

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

<p>1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected</p>	<p>2. Date September 29, 2023</p>
<p>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) Phar 1, 5, 6, 7, and 8 - Permanent Rule</p>	
<p>4. Subject Remote Dispensing</p>	
<p>5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S</p>	<p>6. Chapter 20, Stats. Appropriations Affected s. 20.165 (1) (g)</p>
<p>7. Fiscal Effect of Implementing the Rule <input type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input checked="" type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input checked="" type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget</p>	
<p>8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input checked="" type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)</p>	
<p>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0</p>	
<p>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)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>11. Policy Problem Addressed by the Rule These rules implement the statute changes from 2021 Wisconsin Act 101. The Board also added a definition of pharmacy graduates, and modified requirements to allow them to practice pharmacy while waiting for their license to be granted.</p>	
<p>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 will be posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.</p>	
<p>13. Identify the Local Governmental Units that Participated in the Development of this EIA. None.</p>	
<p>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) DSPS estimates a total of \$8,900 in one-time costs and \$2,800 in annual costs for staffing and an indeterminate IT impact to implement the rule. This rule permanently implements the statutory changes from the 2021 Wisconsin Act 101. The estimated one-time staffing need for .1 limited term employees (LTE) is for staff training, forms and sites updates, and developing reference materials to reflect new statutory provisions. The estimated annual staffing need addresses an increase in questions and workload related to processing submitted applications for the department, the applicant, and the call center, as well as necessary board coordination to implement the rule. The one-time and annual estimated costs cannot be absorbed in the currently appropriated agency budget.</p>	
<p>15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefits of implementing this rule are that the Pharmacy Examining Board's sections of the Administrative Code will be aligned with Wisconsin State Statutes.</p>	
<p>16. Long Range Implications of Implementing the Rule</p>	

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

The long range implications of implementing this rule are clear rules for remote dispensing for pharmacies in Wisconsin.

17. Compare With Approaches Being Used by Federal Government

The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

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 Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains requirements for pharmacy licensure and dispensing. There is a provision that allows a pharmacy that is not in the same location as its home pharmacy, and services are being provided during an emergency situation, to operate as an emergency remote pharmacy. The Illinois Department of Financial and Professional Regulation may also waive the requirement for a pharmacist to be on duty at all times for state facilities that are not treating human ailments. Additionally, automated pharmacy systems operated from a remote site must be under continuous supervision of a pharmacist however, that pharmacist is not required to be physically present if they can monitor the system electronically [225 Illinois Compiled Statutes ch. 85 s. 15 and 22b]. The Illinois Department of Financial and Professional Regulation is also responsible for the promulgation of rules to implement certain sections of the Illinois Pharmacy Practice Act. These rules in the Illinois Administrative Code include definitions for “emergency situation” and what is required in order to operate an emergency remote temporary pharmacy [Illinois Administrative Code s. 1330.420].

In Illinois, graduate of a pharmacy program approved by the Illinois Department of Financial and Professional Regulation may be registered as a pharmacy technician with the “student pharmacist” designation, if they have graduated from said program within the last 18 months. Student pharmacists are allowed to practice pharmacy under the supervision of a pharmacist [225 Illinois Compiled Statutes ch. 85 s. 9 (c)].

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 remote dispensing in hospital pharmacies. Additionally, a pharmacist is required to be onsite at a telepharmacy site for at least 16 hours per month and can otherwise monitor the site remotely. The telepharmacy site is a separate licensure category from a correctional, hospital, nuclear, or general pharmacy site. If the average number of prescriptions dispensed per day exceeds 150 at a telepharmacy site, the pharmacist is required to be on site 100 percent of the time and the site must apply for licensure as a general pharmacy [657 Iowa Administrative Code sections 7.7 and 13.9 (6)].

In Iowa, graduates of a college of pharmacy approved by the Iowa Board can register as a “pharmacist-intern.” Pharmacist-interns are required to practice under the supervision of a licensed pharmacist. This registration automatically terminates upon the pharmacist-intern receiving “licensure to practice pharmacy in any state, lapse in the pursuit of a degree in pharmacy, or one year following graduation from the college of pharmacy,” whichever happens sooner [657 Iowa Administrative Code sections 4.1 and 4.6 (3)].

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 pharmacy in Michigan, among several other occupations. Unless at a mental health facility or hospital, remote pharmacies cannot be located within 10 miles of another pharmacy, unless a waiver is granted by the Michigan Board. A pharmacist is required to oversee a remote pharmacy; however, a qualified pharmacy technician must be on site at all times that the pharmacy is

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

open if the pharmacist in charge is not physically present. A Pharmacist may not be responsible for more than three remote pharmacy sites at any one time [Michigan Compiled Laws s. 333.17742a and b].

In Michigan, pharmacy graduates can apply for an educational limited license if they are within 180 days of completing an approved educational program. Pharmacy graduates practicing under an educational limited license may only do so under the “personal charge of a pharmacist” [Michigan Administrative Code R 338.513].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Part 6800 of the Minnesota Administrative Code includes the regulations for pharmacy in Minnesota. [Minnesota Administrative Rules part 6800]. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes pharmacy regulations. According to Section 34 (10) of this chapter, it is unlawful to run a pharmacy without a pharmacist in charge. Operation of a pharmacy without a pharmacist present and on duty is only allowed under an approved variance by the Board. [Minnesota Statutes 151.34 (10), 151.071 (2) (13)].

In Minnesota, pharmacy graduates can apply for a “pharmacist-intern” registration if they are a graduate of a pharmacy college approved by the Minnesota Board. Pharmacist interns must practice under the direct supervision of a licensed pharmacist [Minnesota Administrative Rules Chapter 6800 Parts 5100-5600].

19. Contact Name

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20. Contact Phone Number

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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
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