

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 18

Relating to: Licensure of third-party logistics providers.

Rule Type: Permanent and Emergency

1. Finding/nature of emergency (Emergency Rule only):

2021 Act 25, Section 9 (1) provides:

“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. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to revise the Pharmacy administrative code consistent with 2021 Act 25 to provide criteria for the Wisconsin licensure of third-party logistics providers.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

The Board intends to update the Pharmacy code to bring it into alignment with the statutory provisions enacted by 2021 Act 25 relating to licensure of third-party logistics providers.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

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.”

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

Approximately 100 hours.

6. List with description of all entities that may be affected by the proposed rule:

Pharmacies, pharmacists, licensed third-party logistics providers, those seeking licensure as a third-party logistics provider, and consumers of pharmaceuticals.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

The rules will comply with the federal drug supply chain security act, 21 USC 360eee, et seq., which establishes national standards for third-party logistics providers.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

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