

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to create Phar 18, relating to licensure of third-party logistics providers.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.075 (4), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), 450.02 (3) (d), and 450.075 (4), Stats.

Explanation of agency authority:

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

Section 450.02 (3) (a), Stats. Authorizes 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. provides that the board “may promulgate rules necessary for the administration and enforcement of this chapter and Ch. 961.”

Section 450.075 (4), Stats. says: “The board shall promulgate rules implementing this section. The rules shall ensure compliance with the federal drug supply chain security act, 21 USC 360eee, et seq. The board may not promulgate rules that impose requirements more strict than the federal drug supply chain security act or any regulations passed under the federal drug supply chain security act. The board may not promulgate rules that require a license under this section.”

Related statute or rule: Wisconsin Administrative Code Chapter Phar 18

Plain language analysis: The object of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 25.

Summary of, and comparison with, existing or proposed federal regulation:

21 U.S. Code s. 360eee includes national standards for third-party logistics providers. These standards include guidelines for a federal licensure program issued by the Secretary of the U.S. Department of Health and Human Services. This section also includes clarifications for those states that have a licensure program. Third-party logistics providers must either be licensed at the state level, if such a licensure program exists, or federally. On February 4, 2022, the U.S. Food and Drug Administration announced a proposed rule in National Standards for Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers. This rule has not been finalized yet.

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: 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 wholesale distribution in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Wholesale Distribution Act contains requirements for licensure of resident and non-resident third-party logistics providers. In addition to obtaining licensure, each third-party logistics provider must also submit the information of a designated representative responsible for operations at each site [225 Illinois Compiled Statutes ch. 120 s. 25.5].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and include requirements for licensure of third-party logistics providers. In addition to obtaining licensure, each third-party logistics provider must also submit the information of a facility manager responsible for operations at each site [657 Iowa Administrative Code ch. 43].

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 wholesale distribution in Michigan, among several other occupations. Wholesale distributor-brokers serve the same function as third-party logistics providers. In Michigan, wholesale distributor-brokers are required to be licensed and must designate a facility manager or pharmacist-in-charge to be responsible for each site [Michigan Compiled Laws s. 333.17748].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice and wholesale distribution in Minnesota. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes licensure requirements for third-party logistics providers. In Minnesota, the facility manager or designated representative responsible for each third-party logistic provider license cannot have any felony convictions relating to wholesale distribution and

must be fingerprinted as authorized by the Minnesota Board. [Minnesota Statutes s. 151.471].

Summary of factual data and analytical methodologies: The Board reviewed the statutory changes from 2021 Wisconsin Act 25 and added to the Wisconsin Administrative Code accordingly.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis: The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis: The Fiscal Estimate and Economic Impact Analysis is attached.

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

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 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 August 31, 2023, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter Phar 18 is created to read:

CHAPTER PHAR 18
THIRD-PARTY LOGISTICS PROVIDERS

Phar 18.01 Authority. The rules in this chapter are adopted pursuant to the authority delegated by ss. 15.08 (5) (b), 450.02 (3), and 450.075 (4), Stats.

Phar 18.02 Definitions. In this chapter:

- (1) “Designated representative” means an individual who functions on behalf of a third-party logistics provider or an out-of-state third-party logistic provider as specified in Phar 18.05.
- (2) “Facility” has the meaning given in s. 450.01 (11m), Stats.
- (3) “Out-of-state third-party logistics provider” has the meaning given s. 450.01 (13w), Stats.
- (4) “Third-party logistics provider” has the meaning given in s. 450.01 (21s), Stats.

Phar 18.03 Licensure, Renewal, and Reinstatement.

- (1) LICENSE ALLOWED. A person acting as a third-party logistics provider or an out-of-state third-party logistics provider of any drug or device may apply to obtain a license from the board.
- (2) LICENSURE. Except as provided under Phar 18.03 (4), the board shall grant a license to operate as a third-party logistics provider or out-of-state third-party logistics provider, to any applicant that satisfies all of the following requirements, as determined by the Board:
 - (a) The applicant shall submit all of the following:
 1. A completed application form.
Note: Application forms are available from the department of safety and professional services’ website at <http://dsps.wi.gov>.
 2. The fee specified in s. 440.05, Stats.
 3. All of the following information relating to a designated representative:
 - a. Name, address, and telephone number
 - b. Date and place of birth
 - c. A photograph of the person taken within the 12-month period immediately preceding the date of the application
 - d. A personal information statement that includes all of the following for the 7-year period immediately preceding the application:
 - i. Place of residence
 - ii. Occupations, positions of employment, and offices held
 - iii. The name and addresses for each business, corporation or entity listed in subs. ii.
 - iv. Whether the person has been the subject of any proceeding for the revocation of any business or professional licensure and the disposition of that proceeding.
 - v. Whether the person has been enjoined by a court, either temporarily or permanently, from possessing, controlling, or distributing any prescription drug, and a description of the circumstances surrounding the injunction

- vi. A description of any involvement with any business, including investments other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and list of any lawsuits in which such a business was named as a party.
 - e. A description of any misdemeanor or felony criminal offense of which the person was, as an adult, found guilty, whether adjudication of guilt was withheld, or the person pleaded guilty or no contest. If the person is appealing a criminal conviction, the application shall include a copy of the notice of appeal, and the person shall submit a copy of the final disposition of the appeal not more than 15 days after a final disposition is reached.
 - f. Verification that the requirements in Phar 18.05 (1) have been met.
4. A statement that each facility used by the applicant for third-party logistics provider services has been inspected in the 3-year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each such inspection.
- (b) Subject to ss. 111.321, 111.322, and 111.335, Stats., the applicant does not have an arrest or conviction record.
 - (c) Where operations are conducted at more than one facility, a person acting as a third-party logistics provider or out-of-state logistics provider may apply for a license for each such facility.
- (3) RENEWAL. (a) Each license shall be renewed biennially. The renewal date and fee are specified by s. 440.08 (2), Stats.
- (b) Every even-numbered year, each license shall complete a renewal application and return it with the required fee prior to July 1 of that year.
- Note: Instructions for renewal applications can be found on the department of safety and professional services' website at <http://dsps.wi.gov>.
- (4) REINSTATEMENT. A licensee who has unmet disciplinary requirements and failed to renew the license within 5 years or whose license has been surrendered or revoked may apply to have the license reinstated in accordance with all of the following:
- (a) Evidence of completion of the requirements in Phar 18.03 (2) if the license has not been active within 5 years.
 - (b) Evidence of completion of disciplinary requirements, if applicable.
 - (c) Evidence of rehabilitation or change in circumstances warranting reinstatement.

Phar 18.04 Inspections. A third-party logistics provider or out-of-state third-party logistics provider licensed under this chapter shall permit the board or its authorized representatives and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to the third-party logistics provider or out-of-state third-party logistics provider's premises and delivery vehicles.

Phar 18.05 Responsible Persons. (1) DESIGNATED REPRESENTATIVE. The individual acting as the designated representative for a third-party logistics provider or an out-of-state third-party logistics provider shall meet all of the following requirements:

- (a) Be at least 21 years old
- (b) Has been employed full-time for at least three years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing of and distribution of, and recordkeeping related to, prescription drugs.
- (c) Is employed full-time in a managerial position
- (d) Is physically present at the third-party logistics provider's or out-of-state third-party logistics provider's facility during regular business hours This subsection does not preclude the person from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.
- (e) Is actively involved in and aware of the daily operation of the third-party logistics provider or the out-of-state third-party logistics provider.
- (f) Is a designated representative for only one applicant at any given time. This subsection does not apply if more than one third-party logistics provider or out-of-state third-party logistics provider is located at the facility and the third-party logistics provider or out-of-state third-party logistics providers located at the facility are members of an affiliated group.
- (g) Have not been convicted of violating any federal, state, or local law relating to distribution of a controlled substance.
- (h) Has not been convicted of a felony
- (i) Submits to the department 2 fingerprint cards, each bearing a complete set of the person's fingerprints. The department of justice shall provide for the submission of the fingerprint cards to the federal bureau of investigation for purposes of verifying the identity of the person and obtaining the person's criminal arrest and conviction record.

(2) OFFICERS, DIRECTORS AND MANAGERS. A third-party logistics provider or out-of-state third-party logistics provider licensed under this chapter shall maintain a list of officers, directors, and managers, including a description of their duties and a summary of their qualifications.

Phar 18.06 Facility and Storage Requirements. All facilities licensed as third-party logistics providers or out-of-state third-party logistics providers shall ensure the following:

- (1) Maintain access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;
- (2) Have written policies and procedures for all of the following:
 - (a) Address receipt, security, storage, inventory, shipment, and distribution of a product;
 - (b) Identify, record, and report confirmed losses or thefts;
 - (c) Correct errors and inaccuracies in inventories;
 - (d) Provide support for manufacturer recalls;
 - (e) Prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;
 - (f) Ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;
 - (g) Maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and
 - (h) Quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

Phar 18.07 Security Requirements. All facilities shall require the following:

- (1) Access from outside the premises is kept to a minimum and is well controlled;
- (2) The outside perimeter of the premises is well lighted;
- (3) Entry into areas where prescription drugs are held is limited to authorized personnel;
- (4) An alarm system is maintained to detect entry after hours; and
- (5) A security system is maintained that will provide suitable protection against theft and diversion, including, when appropriate, a system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Phar 18.08 Compliance. A licensee who fails to comply with all applicable federal and state laws and regulations shall be subject to disciplinary action by the board under s. 450.10, Stats.

SECTION 2. 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)
