



State of Wisconsin
2021 - 2022 LEGISLATURE

LRB-2168/1
JPC:skw&amn

2021 ASSEMBLY BILL 120

March 1, 2021 - Introduced by Representative KERKMAN, cosponsored by Senator WANGGAARD. Referred to Committee on Regulatory Licensing Reform.

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

Analysis by the Legislative Reference Bureau

This bill creates an optional license for third-party logistics providers that are located in the state or are located outside the state but provide third-party logistics provider services in the state. A third-party logistics provider is defined under current law as 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.

The bill requires an applicant for a third-party logistics provider license to submit certain information prior to licensure, including proof of a recent facility inspection, and a personal statement relating to a designated representative of the facility. The license created by this bill will no longer apply if the federal Food and Drug Administration establishes a licensing program for third-party logistics providers under federal law and the Pharmacy Examining Board determines that state licensure is not required for a resident third-party logistics provider to provide third-party logistics services in another state.

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The bill also directs the Pharmacy Examining Board to promulgate rules that regulate third-party logistics providers and out-of-state third-party logistics providers consistent with federal law. The authority of the Pharmacy Examining Board to promulgate rules is restricted to only rules that are equivalent to requirements under federal law, and only rules that do not mandate licensing under state law.

The bill requires the Pharmacy Examining Board to issue interim licenses for third-party logistics providers and out-of-state third-party logistics providers between the date of enactment until permanent or emergency rules take effect, whichever is sooner, if, in the opinion of the board, the applicant is currently in compliance with federal law relating to third-party logistics providers. An interim license to act as a third-party logistics provider or out-of-state third-party logistics provider expires 90 days after the date that emergency rules take effect, or 90 days after the date that permanent rules take effect, whichever is sooner. No fee is required for a holder of an interim license to act as a third-party logistics provider or an out-of-state third-party logistics provider.

Finally, the bill requires third-party logistics providers, whether or not licensed under the bill, to cooperate with inspections of their facilities and delivery vehicles.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

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

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

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

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

5 **440.15 No fingerprinting.** Except as provided under ss. 440.03 (13) (c),
6 441.51 (5) (a) 5., 448.980 (5) (b) 3., and 448.985 (3) (a) 4., 450.071 (3) (c) 9., and 450.075
7 (3) (c) 9., the department or a credentialing board may not require that an applicant
8 for a credential or a credential holder be fingerprinted or submit fingerprints in
9 connection with the department's or the credentialing board's credentialing.

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

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1 450.01 (11m) “Facility” means a location where a wholesale distributor or
2 3rd-party logistics provider stores, distributes, handles, repackages, or offers for
3 sale other services related to prescription drugs.

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

5 450.01 (13w) “Out-of-state 3rd-party logistics provider” means a person
6 located outside this state that contracts with a prescription drug manufacturer to
7 provide or coordinate warehousing, distribution, or other services within this state
8 on behalf of the manufacturer but that does not take title to the manufacturer’s
9 prescription drug or have general responsibility to direct the prescription drug’s sale
10 or disposition.

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

12 450.01 (21s) “Third party Third-party logistics provider” means a person that
13 contracts with a prescription drug manufacturer to provide or coordinate
14 warehousing, distribution, or other services on behalf of the manufacturer but that
15 does not take title to the manufacturer’s prescription drug or have general
16 responsibility to direct the prescription drug’s sale or disposition.

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

18 450.01 (23) (p) The services of a 3rd-party logistics provider or out-of-state
19 3rd-party logistics provider.

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

21 450.02 (1) The department shall keep a record of the proceedings and a register
22 of the names and places of practice or business of pharmacies, manufacturers,
23 wholesale distributors, 3rd-party logistics providers, out-of-state 3rd-party
24 logistics providers, and other persons licensed under this chapter, and the books,

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1 registers and records of the department shall be prima facie evidence of the matters
2 recorded.

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

4 **450.075 Third-party logistics providers; licensure. (1) LICENSE ALLOWED.**

5 A person acting as a 3rd-party logistics provider or an out-of-state 3rd-party
6 logistics provider of any drug or device may apply to obtain a license from the board
7 under this section. Where operations are conducted at more than one facility, a
8 person acting as a 3rd-party logistics provider or out-of-state 3rd-party logistics
9 provider may apply to obtain a license from the board for each such facility.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 5. A statement indicating whether the person has been, during the 7-year
14 period immediately preceding the date of the application, the subject of any
15 proceeding for the revocation of any business or professional license and the
16 disposition of the proceeding.

17 6. A statement indicating whether the person has been, during the 7-year
18 period immediately preceding the date of the application, enjoined by a court, either
19 temporarily or permanently, from possessing, controlling, or distributing any
20 prescription drug, and a description of the circumstances surrounding the
21 injunction.

22 7. A description of any involvement by the person during the past 7 years with
23 any business, including investments other than the ownership of stock in a publicly
24 traded company or mutual fund, that manufactured, administered, prescribed,

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1 distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits
2 in which such a business was named as a party.

3 8. A description of any misdemeanor or felony criminal offense of which the
4 person was, as an adult, found guilty, whether adjudication of guilt was withheld or
5 the person pleaded guilty or no contest. If the person is appealing a criminal
6 conviction, the application shall include a copy of the notice of appeal, and the person
7 shall submit a copy of the final disposition of the appeal not more than 15 days after
8 a final disposition is reached.

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

11 (k) A statement that each facility used by the applicant for 3rd-party logistics
12 provider services has been inspected in the 3-year period immediately preceding the
13 date of the application by the board, a pharmacy examining board of another state,
14 the National Association of Boards of Pharmacy, or another accrediting body
15 recognized by the board, with the date of each such inspection.

16 **(3) LICENSURE.** The board shall grant a license to an applicant to act as a
17 3rd-party logistics provider or an out-of-state 3rd-party logistics provider if all of
18 the following apply:

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

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

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

25 1. The person is at least 21 years old.

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

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

5 4. The person is physically present at the 3rd-party logistics provider's or
6 out-of-state 3rd-party logistics provider's facility during regular business hours
7 and is involved in and aware of the daily operation of the 3rd-party logistics provider
8 or the out-of-state 3rd-party logistics provider. This subdivision does not preclude
9 the person from taking authorized sick leave and vacation time or from being absent
10 from the facility for other authorized business or personal purposes.

11 5. The person is actively involved in and aware of the daily operation of the
12 3rd-party logistics provider or the out-of-state 3rd-party logistics provider.

13 6. The person is a designated representative for only one applicant at any given
14 time. This subdivision does not apply if more than one 3rd-party logistics provider
15 or out-of-state 3rd-party logistics provider is located at the facility and the
16 3rd-party logistics providers or out-of-state 3rd-party logistics providers located at
17 the facility are members of an affiliated group.

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

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

21 9. The person submits to the department 2 fingerprint cards, each bearing a
22 complete set of the applicant's fingerprints. The department of justice shall provide
23 for the submission of the fingerprint cards to the federal bureau of investigation for
24 purposes of verifying the identity of the person and obtaining the person's criminal
25 arrest and conviction record.

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

3 (4) RULES. The board shall promulgate rules implementing this section. The
4 rules shall ensure compliance with the federal drug supply chain security act, 21
5 USC 360eee, et seq. The board may not promulgate rules that impose requirements
6 more strict than the federal drug supply chain security act, or any regulations passed
7 under the federal drug supply chain security act. The board may not promulgate
8 rules that require a license under this section.

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

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

18 (7) APPLICABILITY. This section does not apply if the board determines that the
19 federal food and drug administration has established a licensing program for
20 3rd-party logistics providers under 21 USC 360eee-3 and that licensing by this state
21 of resident 3rd-party logistics providers is not required for a resident 3rd-party
22 logistics provider to provide 3rd-party logistics provider services in another state.

23 **SECTION 9. Nonstatutory provisions.**

24 (1) EMERGENCY RULES RELATED TO 3RD-PARTY LOGISTICS PROVIDERS. The pharmacy
25 examining board may promulgate emergency rules under s. 227.24 implementing s.

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1 450.075. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated
2 under this subsection remain in effect until June 30, 2023, or the date on which
3 permanent rules take effect, whichever is sooner. Notwithstanding s. 227.24 (1) (a)
4 and (3), the board is not required to provide evidence that promulgating a rule under
5 this subsection as an emergency rule is necessary for the preservation of the public
6 peace, health, safety, or welfare and is not required to provide a finding of emergency
7 for a rule promulgated under this subsection.

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

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

10 (b) The board shall grant an interim license to an applicant to act as a 3rd-party
11 logistics provider or an out-of-state 3rd-party logistics provider if, in the opinion of
12 the board, the applicant is currently in compliance with federal law relating to
13 3rd-party logistics providers. The holder of an interim license under this subsection
14 shall apply for a license under s. 450.075 on or after the date that emergency rules
15 take effect under sub. (1), or the date on which permanent rules take effect,
16 whichever is sooner. An interim license granted under this subsection expires 90
17 days after the date that emergency rules take effect under sub. (1), or 90 days after
18 the date on which permanent rules take effect, whichever is sooner.
19 Notwithstanding s. 440.05, no fee is required for an interim license issued under this
20 subsection.

21 (END)