:

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

(b) Define the activities that constitute the practice of a pharmacy technician for purposes if the registration requirement under s. 450.68.”

Section 450.02 (3) (a), Stats., states “[t]he Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.”

Section 450.02 (3) (b), Stats., states “[t]he Board may promulgate rules establishing security standards for pharmacies.”

Section 450.02 (3) (d), Stats., states “[t]he Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.”

Section 450.02 (3) (e), Stats., states “[t]he Board may promulgate rules establishing minimum standards for the practice of pharmacy.”

Section 450.02 (5), Stats., states “[t]he Board may promulgate rules governing pharmacies that are operated as remote dispensing sites.”

**Related statute or rule:** s. 961.31, Stats.

**Plain language analysis:** The objective of this rule was to update requirements in Wisconsin Administrative Code Phar 7 to align with current pharmacy practice in the areas of electronic prescriptions, prescription labelling, CPR for pharmacists, controlled substance prescription transfers, remote dispensing, and the definition of a managing pharmacist. Additionally, the rule will implement the statutory changes from 2023 Wisconsin Act 27 by updating requirements for epinephrine delivery systems. This rule updates chapter Phar 7 as follows:

- A definition for “HIPAA” was added to Phar 7.01
- Phar 7.01 (2) was repealed
- Phar 7.02 (4) was amended to include prescriptions sent via secure texting platforms
- Phar 7.02 (5) was amended to include additional requirements for alterations to a prescription
- Phar 7.04 (3) was repealed and recreated
- Phar 7.05 (2) (a) 4. was amended to say “epinephrine delivery system”
- Phar 7.05 (5) was created to add requirements about labelling non-patient specific compounded preparations
- Phar 7.07 (2) was amended to reflect that final check may involve other pharmacy personnel besides the pharmacist
- Phar 7.08 (1) (a) was amended to include that a prescription that has not been previously dispensed by that pharmacy or a pharmacy in the same computer system
- Phar 7.16 is created to require CPR training and basic life support for all pharmacists who administer drug product or devices or vaccines
- Phar 7.40 (2) was repealed
- Phar 7.42 (2) (intro) was amended to include an updated statute on remote dispensing
- Phar 7.43 (4) (d) was created to clarify that no vaccines or drug product or devices shall be administered at a remote dispensing site

**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:** The Pharmacy Examining Board held a Preliminary Hearing on Statement of Scope on August 29, 2024 at 11:00am. No comments were received.

**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 various requirements on licensure, dispensing, and practice. Some of those requirements include that a prescription includes electronically transmitted orders for drugs from a licensed health care prescriber. Additionally, an electronically transmitted prescription means a prescription issued with an electronic signature and is transmitted and stored via electronic means. In Illinois, “remote prescription processing” includes outsourcing certain prescription services to a remote pharmacy. Such services may include entering prescription or patient data into a pharmacy system, drug regimen review, getting refill authorizations and communicating with prescribers, and transferring prescription information. Remote prescription processing may only occur between pharmacies that share a common electronic file or have technology that allows information to be sufficiently processed. Outside of remote prescription processing, Illinois licensees may also engage in “telepharmacy” under certain conditions. In this context, “telepharmacy” means the practice of pharmacy by a pharmacist through telecommunications or other technology. A pharmacy engaged in the practice of telepharmacy shall use an automated pharmacy system and be under the supervision of a pharmacist in charge [225 Illinois Compiled Statutes ch. 85 ss. 3, 25.10, and 25.15].

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 that a “remote consultation site” means a site separate from a pharmacy where prescriptions that were filled at that pharmacy are stored and dispensed by a pharmacy technician or student pharmacist under remote supervision of a pharmacist who is located at the home pharmacy. A “remote dispensing site” means a site separate from the home pharmacy where a supply of prescriptions drugs is kept and prescriptions are filled and dispensed by a pharmacy technician or student pharmacist under the remote supervision of a pharmacist who is located at the pharmacy. Additionally, any compounded drug for

office use must have a label with the name, address, and phone number of the compounding pharmacy; the name, strength, and dose of the compounded drug; the pharmacy's lot number and a beyond-use date; quantity or amount; storage instructions or hazardous drug warning labels; and a statement that says "For Office Use Only – Note for Resale." Illinois pharmacies are required to have a Pharmacist-in-Charge, similar to a Managing Pharmacist in Wisconsin, who is responsible for supervision of the activities all employees that relate to the practice of pharmacy, of the method for storage and safekeeping of drugs, of the pharmacy recordkeeping system. The Pharmacist-in-Charge is responsible for the security of the pharmacy along with the pharmacy owner [Illinois Administrative Code ss. 1330.10, 1330.640, and 1330.660].

The Illinois Pharmacy Practice Act Statute and its related Administrative Rules do not appear to address cardiopulmonary resuscitation (CPR) training for pharmacists, epinephrine delivery systems, controlled substance prescription transfers, initial patient consultation, prescription alteration, or final check.

**Iowa:** The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. Chapter 155A of the Iowa Code contains various statutes regarding pharmacy practice including requirements for a prescription. In Iowa, a prescription is required to be submitted electronically unless it qualifies for an exemption. Some of the exemptions include, a prescription for a device, for a compounded preparation with two or more components, for an opioid antagonist, and for an emergency situation. Exempted prescriptions may be submitted in writing as an original signed by the prescriber, by facsimile, or orally [Iowa Code ch. 155A s. 115A.27]. The Iowa Administrative Code also includes various pharmacy practice rules. Some of those requirements include rules for controlled substance prescription transfers, telepharmacy, labelling of non-patient specific compounded prescriptions, and patient consultation. In Iowa, transfers of controlled substance prescriptions is allowed pursuant to 21 CFR 1306 and are limited to authorization by the pharmacist at the patient's request. Telepharmacy requirements include that a telepharmacy site must have a managing pharmacy located in Iowa and an on-site pharmacist at least 16 hours per month. A pharmacist may provide remote supervision of pharmacy personnel at a telepharmacy site. Requirements for labelling of non-patient specific compounded prescriptions include the name, strength, dosage form and quantity; name of each active ingredient; pharmacy name, address, and phone number; preparation and beyond-use date; storage and handling instructions; lot or control number; a statement identifying the prescription as a compounded drug and whether it is sterile; and a statement that the prescription is not for distribution or is limited to direct patient administration. Patient consultation is required prior to dispensing any new or changed prescription. A pharmacist will counsel the patient on matters that the pharmacist determines will enhance drug therapy [481 Iowa Administrative Code ch. 552 ss. 552.8, 552.16, 552.18, 552.21, and 552.23].

The Iowa Board of Pharmacy's Administrative Rules and related Statutes do not appear to address CPR training for pharmacists, epinephrine delivery systems, managing pharmacist requirements, prescription alteration, or final check.

**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. Those regulations include requirements for electronic prescriptions, epinephrine delivery systems, remote dispensing, and pharmacist-in-charge requirements. In Michigan, an electronically transmitted prescription is a prescription communicated via electronic means, such as computer to computer or computer to facsimile machine, but does not include a prescription transmitted by telephone or facsimile machine. For prescribing auto-injectable epinephrine, or an epinephrine delivery system in Wisconsin, a pharmacist may dispense to an authorized entity. Authorized entities include a school board, a person or governmental entity that operates where allergens that can cause anaphylaxis may be present such as an amusement park, religious institution or recreation camp, and an entity eligible under the laws enforcement and firefighter access to epinephrine act. The pharmacist shall use the name of the authorized entity as the name of the patient for the prescription of the auto-injectable epinephrine. Requirements for a remote pharmacy include that both a parent pharmacy and an associated remote pharmacy must have a common owner, both be licensed as pharmacies, and located in the state of Michigan. A remote pharmacy cannot be within 10 miles of another pharmacy unless a waiver has been granted by the Michigan Board. If a pharmacist is not on site at a remote pharmacy, the pharmacist in charge of the parent pharmacy shall ensure that there is a pharmacist overseeing pharmacy technicians at the remote pharmacy via video and a telepharmacy system. A pharmacist cannot oversee 3 or more remote pharmacies at the same time. For a Pharmacist in Charge, or managing Pharmacist in Wisconsin, they are responsible for supervising the practice of pharmacy at the pharmacies they are assigned to. A Pharmacist in Charge may not supervise more than 3 pharmacies at one time, including remote pharmacy sites [Michigan Compiled Laws ss. 333.17703, 333.17742a and b, 333.17744a, and 333.17748].

Additional pharmacy practice regulations are also located in the Michigan Administrative Rules and include requirements on patient consultation. Patient consultation includes that a pharmacist is required to provide consultation on a prescription orally and in-person, except when the patient is not present at the pharmacy. The pharmacist providing the information printed or electronically also satisfies the consultation requirement. Consultation is to be provided with refills if the pharmacist deems it to be appropriate.[Michigan Administrative Rules R 338.589 (4)] The Michigan Board of Pharmacy's statutes and related administrative rules do not appear to address CPR training for pharmacists, labelling of non-patient specific compounded prescriptions, controlled substance prescription transfers, prescription alteration, and final check.

**Minnesota:** The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Chapter 151 of the Minnesota Statutes, the Pharmacy Practice and Wholesale Distribution Act, includes pharmacy regulations. In Minnesota, an electronic prescription order is allowed if it has that practitioner's electronic signature. The electronic prescription should contain the same information as any other prescription order [Minnesota Statutes 151.01 (16a)].



Part 6800 of the Minnesota Administrative Code also includes regulations for pharmacy in Minnesota. Some of those regulations include requirements for a Pharmacist-in-Charge, controlled substance prescription transfers, patient consultation, In Minnesota, a Pharmacist-in-Charge is responsible for supervising and establishing the procedures for all pharmacy employees. They also are required to supervise the method of storage of drugs and the record keeping system for pharmacy transactions. A Pharmacist-in-Charge may not be designated to supervise more than one pharmacy. For controlled substance prescription transfers, schedule III-V transfers are allowed pursuant to the requirements of the Drug Enforcement Administration. Schedule II controlled substance prescriptions cannot be transferred. For patient consultation, every pharmacy is required to have a procedure for consultation that allows for oral communication between the patient and the pharmacist about the patient's drug therapy. The pharmacist shall initiate the consultation for any new prescription. The consultation must be in person, whenever applicable, but can be supplemented with written information [Minnesota Administrative Rules part 6800, sections 6800.0910, 6800.2400, 6800.3120 ].

The Minnesota Board of Pharmacy's statutes and related administrative rules do not appear to address labelling of non-patient specific compounded prescriptions, CPR training for pharmacists, epinephrine delivery systems, remote dispensing, prescription alteration, and final check.

**Summary of factual data and analytical methodologies:** The Pharmacy Examining Board reviewed Wisconsin Administrative Code chapter Phar 7 and made updates where needed.

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

The rule will be 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.

**Fiscal Estimate and Economic Impact Analysis:**

The Fiscal Estimate and Economic Impact Analysis 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](mailto: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, P.O. Box 8366, Madison, Wisconsin 53708-8366; email at [DSPSAdminRules@wisconsin.gov](mailto: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](mailto: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.

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TEXT OF RULE

SECTION 1. Phar 7.01 (1a) is created to read:

**Phar 7.01 (1a)** “HIPAA” means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

SECTION 2. Phar 7.01 (2) is repealed.

SECTION 3. Phar 7.02 (4) is amended to read:

**Phar 7.02 (4)** VERBAL PRESCRIPTION AND PRESCRIPTION VIA SECURE TEXTING PLATFORM. Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. Prescription orders via text may be received at a pharmacy through a HIPAA compliant secure texting platform. The verbal prescription or prescription order via secure texting platform 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.

SECTION 4. Phar 7.02 (5) is renumbered to 7.02 (5) (intro) and amended to read:

**Phar 7.02 (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. If an alteration does not modify the original intent of the prescription, the pharmacist shall use their professional judgement when determining whether it is necessary to contact the practitioner or practitioner’s delegate before performing the following alterations to an initial fill of a non-controlled substance prescription:

SECTION 5. Phar 7.02 (5) (a) to (c) are created to read:

**Phar 7.02 (5) (a)** Changing the quantity, dosage, or directions for use of the medication if doing so does not alter the intended treatment parameters.

- (b) Changing the dosage form, with patient consent, if the form dispensed contains the identical amount of the active ingredients as the dosage prescribed and if doing so does not alter the intended treatment parameters.
- (c) Adding missing information on a prescription label required under s. Phar 7.05 (2) (a).

SECTION 6. Phar 7.04 (3) is repealed and recreated to read:

**Phar 7.04 (3)** CONTROLLED SUBSTANCES. The transfer of controlled substance prescriptions is allowed consistent with 21 CFR 1306.

SECTION 7. Phar 7.05 (2) (a) 4. is amended to read:

**Phar 7.05 (2) (a) 4.** For an epinephrine ~~auto-injector~~ delivery system 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.

SECTION 8. Phar 7.05 (5) is created to read:

**Phar 7.05 (5)** Notwithstanding sub. (2), compounded preparations dispensed or distributed to a practitioner pursuant to a non-patient specific order to be administered by a practitioner or a practitioner's agent shall comply with ch. Phar 15 and meet all of the following:

- (a) The order shall include the name and address of the practitioner, drug, strength, quantity, and the purpose of the compounded preparation.
- (b) The label shall include the practitioner's name in place of the patient's name and state "For practitioner Administration Only – Not for Dispensing or Distribution." If the sterility or integrity of the compounded preparation is not maintained after the initial opening of the container, the label shall state "Single-Dose Only."
- (c) The pharmacist shall record the name and address of the location the compounded preparation was dispensed or distributed, and the lot number and beyond-use date of all preparations dispensed or distributed to the practitioner.

SECTION 9. Phar 7.07 (2) is amended to read:

**Phar 7.07 (2)** For all prescription drug products or devices dispensed by a pharmacist, the prescription record shall identify the ~~pharmacist~~ individual responsible for each part of the final check. If sub. (1) (a) or (b) is completed by a pharmacy product verification technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the pharmacy product verification technician performing the check.

SECTION 10. Phar 7.08 (1) (a) is amended to read:

**Phar 7.08 (1) (a)** Has not been dispensed previously to the patient by that pharmacy or a pharmacy within the same shared computer system.

SECTION 11. Phar 7.16 is created to read:

**Phar 7.16 Additional Certification for Pharmacists.** Every licensed pharmacist who administers drug product or devices or vaccines pursuant to s. 450.035, Stats., shall maintain current certification in cardiopulmonary resuscitation and basic life support.

SECTION 12. Phar 7.40 (2) is repealed.

SECTION 13. Phar 7.42 (2) (intro) is amended to read:

**Phar 7.42 (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)~~450.09 (2) (b) 1. a. to d., Stats., may operate for purposes of practitioner dispensing. The supervising practitioner will ensure all of the following requirements are met:

SECTION 14. Phar 7.43 (4) (d) is created to read:

**Phar 7.43 (4) (d)** No vaccines or drug product or devices shall be administered at a remote dispensing site.

SECTION 15. 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.

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(END OF TEXT OF RULE)

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July 17, 2025

John G. Weitekamp, Chairperson  
Wisconsin Pharmacy Examining Board  
Dept. of Safety & Professional Services  
P.O. Box 8366  
Madison, WI 53708

Dear Chairperson Weitekamp,

I am writing to express concerns with regard to an emergency rule being developed by the Pharmacy Examining Board (PEB) related to pharmacy workplace conditions (Scope Statement 002-25). Wisconsin Manufacturers & Commerce (WMC) has concerns that several of the policies being contemplated reach beyond the legal authority granted to the PEB.

By way of background, WMC is the state's largest general business association, with roughly 3,800 members located all throughout Wisconsin. We represent small, medium, and large employers, and since our founding in 1911, our mission has been to make Wisconsin the most competitive state in the nation to do business. An important part of that mission is to ensure that government regulators operate within the four corners of the legal authority granted to them by law.

As an initial matter, WMC is concerned this rulemaking effort is being pursued as an emergency rule instead of the traditional rulemaking process. It is unclear what actual "emergency" exists that meets the statutory justification for emergency rulemaking under s. 227.24 Wis. Stats. In addition, we are concerned that imposition of these rules through emergency rulemaking denies impacted stakeholders the robust opportunities to engage in the policymaking process afforded by traditional rulemaking. We therefore urge the PEB to abandon the effort to promulgate these rules as emergency rules.

Focusing on the substance of the rules, WMC is particularly concerned with the proposed workplace conditions and unprofessional conduct changes under consideration because the PEB lacks explicit statutory authority to promulgate them. Section 227.10(2m) Wis. Stats. states, in relevant part, that "No agency may implement or enforce any standard, requirement, or threshold, including as a term or condition of any license issued by the agency, unless that standard, requirement, or threshold is explicitly required or explicitly permitted by statute..." In addition, s. 227.10(2) Wis. Stats. commands that "No agency may promulgate a rule with conflicts with state law." Finally, s. 227.11(2)(a) Wis. Stats. further asserts that "...a rule is not valid if the rule exceeds the bounds of correct interpretation [of statutory authority]."

Based upon information from the June 19, 2025 Pharmacy Rules Committee of the PEB, WMC believes the following proposed rule changes violate ss. 227.10(2), (2m), and 227.11(2)(a) Wis. Stats. because the policies lack explicit statutory authority, conflict with state law, and exceed the bounds of correct interpretation of the PEB's statutory authority.

- **Proposed Phar 6.09 – Workplace Conditions.** This proposal would establish minimum staffing levels for pharmacies, as well as staffing ratios for pharmacist supervision of pharmacy technicians. There is no explicit authority in Ch. 450 Wis. Stats. conferred on the PEB to regulate staffing levels at pharmacies or the ratio of pharmacists to pharmacy technicians. Although Ch. 450 Wis. Stats. requires pharmacists to supervise the practice of pharmacy technicians, there is no grant of authority to the PEB to determine ratios for that supervision. Accordingly, the PEB does not have the requisite statutory authority to promulgate these requirements as rules. As a policy matter, we question what evidence, including peer reviewed studies, the PEB used as a basis to determine that imposing supervisory ratios for pharmacy technicians administering vaccines result in superior outcomes versus the current standards of practice. Even if the Board had the legal authority to impose numeric supervisory ratios, and it does not, this proposal should not move forward in the absence of clear empirical evidence demonstrating significant improvements to outcomes.
- **Phar 10.03(2) – Unprofessional Conduct.** The rule proposes to amend Phar 10.03(2) by making a pharmacy liable for unprofessional conduct based upon a departure from the ordinary standard of care exhibited by a pharmacist or pharmacy technician. First, it is patently unfair to impose disciplinary liability on a pharmacy business because of the unprofessional conduct of individual employees. However, doing so is also contrary to the law. Section 450.10(1) Wis. Stats. defines the grounds for unprofessional conduct, and it does so clearly and unambiguously in a manner that imposes liability on individual pharmacists and pharmacy technicians based on their conduct in activities related to the practice of pharmacy. Further, s. 450.10(1)(b) Wis. Stats. authorizes reprimand, denial, revocation, suspension, or limitation of a license of any *person* licensed under the chapter who has (1) engaged in unprofessional conduct; (2) been adjudicated mentally incompetent by a court; or (3) been found guilty of an offense the circumstances of which substantially relate to the practice of the pharmacist or pharmacy technician.

The statutorily authorized disciplinary actions contemplated under s. 450.10 for unprofessional conduct quite clearly apply to individual pharmacists and pharmacy technicians, and not the pharmacy itself. If the Legislature wished to apply any or all of the unprofessional conduct standards to the pharmacy itself it could have done so in the text of the statute. It did not. Consequently, the proposal to impose disciplinary actions against a pharmacy for the unprofessional conduct of its employees is unlawful, and conflicts with the rule promulgation restrictions in ss. 227.10(2), (2m), and 227.11(2)(a) Wis. Stats.

- **Phar 10.03(13) – Unprofessional Conduct.** The rule proposes to amend Phar 10.03(13) by making a pharmacy liable for unprofessional conduct based on exercising undue influence or taking unfair advantage of a patient in the promotion or sale of services, drugs or other products for the financial gain of the pharmacy. For the reasons stated in the previous bullet point, the PEB lacks the requisite statutory authority to impose disciplinary liability on a pharmacy for unprofessional conduct.

Beyond this legal concern is one of practicality and enforcement. Phar 10.03 currently prohibits exerting undue influence on patients for the financial gain of pharmacists or third parties. This regulation makes sense because the public interest is served by prohibiting pharmacists from

exercising undue influence on patients that would provide a personal financial gain for himself or herself, or for that of a third party. However, pharmacies are different. Pharmacies are businesses that engage in the sale of services or products specifically for the purpose of financial gain. If pharmacies do not realize financial gains, they will not remain in business, and their customers will not have access to the services and prescription drugs necessary to meet their healthcare needs. It is wholly unclear under what authority the PEB believes it may prevent pharmacies realizing financial gains from the promotion or sale of services, drugs or services – it's literally the business model of every pharmacy, and the statutes provide the PEB with no authority regulate in this area.

If the PEB is concerned that pharmacies are engaging in deceptive advertising, pricing, or business practices, the statutes confer authority onto a different state agency to deal with those circumstances. Specifically, Ch. 100 Wis. Stats. confers authority on the Department of Agriculture, Trade & Consumer Protection (DATCP) to regulate business advertising and pricing to protect consumers. Beyond the concern that the statutes do not confer authority on the PEB to regulate pharmacy advertising or pricing, doing so would be redundant to and would likely conflict with the authority granted to DATCP. This proposed rule revision should not move forward because of both legal and practical concerns.

- **Phar 10.03(17) – Unprofessional Conduct.** The rule proposes to amend Phar 10.03(17) by making a pharmacy liable for unprofessional conduct based on a pharmacy's license being revoked or suspended in another state, or having been subject to disciplinary action in another state. For the reasons stated in prior bullet points, the PEB does not have explicit statutory authority to impose disciplinary liability for unprofessional conduct on pharmacies. In addition, Ch. 450 Wis. Stats. provides no explicit authority to the PEB to impose disciplinary or enforcement action against a Wisconsin pharmacy based upon conduct that occurred at a different pharmacy in another state.

Tellingly, s. 450.05 Wis. Stats. allows the PEB to deny a license to a **pharmacist** if his or her license to practice was surrendered, limited, suspended or revoked in another state. However, there is no corresponding statutory provision regulating a pharmacy based upon conduct that occurred at a different pharmacy in another state. If the Legislature wanted to treat disciplinary actions occurring in another state for pharmacies in the same manner as it chose to regulate pharmacists, it could have done so. It did not. As a result, the PEB has no statutory authority to promulgate the proposed rule that would impose disciplinary action on pharmacies for actions that occurred at a different pharmacy in another state.

Beyond the legal barriers to moving forward with these four rule changes, WMC is concerned that the proposals represent an inappropriate level of micromanagement by the PEB in the day-to-day operation of pharmacies. The statutory framework laid out in Ch. 450 Wis. Stats. as it relates to pharmacies is generally limited to ensuring their proper licensure, their cleanliness and sanitation, their security, maintenance of appropriate records, and ensuring each pharmacy is under the control of the managing pharmacist. The vast majority of the chapter is focused on the practice of pharmacy by pharmacists and pharmacy technicians, as well as the safety and security of the prescription drug supply chain. Chapter

450 simply does not empower the PEB to micromanage the day-to-day operations of pharmacies, nor does it allow the PEB to set personnel or staffing requirements.

Finally, several of the proposed rule changes appear to be based upon Virginia regulations. WMC would like to remind the Board that its authority to regulate is confined to the authority granted by the Wisconsin Statutes – not the Commonwealth of Virginia. Although Board members may find Virginia's regulatory approach desirable, that is simply not a basis to regulate. If authority for a regulation is not explicitly granted by the Wisconsin Statutes, the Board is prohibited from promulgating that regulation.

WMC urges members of the Board to keep these legal and policy concerns in mind, and reject any effort to impose unlawful regulations on pharmacies, including each of the proposals referenced above.

Thank you for your thoughtful consideration, and please let me know if you have any questions or would like additional information.

Sincerely,



**Scott Manley**  
Executive Vice President, Government Relations

c: Scott Rosenow, Executive Director – WMC Litigation Center  
Members, Wisconsin Pharmacy Examining Board  
Brad Wojciechowski, Executive Director  
Whitney DeVoe, Legal Counsel  
Nilajah Hardin, Administrative Rules Coordinator



Chapter Phar 1

**AUTHORITY AND DEFINITIONS**

Phar 1.01 Authority.

Phar 1.02 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 19 are adopted under authority of ss. 15.08 (5) (b) and 227.11 (2), Stats., and ch. 450, Stats.

**Phar 1.02 Definitions.** As used in chs. Phar 1 to 19:

(1) “Board” means the pharmacy examining board.

**Note:** The board office is located at 4822 Madison Yards Way, Madison, WI 53705.

(2) “Community pharmacy” means practice in a licensed pharmacy providing pharmaceutical services primarily on an out- patient basis.

(2m) “Department” means the Wisconsin department of safety and professional services.

(3) XDEAY 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 in- patient 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.

(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 board, who has submitted an application for pharmacist licensure or a qualified applicant awaiting examination for licensure approved by the board.

(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.

(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.

(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.

## Chapter Phar 6

### PHARMACY LICENSES AND EQUIPMENT

Phar 6.01	Licenses; application.	Phar 6.05	Sanitation.
Phar 6.02	Licenses; change of location or ownership.	Phar 6.06	Laws and other references.
Phar 6.025	Licenses; remote dispensing sites.	Phar 6.07	Storage.
Phar 6.03	Changes in managing pharmacist.	Phar 6.075	Temperature; Humidity.
Phar 6.04	Floor design.	Phar 6.08	Security.

**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 owner- ship. (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 re- turned. 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:

**(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.** If the building is open at any time while the professional service area is closed, the professional service area shall be secured as specified in sub. (3).

**(2) REQUIREMENTS WHEN THE PROFESSIONAL SERVICE AREA IS CLOSED.** When the pharmacy professional service area is closed, the pharmacy shall meet all of the following requirements:

- (am)** A locked, secure physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by 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.

- (bm) Signs of reasonable size are posted at the professional service area which prominently display the hours the professional services are available.
- (cm) The manner in which the telephone is answered does not imply that the professional services are available.

**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.

**Phar 6.09 Workplace Conditions.** A pharmacy shall provide a safe working environment by ensuring all of the following:

Commented [NH1]: Staffing ratios?

(1) Provide appropriate staffing levels to operate in a safe and effective manner.

(2) Carry and utilize the equipment necessary to conduct the practice of pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws.

(3) Enough time is allotted for pharmacy staff to complete services safely and accurately.

(4) A pharmacist may supervise no more than X pharmacy technicians engaged in administration of vaccines.

(5) Staff are sufficiently trained and demonstrate competency in their assigned tasks as determined by the managing pharmacist.

(+)(6)

## Chapter Phar 7

### PHARMACY PRACTICE

#### Subchapter I — General

- Phar 7.01 Definitions.
- Phar 7.02 Prescription.
- Phar 7.03 Drug utilization review.
- Phar 7.04 Transferring prescription order information.
- Phar 7.05 Label requirements.
- Phar 7.06 Repackaging for stock.
- Phar 7.07 Final check.
- Phar 7.08 Patient consultation.
- Phar 7.085 Delivery by common carrier or delivery services.
- Phar 7.09 Procurement, recall and out-of-date drugs and devices.
- Phar 7.10 Return or exchange of health items.
- Phar 7.11 Pharmacy records.
- Phar 7.12 Delegation by a physician.
- Phar 7.13 Administration of drug products and devices other than vaccines.
- Phar 7.14 Pharmacy product verification technician-check-pharmacy technician.
- Phar 7.15 Consumer disclosures.

#### Subchapter II — Central Shared Services

- Phar 7.30 Definitions.

- Phar 7.31 Requirements.

#### Subchapter III — Delivery Systems and Remote Dispensing

- Phar 7.40 Definitions.
- Phar 7.41 Delivery system.
- Phar 7.42 Automated direct-to-patient dispensing system.
- Phar 7.43 Remote dispensing.

#### Subchapter IV — Institutional Pharmacies

- Phar 7.50 Definitions.
- Phar 7.51 Chart orders.
- Phar 7.52 Labels.
- Phar 7.53 Security and access.
- Phar 7.54 Return or exchange of health items.
- Phar 7.55 Automated technology product verification.

#### Subchapter V — Uncredentialed Pharmacy Staff

- Phar 7.60 Definition.
- Phar 7.62 Uncredentialed pharmacy staff.

**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.

~~(1a) “HIPAA” means the Health Insurance Portability and Accountability Act of 1996 , Public Law 104-191.~~

~~(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 AND PRESCRIPTION VIA SECURE TEXTING PLATFORM. Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. Prescription orders via text may be received at a pharmacy through a HIPAA compliant secure texting platform. The verbal prescription or prescription order via secure texting platform 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. If an alteration does not modify the original intent of the prescription, the pharmacist shall use their professional judgement when determining whether it is necessary to contact the practitioner or practitioner's delegate before performing the following alterations to an initial fill of a non-controlled substance prescription:
1. Changing the quantity, dosage, or directions for use of the medication if doing so does not alter the intended treatment parameters.
  2. Adding missing information on a prescription label required under s. Phar 7.05 (2) (a).

**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~~ prescriptions is allowed consistent with 21 CFR 1306, listed in Schedule III – 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.~~

~~(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.~~

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(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~~ delivery system 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.

(5) Notwithstanding sub. (2), compounded preparations dispensed or distributed to a practitioner pursuant to a non-patient specific order to be administered by a practitioner or a practitioner's agent shall comply with ch. Phar 15 and meet all of the following:

(a) The order shall include the name and address of the practitioner, drug, strength, quantity, and the purpose of the compounded preparation.

(b) The label shall include the practitioner's name in place of the patient's name and state "For practitioner Administration Only – Not for Dispensing or Distribution." If the sterility or integrity of the compounded preparation is not maintained after the initial opening of the container, the label shall state "Single-Does Only."

(c) The pharmacist shall record the name and address of the location the compounded preparation was dispensed or distributed, and the lot number and beyond-use date of all preparations dispensed or distributed to the practitioner.

**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:

- (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 products or devices dispensed by a pharmacist, the prescription record shall identify the pharmacist the individual responsible for each part of the final check. If sub. (1) (a) or (b) is completed by a pharmacy product verification technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the 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 by that pharmacy or a pharmacy within the same shared computer system.

- (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 Pharmacy product verification technician-check-pharmacy technician. (1)**

**DEFINITIONS.** In this section:

(a) “Pharmacy product verification technician” means a registered pharmacy technician to whom the pharmacist has delegated the task of product verification.

(b) “Pharmacy product verification technician-check- pharmacy technician” means the process in which a pharmacy product verification technician conducts the task of product verification of technical dispensing functions completed by a pharmacy technician. A 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 pharmacy product verification technician and ensuring for direct supervision of the pharmacy product verification technician.

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

(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 products for pharmacy product verification technician-check-pharmacy 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 pharmacy 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 pharmacy technician being validated shall make a product verification on the work of a pharmacist or another 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 pharmacy technician during the validation process.

(e) Notwithstanding pars. (b) to (d), an individual who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the pharmacy product verification technician qualifications unless the individual fails to meet the quality assurance standards under sub. (4).

(3) **ELIGIBLE PRODUCT.** (a) *Institutional pharmacies.* The 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 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 pharmacy product verification technician's verifications shall be audited by a licensed pharmacist. The accuracy of each pharmacy product verification technician shall be tracked individually.

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

1. Name of the pharmacy product verification 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 pharmacy product verification technician's previous 12 months accuracy and correctness of pharmacy product verifications including a review of the quality assurance log.

(d) A pharmacy product verification technician shall be revalidated if the 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 verifications within the last 6 months.

(5) **POLICIES AND PROCEDURES.** Each pharmacy shall maintain policies, procedures, and training materials for the 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 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 pharmacist, indicating the name of the supervising 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.

**Phar 7.15 Consumer disclosures. (1)** Each pharmacy shall post in a prominent place and maintain the consumer disclosures required in ss. 450.13 (5m) and 450.135 (8m), Stats.

(2) A link to the 100 most commonly prescribed generic drug product equivalents as determined by the board, shall be maintained on the department's website as required in s. 450.13 (5m) (b), Stats.

**Note:** Copies of the required consumer disclosures are located on the Department of Safety and Professional Service's website: <https://dsps.wi.gov>.

(3) Pursuant to s. 450.13 (5m) (c), Stats., each pharmacy shall maintain and make available to the public a list of the drugs from the list in sub. (2) that are available for purchase at that pharmacy. The list shall be updated monthly, with all of the following information included:

- (a) Brand name.
- (b) Generic equivalent drugs and biological products.
- (c) Interchangeable biological products.
- (d) Retail price.

(4) The list required under sub. (3) may differ depending on whether the drugs on the list from sub. (2) are available for purchase at a specific pharmacy.

**Phar 7.16 Additional Certification for Pharmacists.** Every licensed pharmacist who administers drug product or devices or vaccines pursuant to s. 450.035, Stats., shall maintain current certification in cardiopulmonary resuscitation and basic life support.

## 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)~~450.09 (2) (b) 1. a. to d., 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. (2) LOCATION.** A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), 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. 450.09 (2) (b) 1. a. to d., Stats.

**(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 employed by:
  - 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 a pharmacist is not available remotely.

**(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)** No vaccines shall be administered at a remote dispensing site.

**(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 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.** 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 ongoing 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.
- (7) **DELEGATE REQUIREMENTS.** A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), 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.

#### **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 — Uncredentialed Pharmacy Staff**

**Phar 7.60 Definition.** In this subchapter, "uncredentialed pharmacy staff" means any staff practicing in the pharmacy who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats.

- Phar 7.62 Uncredentialed pharmacy staff. (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).
- (2) A pharmacist shall provide direct supervision of uncredentialed pharmacy staff. A pharmacist shall be available to the uncredentialed pharmacy staff person for consultation either in person or contact by telecommunication means.
  - (3) An uncredentialed pharmacy staff person may not 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.
  - (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 uncredentialed pharmacy staff person prior to the 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 uncredentialed pharmacy staff. This record shall be provided to the board upon request.
- (7) A pharmacist may delegate to an uncredentialed pharmacy staff person any delegated act approved by the managing pharmacist outside of the restrictions in sub. (3).



## Chapter Phar 10

### STANDARDS OF PROFESSIONAL CONDUCT

Phar 10.01 Authority.  
Phar 10.02 Definitions.

Phar 10.03 Unprofessional conduct.

**Phar 10.01 Authority.** The rules in this chapter are adopted pursuant to the authority in ss. 15.08, 227.11 and 450.02, Stats.

**Phar 10.02 Definitions.** In this chapter:

- (1) “Dispense” has the meaning given in s. 450.01 (7), Stats.
- (2) “Drug” has the meaning given in s. 450.01 (10), Stats.
- (3) “Patient” has the meaning given in s. 450.01 (14), Stats.

**Phar 10.03 Unprofessional conduct.** The following, without limitation because of enumeration, are violations of standards of professional conduct and constitute unprofessional conduct in addition to those grounds specified under s. 450.10 (1), Stats.:

- (1) Administering, dispensing, supplying or obtaining a drug other than in legitimate practice, or as prohibited by law.
- (2) Engaging in any pharmacy practice which constitutes a danger to the health, welfare, or safety of patient or public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacy, pharmacist or pharmacy technician | which harmed or could have harmed a patient.
- (3) Dispensing a drug which the pharmacist should have known would harm the patient for whom the medication was prescribed.
- (4) Dispensing or causing to be dispensed a drug which is outdated or contaminated or known by the pharmacist to be unsafe for consumption.
- (5) Falsifying patient records.
- (6) Disclosing to the public information concerning a patient without the consent of the patient unless the information is requested by the pharmacy examining board or the department of safety and professional services or unless release is otherwise authorized by law.
- (7) Failing to report to the pharmacy examining board any pharmacy practice which constitutes a danger to the health, safety or welfare of patient or public.
- (7m) Failing to report to the board information that reasonably suggests there is a probability that a prescription drug or device dispensed by a pharmacist has caused or contributed to the substantial bodily injury or death of a customer or patient.
- (8) Providing false information to the pharmacy examining board or its agent.
- (9) Refusing to render professional services to a person because of race, color, sex, religion, or age.
- (10) Aiding or abetting the unlicensed practice of pharmacy.
- (11) Advertising in a manner which is false, deceptive or misleading.
- (12) Dispensing sample drug products for any financial consideration.
- (13) Exercising undue influence on or taking unfair advantage of a patient in the promotion or sale of services, drugs or other products for the financial gain of the pharmacy, pharmacist or a third | party.
- (14) Participating in rebate or fee-splitting arrangements with health practitioners or with health care facilities.
- (15) Furnishing a prescriber with any prescription order blanks imprinted with the name of a

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specific pharmacist or pharmacy.

(16) Using secret formula or code in connection with prescription orders.

(17) Having a pharmacy license, pharmacist license or pharmacy technician registration revoked or suspended in another state or United States jurisdiction or having been subject to other disciplinary action by the licensing authority thereof.

(18) Violating or attempting to violate any formal disciplinary order of the board.

(19) Practicing without a current license or registration.

(20) Violating or attempting to violate any provision or term of ch. 450, Stats., or of any rule of the board.

(21) Failure to comply with s. 450.13 (5m) or 450.135 (8m), Stats.

**Board of Pharmacy**

**Pharmacy working conditions**

**18VAC110-20-110. Pharmacy permits generally.**

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist may, however, volunteer to work longer than 12 continuous hours. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break. Breaks, including uninterrupted rest periods and meal breaks, shall be provided consistent with 18VAC110-20-113 B 5.

C. The PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

E. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

F. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedules II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

H. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

I. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

J. Before any permit is issued, the applicant shall attest to compliance with all federal, state, and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

**18VAC110-20-113. Pharmacy working conditions.**

A. A pharmacy permit holder shall protect the health, safety, and welfare of patients by consulting with the PIC or pharmacist on duty and other pharmacy staff to ensure patient care services are safely provided in compliance with applicable standards of patient care. A permit holder's decisions shall not override the control of the PIC or other pharmacist on duty regarding appropriate working environments for all pharmacy personnel necessary to protect the health, safety, and welfare of patients.

B. To provide a safe working environment in a pharmacy, a permit holder shall, at a minimum:

1. Ensure sufficient personnel are scheduled to work at all times in order to prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety. Staffing levels shall not be solely based on prescription volume, but shall consider any other requirements of pharmacy staff during working hours;

2. Provide sufficient tools and equipment in good repair and minimize excessive distractions to support a safe workflow for a pharmacist to practice with reasonable competence and safety to address patient needs in a timely manner;

3. Avoid the introduction of external factors, such as productivity or production quotas, or other programs to the extent that they interfere with the pharmacist's ability to provide appropriate professional services to the public;

4. Ensure staff are sufficiently trained to safely and adequately perform their assigned duties, ensure staff demonstrate competency, and ensure that pharmacy technician trainees work closely with pharmacists and pharmacy technicians with sufficient experience as determined by the PIC;

5. Provide appropriate opportunities for uninterrupted rest periods and meal breaks consistent with 18VAC110-20-110 and the following:

a. A pharmacy may close when a pharmacist is on break based on the professional judgment of the pharmacist on duty provided that it has complied with the 14-day notice to the public pursuant to § 54.1-3434 of the Code of Virginia and 18VAC110-20-135;

b. If a pharmacy does not close while the pharmacist is on break, the pharmacist must ensure adequate security of drugs by taking his break within the prescription department or on the premises. The pharmacist on duty must determine if pharmacy technicians or pharmacy interns may continue to perform duties and if the pharmacist is able to provide adequate supervision; and

c. If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel any person filling a new prescription must be offered pursuant to § 54.1-3319 of the Code of Virginia. Persons who request to speak to the pharmacist shall be told that the pharmacist is on break and that they may wait to speak with the pharmacist or provide a telephone number for the pharmacist to contact them upon return from break. Pharmacists returning from break shall immediately attempt to contact persons who requested counseling and document when such counseling is provided;

6. Provide adequate time for a pharmacist to complete professional duties and responsibilities, including:

a. drug utilization review;

b. immunization;



c. counseling;

d. verification of prescriptions;

e. patient testing; and

f. all other duties required by §§ 54.1-3300 *et seq.* and 54.1-3400 *et seq.* of the Code of Virginia and 18VAC110-20-10 *et seq.*; and

7. Ensure that pharmacy technicians shall never perform duties otherwise restricted to a pharmacist.

C. A pharmacy permit holder shall not override the control of the pharmacist on duty regarding all aspects of the practice of pharmacy, including a pharmacist's decision not to administer vaccines when one pharmacist is on duty and, in the pharmacist's professional judgment, vaccines cannot be administered safely.

D. Staffing requests or concerns shall be communicated by the PIC or pharmacist on duty to the permit holder using a form developed by the board.

1. Executed staffing forms shall be provided to the immediate supervisor of the PIC or pharmacist on duty, with one copy maintained in the pharmacy for three years, and produced for inspection by the board.

2. The PIC or pharmacist on duty may report any staffing issues directly to the board if the PIC or pharmacist on duty believes the situation warrants immediate board review.

3. Under no circumstances shall a good faith report of staffing concerns by the PIC, pharmacist on duty, or notification of such issues by pharmacy personnel to the PIC or pharmacist on duty result in workplace discipline against the reporting staff member.

E. Permit holders shall review completed staffing reports and shall:

1. Respond to reporting staff member to acknowledge receipt of the staffing request or concern;
2. Resolve any issues listed in a timely manner to ensure a safe working environment for pharmacy staff and appropriate medication access for patients;
3. Document any corrective action taken, steps taken toward corrective action as of the time of inspection, or justification for inaction, which documentation shall be maintained on-site or produced for inspection by the board within 48 hours of request; and
4. Communicate corrective action taken or justification for inaction to the PIC or reporting pharmacist on duty.