

Chapter Phar 18

THIRD-PARTY LOGISTICS PROVIDERS

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Phar 18.01 Authority and applicability. (1) 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.

(2) Pursuant to s. 450.075 (7) (b), Stats., the rules in this chapter only apply if the Pharmacy Examining Board makes a determination on a biennial basis, that continued licensure by this state of third-party logistics providers is required.

History: CR 23-031: cr. Register June 2024 No. 822, eff. 7-1-24; correction in (2) made under s. 35.17, Stats., Register June 2024 No. 822.

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 s. 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.

History: CR 23-031: cr. Register June 2024 No. 822, eff. 7-1-24; correction in (1) made under s. 35.17, Stats., Register June 2024 No. 822.

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 sub. (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) Submits a completed application form.

Note: Application forms are available from the department of safety and professional services’ website at <http://dps.wi.gov>.

(b) Pays the fee specified in s. 440.05, Stats.

(c) Submits all of the following information relating to a designated representative:

1. Name, address, and telephone number.

2. Date and place of birth.

3. A photograph of the person taken within the 12-month period immediately preceding the date of the application.

4. A personal information statement that includes all of the following for the 7-year period immediately preceding the application:

a. Place of residence.

b. Occupations, positions of employment, and offices held.

c. The name and addresses for each business, corporation, or entity listed in subd. 4. b.

d. Whether the person has been the subject of any proceed-

ing for the revocation of any business or professional licensure and the disposition of that proceeding.

e. 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.

f. 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.

5. 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.

6. Verification that the requirements in s. Phar 18.05 (1) have been met.

7. 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.

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

(2m) MULTIPLE FACILITIES. 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 licensee may elect to renew biennially. Renewal is required to maintain a license issued under this chapter. The renewal date and fee are specified by s. 440.08 (2), Stats.

(b) Every even-numbered year, each licensee 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://dps.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 sub. (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.

History: CR 23-031: cr. Register June 2024 No. 822, eff. 7-1-24; s. 35.17 correction in (2) (intro.), (c) 4. c., 6., (4) (a) made under s. 35.17, Stats., renum. (2m) from (2) (e) under s. 13.92 (4) (b) 1., Stats., and create (2m) (title) under s. 13.92 (4) (b) 2., Stats., Register June 2024 No. 822.

Phar 18.04 Inspections. Pursuant to s. 450.075 (6), Stats., a third-party logistics provider or out-of-state third-party logistics provider regardless of licensure status 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.

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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) Is 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 paragraph 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 paragraph 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) Has 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.

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Phar 18.06 Facility and storage requirements. All facilities licensed as third-party logistics providers or out-of-state third-party logistics providers shall:

(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 to:

(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.

(h) Quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

History: CR 23-031: cr. Register June 2024 No. 822, eff. 7-1-24.

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.

(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.

History: CR 23-031: cr. Register June 2024 No. 822, eff. 7-1-24.

Phar 18.08 Compliance. A third-party logistics provider or an out-of-state third-party logistics provider who elects to be licensed under this chapter and fails to comply with all applicable federal and state laws and regulations may be subject to disciplinary action by the board under s. 450.10, Stats.

History: CR 23-031: cr. Register June 2024 No. 822, eff. 7-1-24.