

State of Wisconsin



2021 Assembly Bill 120

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2021 WISCONSIN ACT 25

AN ACT *to amend* 440.15, 450.01 (11m), 450.01 (21s) and 450.02 (1); and *to create* 440.08 (2) (a) 69g., 450.01 (13w), 450.01 (23) (p) and 450.075 of the statutes; **relating to:** third-party logistics providers, extending the time limit for emergency rule procedures, providing an exemption from emergency rule procedures, and granting rule-making authority.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 440.08 (2) (a) 69g. of the statutes is created to read:

440.08 (2) (a) 69g. Third-party logistics provider: July 1 of each even-numbered year.

SECTION 2. 440.15 of the statutes is amended to read:

440.15 No fingerprinting. Except as provided under ss. 440.03 (13) (c), 441.51 (5) (a) 5., 448.980 (5) (b) 3., and 448.985 (3) (a) 4., 450.071 (3) (c) 9., and 450.075 (3) (c) 9., the department or a credentialing board may not require that an applicant for a credential or a credential holder be fingerprinted or submit fingerprints in connection with the department's or the credentialing board's credentialing.

SECTION 3. 450.01 (11m) of the statutes is amended to read:

450.01 (11m) "Facility" means a location where a wholesale distributor or 3rd-party logistics provider stores, distributes, handles, repackages, or offers for sale other services related to prescription drugs.

SECTION 4. 450.01 (13w) of the statutes is created to read:

450.01 (13w) "Out-of-state 3rd-party logistics provider" means a person located outside this state that

contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services within this state on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

SECTION 5. 450.01 (21s) of the statutes is amended to read:

450.01 (21s) "~~Third-party~~ Third-party logistics provider" means a person that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

SECTION 6. 450.01 (23) (p) of the statutes is created to read:

450.01 (23) (p) The services of a 3rd-party logistics provider or out-of-state 3rd-party logistics provider.

SECTION 7. 450.02 (1) of the statutes is amended to read:

450.02 (1) The department shall keep a record of the proceedings and a register of the names and places of practice or business of pharmacies, manufacturers, wholesale distributors, 3rd-party logistics providers,

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

~~out-of-state 3rd-party logistics providers~~, and other persons licensed under this chapter, and the books, registers and records of the department shall be prima facie evidence of the matters recorded.

SECTION 8. 450.075 of the statutes is created to read:

450.075 Third-party logistics providers; licensure. (1) LICENSE ALLOWED. A person acting as a 3rd-party logistics provider or an out-of-state 3rd-party logistics provider of any drug or device may apply to obtain a license from the board under this section. Where operations are conducted at more than one facility, a person acting as a 3rd-party logistics provider or out-of-state 3rd-party logistics provider may apply to obtain a license from the board for each such facility.

(2) APPLICATION. An applicant for a license under this section shall submit a form provided by the board showing all of the following and swear or affirm the truthfulness of each item in the application:

(a) The name, business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) Names, addresses, and telephone numbers of contact persons for all facilities used by the applicant for the warehousing, distribution, or other services on behalf of the manufacturer of prescription drugs.

(d) The type of ownership or operation for the applicant's business.

(e) If the applicant's 3rd-party logistics provider business is a partnership, the name of each partner and the name of the partnership.

(f) If the applicant's 3rd-party logistics provider business is a corporation, the name of each corporate officer and director, the name of the corporation, and the state of incorporation.

(g) If the applicant's 3rd-party logistics provider business is a sole proprietorship, the name of the sole proprietor and the name of the business entity.

(h) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to warehouse or distribute prescription drugs.

(i) The name, address, and telephone number of a designated representative.

(j) For the person identified as the designated representative in par. (i), a personal information statement that contains all of the following:

1. The person's date and place of birth.

2. The person's place of residence for the 7-year period immediately preceding the date of the application.

3. The person's occupations, positions of employment, and offices held during the 7-year period immediately preceding the date of the application.

4. The name and addresses for each business, corporation, or other entity listed in subd. 3.

5. A statement indicating whether the person has been, during the 7-year period immediately preceding the date of the application, the subject of any proceeding

for the revocation of any business or professional license and the disposition of the proceeding.

6. A statement indicating whether the person has been, during the 7-year period immediately preceding the date of the application, 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.

7. A description of any involvement by the person during the past 7 years 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 a list of any lawsuits in which such a business was named as a party.

8. 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.

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

(k) A statement that each facility used by the applicant for 3rd-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.

(3) LICENSURE. The board shall grant a license to an applicant to act as a 3rd-party logistics provider or an out-of-state 3rd-party logistics provider if all of the following apply:

(a) The applicant pays the fee specified in s. 440.05 (1).

(b) The inspections conducted pursuant to sub. (2) (k) satisfy requirements adopted by the board for 3rd-party logistics providers or out-of-state 3rd-party logistics providers.

(c) All of the following apply to each person identified by the applicant as a designated representative:

1. The person is at least 21 years old.

2. The person has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing of and distribution of, and record keeping related to, prescription drugs.

3. The person is employed by the applicant full time in a managerial position.

4. The person is physically present at the 3rd-party logistics provider's or out-of-state 3rd-party logistics provider's facility during regular business hours and is

involved in and aware of the daily operation of the 3rd-party logistics provider or the out-of-state 3rd-party logistics provider. This subdivision 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.

5. The person is actively involved in and aware of the daily operation of the 3rd-party logistics provider or the out-of-state 3rd-party logistics provider.

6. The person is a designated representative for only one applicant at any given time. This subdivision does not apply if more than one 3rd-party logistics provider or out-of-state 3rd-party logistics provider is located at the facility and the 3rd-party logistics providers or out-of-state 3rd-party logistics providers located at the facility are members of an affiliated group.

7. The person has not been convicted of violating any federal, state, or local law relating to distribution of a controlled substance.

8. The person has not been convicted of a felony.

9. The person submits to the department 2 fingerprint cards, each bearing a complete set of the applicant'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.

(d) The applicant satisfies any other requirements established by the board by rule.

(4) RULES. 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.

(5) ACCESS TO RECORDS. Applications for licensure under this section are not subject to inspection or copying under s. 19.35, and may not be disclosed to any person except as necessary for compliance with and enforcement of the provisions of this chapter.

(6) INSPECTIONS. A 3rd-party logistics provider or an out-of-state 3rd-party logistics provider shall allow the board and authorized federal, state, and local law enforcement officials to enter and inspect its facilities and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law, rule, or regulation.

(7) APPLICABILITY. (a) If the federal government establishes a licensing program for 3rd-party logistics

providers, the board shall evaluate the federal licensing program to determine whether licensing by this state of resident 3rd-party logistics providers is required for a resident 3rd-party logistics provider to provide 3rd-party logistics provider services in another state. If the board determines under this subsection that licensing by this state is not required, this section does not apply.

(b) By 2 years after the effective date of this paragraph ... [LRB inserts date], and biennially thereafter, the board shall evaluate whether continued licensing by this state of resident 3rd-party logistics providers is required for a resident 3rd-party logistics provider to provide 3rd-party logistics provider services in another state and, if the board determines licensing in this state is required, submit to the legislative reference bureau for publication in the Wisconsin Administrative Register a notice continuing the licensing under this section. This section does not apply unless the board submits the notice under this paragraph.

SECTION 9. Nonstatutory provisions.

(1) EMERGENCY RULES RELATED TO 3RD-PARTY LOGISTICS PROVIDERS. The pharmacy examining board may promulgate emergency rules under s. 227.24 implementing s. 450.075. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until June 30, 2023, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 227.24 (1) (a) and (3), the board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.

(2) INTERIM LICENSURE OF 3RD-PARTY LOGISTICS PROVIDERS.

(a) In this subsection, the definitions under s. 450.01 apply.

(b) The board shall grant an interim license to an applicant to act as a 3rd-party logistics provider or an out-of-state 3rd-party logistics provider if, in the opinion of the board, the applicant is currently in compliance with federal law relating to 3rd-party logistics providers. The holder of an interim license under this subsection shall apply for a license under s. 450.075 on or after the date that emergency rules take effect under sub. (1), or the date on which permanent rules take effect, whichever is sooner. An interim license granted under this subsection expires 90 days after the date that emergency rules take effect under sub. (1), or 90 days after the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 440.05, no fee is required for an interim license issued under this subsection.