

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Original Updated Corrected

2. Administrative Rule Chapter, Title and Number

Phar 6.075

3. Subject

Temperature and humidity in pharmacies

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected

20.165(1)(g)

6. Fiscal Effect of Implementing the Rule

No Fiscal Effect Increase Existing Revenues Increase Costs
 Indeterminate Decrease Existing Revenues Could Absorb Within Agency's Budget
 Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

State's Economy Specific Businesses/Sectors
 Local Government Units Public Utility Rate Payers
 Small Businesses (if checked, complete Attachment A)

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes No

9. Policy Problem Addressed by the Rule

Currently there are not rules relating to the temperature and humidity requirements for a pharmacy. Pharmaceuticals need to be stored, compounded or maintained in the correct environment in order to ensure the product quality, safety and efficiency.

10. 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 impact comments for 14 days and none were received.

11. Identify the local governmental units that participated in the development of this EIA.

None.

12. 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)

This rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units and the state's economy as a whole.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The proposed rule addresses the temperature and humidity requirements for pharmacies to ensure the integrity of the pharmaceuticals prior to dispensing.

14. Long Range Implications of Implementing the Rule

The rules would ensure the pharmaceuticals are stored, compounded or maintained in the correct environment.

15. Compare With Approaches Being Used by Federal Government

None

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

Illinois requires pharmacies to maintain temperature within the proper storage of drugs. Iowa does not have rules regarding temperature or humidity for pharmacies but does for wholesale pharmacies. Michigan and Minnesota do not have rules relating to temperature or humidity of pharmacies.

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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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