



State of Wisconsin  
2019 - 2020 LEGISLATURE

LRB-6588/P1  
JPC:cdc

**PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION**

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.

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***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.

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.

Finally, this 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.

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***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:

11          450.01 (11m) "Facility" means a location where a wholesale distributor or  
12 3rd-party logistics provider stores, distributes, handles, repackages, or offers for  
13 sale other services related to prescription drugs.

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

15          450.01 (13w) "Out-of-state 3rd-party logistics provider" means a person  
16 located outside this state that contracts with a prescription drug manufacturer to

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

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

6 450.01 (21s) "~~Third-party~~ Third-party logistics provider" means a person that  
7 contracts with a prescription drug manufacturer to provide or coordinate  
8 warehousing, distribution, or other services on behalf of the manufacturer but that  
9 does not take title to the manufacturer's prescription drug or have general  
10 responsibility to direct the prescription drug's sale or disposition.

\*\*\*NOTE: Amended the term to be consistent with federal law.

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

12 450.01 (23) (p) The services of a 3rd-party logistics provider or out-of-state  
13 3rd-party logistics provider.

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

15 450.02 (1) The department shall keep a record of the proceedings and a register  
16 of the names and places of practice or business of pharmacies, manufacturers,  
17 wholesale distributors, 3rd-party logistics providers, out-of-state 3rd-party  
18 logistics providers, and other persons licensed under this chapter, and the books,  
19 registers and records of the department shall be prima facie evidence of the matters  
20 recorded.

\*\*\*NOTE: "Distributor" is an obsolete term under ch. 450. "Wholesale distributors"  
references wholesale distributors under ss. 450.071 to 450.074.

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

22 **450.075 Third-party logistics providers; licensure. (1) LICENSE ALLOWED.**

23 A person acting as a 3rd-party logistics provider or an out-of-state 3rd-party

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

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

\*\*\*\*NOTE: The following application requirements were adopted from the licensure requirements of wholesale distributors under s. 450.071. Is this consistent with your intent? Do you want any changes to the application requirements?

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

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

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

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

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

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

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

21 (h) A list of all licenses and permits issued to the applicant by any other state  
22 that authorizes the applicant to warehouse or distribute prescription drugs, or to  
23 provide 3rd-party logistics services.

- 1 (i) The name, address, and telephone number of a designated representative.
- 2 (j) For the person identified as the designated representative in par. (i), a  
3 personal information statement that contains all of the following:
- 4 1. The person's date and place of birth.
  - 5 2. The person's place of residence for the 7-year period immediately preceding  
6 the date of the application.
  - 7 3. The person's occupations, positions of employment, and offices held during  
8 the 7-year period immediately preceding the date of the application.
  - 9 4. The name and addresses for each business, corporation, or other entity listed  
10 in subd. 3.
  - 11 5. A statement indicating whether the person has been, during the 7-year  
12 period immediately preceding the date of the application, the subject of any  
13 proceeding for the revocation of any business or professional license and the  
14 disposition of the proceeding.
  - 15 6. A statement indicating whether the person has been, during the 7-year  
16 period immediately preceding the date of the application, enjoined by a court, either  
17 temporarily or permanently, from possessing, controlling, or distributing any  
18 prescription drug, and a description of the circumstances surrounding the  
19 injunction.
  - 20 7. A description of any involvement by the person during the past 7 years with  
21 any business, including investments other than the ownership of stock in a publicly  
22 traded company or mutual fund, that manufactured, administered, prescribed,  
23 distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits  
24 in which such a business was named as a party.

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

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

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

14           **(3) LICENSURE.** The board shall grant a license to an applicant to act as a  
15 3rd-party logistics provider or an out-of-state 3rd-party logistics provider if all of  
16 the following apply:

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

          \*\*\*\*NOTE: This is the standard credential fee that applies to most initial  
applications for credentials. DSPS sets the fees for these credentials, subject to JCF  
approval.

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

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

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

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.

1           **(4) RULES.** The board shall promulgate rules implementing this section. The  
2 rules shall ensure compliance with the federal drug supply chain security act, 21  
3 USC 360eee, et seq. The board may not promulgate rules that impose requirements  
4 more strict than the federal drug supply chain security act, or any regulations passed  
5 under the federal drug supply chain security act, except for rules related to  
6 inspections of facilities and delivery vehicles, and the board may not promulgate  
7 rules that require a license under this section.

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

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

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

      \*\*\*\*NOTE: State law requires wholesale distributors to provide a bond to the board.  
Do you want a similar requirement for 3PLs?

22           **SECTION 9. Nonstatutory provisions.**



