

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 26 December 2019</p>
<p>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) Phar 6</p>	
<p>4. Subject Storage</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 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 type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input checked="" 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 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). \$0.00</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 type="checkbox"/> No</p>	
<p>11. Policy Problem Addressed by the Rule With health care evolving, there are different types of pharmacies and some may not require the specific items in the current rule. In addition, stakeholders raised concerns they had in implementing CR 16-073 (specifically maintaining temperature and humidity provisions).</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. This rule was posted for economic comments and none were received.</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) There is no economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units and the State's economy as a whole.</p>	
<p>15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit is having a rule which works for the changes in health care and allows for different types of pharmacies. In addition, it is a benefit for all to have a rule which allows for achievable humidity and temperature requirements in pharmacies.</p>	
<p>16. Long Range Implications of Implementing the Rule The long range implication of implementing the rule is have a rule which works for everyone.</p>	
<p>17. Compare With Approaches Being Used by Federal Government None</p>	
<p>18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)</p>	

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Illinois: Illinois requires all pharmacies and equipment in the pharmacy to be maintained in a clean condition and in good repair. Illinois does require a sink to be required in all pharmacies that maintain drug inventory. Refrigeration shall be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

Iowa: Iowa requires effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program.

Michigan: Michigan requires all prescription drugs to be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings. Michigan requires a pharmacy to have necessary drawers, shelves, storage cabinets, prescription files, a sink with hot and cold running water and a refrigerator of reasonable capacity. In Michigan, controlled substances are required to be stored in a securely locked, substantially constructed cabinet, room, or cart or they may be dispersed throughout the stock of noncontrolled substances in a manner to obstruct the theft or diversion of controlled substances.

Minnesota: Minnesota requires a refrigerator and a sink with hot and cold running water. The refrigerator designated for drug storage shall have a manual, electromechanical, or electronic temperature recording equipment, devices, or logs to document proper storage of legend drugs every business day.

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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
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