

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

The statement of scope for this rule, SS 052-22, was approved by the Governor on June 13, 2022, published in Register 798B on June 27, 2022, and approved by the Pharmacy Examining Board on July 8, 2022. This emergency rule was approved by the Governor on January 26, 2023.

ORDER

An order of the Pharmacy Examining Board to amend Phar 1.01, 1.02 (intro), 1.02 (Note), 7.07 (2), 7.14 (2), (2) (b), (2) (c) 3. and 6., (2) (d) 1. and 2., (2) (e), (3) (a) and (b), (4) (a), (b), (c), and (d), (5), (6) (a) 1. and 2, 7.43 (7), ch. Phar 7 subch. V (title), 7.62 (title), (1), (2), (3) (intro.), (5), (6), and (7), 10.03 (2), (17), and (19); create Phar 1.01 (11m), 5.07, 7.60 (intro.) and (3), and ch. Phar 19; and repeal Phar 7.14 (2) and 7.62 (3) (a) to (d), relating to registration of pharmacy technicians.

Analysis prepared by the Department of Safety and Professional Services.

EXEMPTION FROM FINDING OF EMERGENCY

The Legislature by section 40 (1) of 2021 Wisconsin Act 100 provides an exemption from a finding of emergency for the adoption of the rule.

ANALYSIS

Statutes interpreted: s. 450.68, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), (d), and (e). Stats, and 2021 Wisconsin Action 100 s. 40 (1)

Explanation of agency authority:

Section 15.08 (5) (b), Stats. states that “The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession.”

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

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

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

2021 Wisconsin Act 100, Section 40 (1) provides: “The pharmacy examining board may promulgate emergency rules under s. 227.24 necessary to implement this act. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until May 1, 2024, or the date on which permanent rules take effect, whichever is sooner.”

Related statute or rule: s. 961.31, Stats.

Plain language analysis: The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 100.

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

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains requirements for licensure of registered pharmacy technicians, as well as for pharmacists and pharmacies. Registered pharmacy technicians in Illinois have to be at least 16 years old, is attending or has graduated from high school or has a high school equivalency certificate and must complete the requirements to become a licensed registered certified pharmacy technician. A licensed registered certified pharmacy technician must be at least 18 and as of January 1, 2024, have graduated from a pharmacy technician training program or obtained documentation from the pharmacist-in-charge at the pharmacy where they are employed that they have successfully completed a nationally accredited training program. [225 Illinois Compiled Statutes ch. 85 s. 9 and 9.5]. 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 application requirements for both registered and registered certified pharmacy technicians, as well as rules for their training and education [Illinois Administrative Code s. 1330.200-1330.220].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. Title IV Chapter 155A of the Iowa Code includes the statutory requirements for pharmacy technician registration, licensure of pharmacists and pharmacies, and prescription drug orders, among other requirements. In Iowa pharmacy technicians must register with the Iowa Board and the responsibility for their actions is with the licensed pharmacist who is supervising them [Iowa Code ch.155A s.6A]. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and also include requirements for pharmacy technicians. Among those requirements, the chapter includes registration procedures, training, delegation and practice, national certification, as well as unethical conduct and discipline [657 Iowa Administrative Code ch. 3].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for pharmacy in Michigan, among several other occupations. Also included in those regulations are the statutory requirements for licensure and practice of pharmacy technicians. [Michigan Compiled Laws s. 333.17739]. The Michigan Administrative Rules also include requirements for pharmacy technicians administered by the Michigan Department of Licensing and Regulatory Affairs in conjunction with the Michigan Board. These rules include licensure, examination, training, and approved education program requirements for pharmacy technicians [Michigan Administrative Rules R 338.3561-338.3665].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Part 6800 of the Minnesota Administrative Code includes the regulations for pharmacy in Minnesota. These rules include requirements for pharmacy technician registration, education, training, and supervision [Minnesota Administrative Rules part 6800.3850]. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes pharmacy regulations and requirements for pharmacy technicians. This statute specifically clarifies the nature of the supervisory relationship of the pharmacist to the technician, as well as how many technicians each individual pharmacist may supervise. [Minnesota Statutes 151.102].

Summary of factual data and analytical methodologies: The Board reviewed the statutory changes from 2021 Wisconsin Act 100 and updated Wisconsin Administrative Code Chapters Phar 1, 5, 7, 10 and 19 accordingly.

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

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

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

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

TEXT OF RULE

SECTION 1. Phar 1.01, 1.02 (intro.), and 1.02 (Note) are amended to read:

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

Phar 1.02 (intro.) As used in ch. Par 1 to ~~4719~~.

Phar 1.02 (Note) The board office is located at ~~1400 East Washington Avenue~~ 4822 Madison Yards Way Madison, WI ~~53702~~53705.

SECTION 2. Phar 1.01 (11m) is created to read:

Phar 1.01 (11m) “Pharmacy technician” means a person registered by the board under s. 450.068, Stats.

SECTION 3. Phar 5.07 is created to read:

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

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

SECTION 4. Phar 7.07 (2); 7.14 (title); 7.14 (1) (a), (b) and (d); and 7.14 (2) are amended to read:

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

Phar 7.14 (title) ~~Delegate-check-Delegate~~ Pharmacy Product Verification Technician-check-Pharmacy Technician.

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

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

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

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

SECTION 5. Phar 7.14 (2) (a) is repealed.

SECTION 6. Phar 7.14 (2) (b), (2) (c) 3. and 6., (2) (d) 1. and 2., and (2) (e); 7.14 (3) (a) and (b); 7.14 (4) (a), (b), (b) 1., (c), and (d); 7.14 (5); and 7.14 (6) (a) 1. and 2. are amended to read:

Phar 7.14 (2) (b) Completed an accredited pharmacy technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(2) (c) 3. Eligible ~~medications~~ products for ~~delegate-check-delegate~~ pharmacy product verification technician-check-pharmacy technician.

(2) (c) 6. A practical training designed to assess the competency of the ~~delegate~~ pharmacy technician prior to starting the validation process. The practical training shall include simulation of at least 2 occurrences of each of the following:

(2) (d) 1. The ~~delegate~~ pharmacy technician being validated shall make a product verification on the work of a pharmacist or ~~unlicensed person~~ 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) (d) 2. A pharmacist shall audit 100% of the product verifications made by the ~~delegate~~ pharmacy technician during the validation process.

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

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

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

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

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

(4) (b) 1. Name of the pharmacy product verification ~~delegate~~ technician.

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

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

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

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

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

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

Phar 7.43 (7) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), (gm), or (i), Stats., shall meet the following requirements to remote dispense:

SECTION 8. chapter Phar 7 subchapter V (title) is amended to read:

Subchapter V – Unlicensed Persons Pharmacy Staff

SECTION 9. Phar 7.60 (intro) and (3) are created to read:

Phar 7.60 Definitions. In this subchapter:

Phar 7.60 (3) “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.

SECTION 10. Phar 7.62 (title), (1), (2), (3), (3) (intro.) are amended to read:

Phar 7.62 (title) Unlicensed persons Pharmacy staff.

Phar 7.62 (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f), (g) or (gm), Stats.

Phar 7.62 (2) A pharmacist shall provide ~~general~~ direct supervision of unlicensed ~~personnel~~ pharmacy staff. A pharmacist shall be available to the unlicensed pharmacy staff person for consultation either in person or contact by telecommunication means.

Phar 7.62 (3) An unlicensed pharmacy staff person may not ~~do any of the following:~~ engage in the practice of pharmacy as defined in s. 450.01 (16), Stats., or the practice of a pharmacy technician as defined in Phar 19.02.

SECTION 11. Phar 7.62 (3) (a) to (d) are repealed.

SECTION 12. Phar 7.62 (5), (6), and (7) are amended to read:

Phar 7.62 (5) A managing pharmacist shall provide training to or verify competency of an unlicensed pharmacy staff person prior to the unlicensed pharmacy staff person performing a delegated act.

Phar 7.62 (6) The managing pharmacist shall determine which acts may be delegated in a pharmacy. The managing pharmacist has a duty to notify all pharmacists practicing in that pharmacy which acts may be delegated to specific unlicensed ~~persons~~ pharmacy staff. This record shall be provided to the board upon request.

Phar 7.62 (7) A pharmacist may delegate to an unlicensed pharmacy staff person any delegated act approved by the managing pharmacist pursuant to sub. (3).

SECTION 13. Phar 10.03 (2), (17), and (19) are amended to read:

Phar 10.03 (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 pharmacist or pharmacy technician which harmed or could have harmed a patient;

(17) Having a 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;

(19) Practicing without a current license or registration.

SECTION 14. Chapter Phar 19 is created to read:

Chapter Phar 19

REGISTRATION OF PHARMACY TECHNICIANS

Phar 19.01 Registration. (1) No person may engage in the practice of a pharmacy technician or use the title “pharmacy technician” or “pharmacy tech” unless the person is registered as a pharmacy technician by the Board.

(2) A person applying for a pharmacy technician registration shall satisfy all of the following:

(a) Submit a completed application form.

Note: Instructions for applications are available on the department of safety and professional services’ website at <http://dsps.wi.gov>.

(b) Pay the fee determined by the Department under s. 440.05 (1), Stats.

(c) Subject to ss. 111.321, 111.322, and 111.335, stats., the applicant does not have an arrest or conviction record.

(d) The applicant satisfies one of the following:

1. Is at least 18 years of age and has graduated from high school or has attained high school graduation equivalency as determined by the department of public instruction.
 2. Is enrolled in a youth apprenticeship program for pharmacy technicians that is on the list of youth apprenticeship programs approved by the department of workforce development under s. 106.13 (2m), Stats.
- (3) A person who has applied for a registration as a pharmacy technician and whose practice as a pharmacy technician is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board and during the period before which the board takes final action on the persons application may practice as a pharmacy technician.

Phar 19.02 Scope of Practice. A pharmacy technician may administer vaccines as authorized under s. 450.035 (2h), Stats., perform technical dispensing functions, compounding, packaging, labeling and storage, pharmacy and inventory management, and other activities involved in the practice of pharmacy delegated by a pharmacist. A pharmacy technician may not perform any of the following:

- (1) Except as allowed under Phar 7.14, provide the final verification for the accuracy, validity, completeness, or appropriateness of the filled prescription or medication order.
- (2) Complete the drug utilization review under s. Phar 7.03.
- (3) Administer any prescribed drug products, or devices under s. 450.035 (1t), Stats.
- (4) Provide patient specific counseling or consultation.
- (5) Make therapeutic alternate drug selections.
- (6) Provide supervision to other pharmacy technicians or pharmacy support personnel.

Phar 19.03 Renewal and Reinstatement. (1) RENEWAL.

- (a) A person with an expired pharmacy technician registration may not reapply for a registration using the initial application process.
- (b) A person renewing their pharmacy technician registration shall do all of the following:
 1. Submit a completed renewal application.
Note: Instructions for renewal applications are available on the department of safety and professional services' website at <http://dsps.wi.gov>.
 2. Pay the renewal fee as determined by the department under s. 440.03 (9) (a), Stats. and any applicable late renewal fee.
- (c) Notwithstanding sub. (b), if a pharmacy technician fails to obtain renewal on or before the applicable renewal date, the board may suspend the pharmacy technician's registration.

(2) REINSTATEMENT. A registration holder who has unmet disciplinary requirements and failed to renew the registration within 5 years or whose registration has been surrendered or revoked may apply to have the registration reinstated in accordance with all of the following:

- (a) Evidence of completion of the requirements under s. 19.02 (2).
- (b) Evidence of completion of any disciplinary requirements.

Phar 19.04 Change of Address, Employer, or Name. Pursuant to ss. 440.11 (1) and 450.068 (3), each pharmacy technician shall notify the department of an address change or change of employer within 10 days of the change, and a name change within 30 days of the change.

Note: Instructions for providing notification of address change, change of employer, or a name change are available on the department of safety and professional services' website at <http://dps.wi.gov>.

SECTION 15. Pursuant to 2021 Wisconsin Act 100 section 40 (1), this emergency rule shall take effect upon publication in the official state newspaper and remain in effect until May 1, 2024 or until the date on which permanent rules take effect, whichever is sooner.

(END OF TEXT OF RULE)