STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	NOTICE OF TIME PERIOD
PROCEEDINGS BEFORE THE	:	FOR COMMENTS FOR THE
PHARMACY EXAMINING BOARD	:	ECONOMIC IMPACT ANALYSIS

NOTICE IS HEREBY GIVEN of the time period for public comment on the economic impact of this proposed rule of the Pharmacy Examining Board on 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, including how this proposed rule may affect businesses, local government units and individuals. The comments will be considered when the Department of Safety and Professional Services prepares the Economic Impact Analysis pursuant to § 227.137. Written comments may be submitted to:

Nilajah Hardin, Administrative Rules Coordinator
Division of Policy Development
Department of Safety and Professional Services
PO Box 8366
Madison, WI 53708-8935
DSPSAdminRules@wisconsin.gov

The deadline for submitting economic impact comments September 12, 2025.

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.

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 Complied 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. For prescription alteration, a pharmacist may use professional judgement when making a therapeutic substation to a prescribed drug, unless the prescription includes "dispense as written"[Iowa Code ch. 155A ss. 155A.27 and 155A. 32].

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, managing pharmacist requirements, or final check.
The statutory requirements for epinephrine auto-injectors are located under the Department of Health and Human Services - Public Health chapter instead of the Iowa Board of Pharmacy. In Iowa, a person who is authorized to administer epinephrine must be an employee or agent of a "facility" as defined by statute. Licensed healthcare professionals are to use the name of the facility when prescribing epinephrine auto-injectors. The facility may have a prescription for and maintain a supply of epinephrine auto-injectors at a secure location [Iowa Code ch. 135 s. 135.185].

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, 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.

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

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.

(END OF TEXT OF RULE)
