STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
June 20, 2023

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 18

4. Subject
Licensure of Third-Party Logistics Providers

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
s. 20.165 (1) (g)

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☒ Increase Existing Revenues ☒ Increase Costs ☐ Decrease Costs
☒ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 25

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule was posted for 14 days on the Department of Safety and Professional Services' website to solicit comments on the potenetial economic impact. No comments were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
The rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole. The Department of Safety and Professional Services estimates a total of $15,700 in one-time costs to implement the rule. Ongoing costs to license Third-Party Logistics Providers are estimated at $400 annually. The estimated costs may not be absorbed in the agency budget. Additional appropriation authority is needed to expend collected fees to support estimated expenditures for administration of the new license type.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefits to implementing this rule are clear and specific rules for third-party logistics provider licensure in the state of Wisconsin. The alternative to implementing the rule is to continue to relay on the statute for regulation of third-party logistics providers.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are the availability of a third-party logistics provider license at the state level in Wisconsin.

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17. Compare With Approaches Being Used by Federal Government

1 U.S. Code s. 360eee includes national standards for third-party logistics providers. These standards include guidelines for a federal licensure program issued by the Secretary of the U.S. Department of Health and Human Services. This section also includes clarifications for those states that have a licensure program. Third-party logistics providers must either be licensed at the state level, if such a licensure program exists, or federally. On February 4, 2022, the U.S. Food and Drug Administration announced a proposed rule in National Standards for Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers. This rule has not been finalized yet.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of wholesale distribution in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Wholesale Distribution Act contains requirements for licensure of resident and non-resident third-party logistics providers. In addition to obtaining licensure, each third-party logistics provider must also submit the information of a designated representative responsible for operations at each site [225 Illinois Complied Statutes ch. 120 s. 25.5].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and include requirements for licensure of third-party logistics providers. In addition to obtaining licensure, each third-party logistics provider must also submit the information of a facility manager responsible for operations at each site [657 Iowa Administrative Code ch. 43].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for wholesale distribution in Michigan, among several other occupations. Wholesale distributor-brokers serve the same function as third-party logistics providers. In Michigan, wholesale distributor-brokers are required to be licensed and must designate a facility manager or pharmacist-in-charge to be responsible for each site [Michigan Compiled Laws s. 333.17748].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice and wholesale distribution in Minnesota. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes licensure requirements for third-party logistics providers. In Minnesota, the facility manager or designated representative responsible for each third-party logistic provider license cannot have any felony convictions relating to wholesale distribution and must be fingerprinted as authorized by the Minnesota Board. [Minnesota Statutes s. 151.471].

19. Contact Name	20. Contact Phone Number
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ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes ☐ No