STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R03/2012)

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

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

2. Administrative Rule Chapter, Title and Number
Phar 15

3. Subject
Compounding Pharmaceuticals

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
This rule repeals and recreates the requirements for compounding pharmaceuticals.

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 comments for 30 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 impact on public utility rate payers, local governmental units or the State's economy. The Board does not know how many or which pharmacies are compounding sterile pharmaceuticals, therefore, is unable to determine whether this rule will have an economic impact on specific businesses.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit to the rule is to update the standards of compounding in the state of Wisconsin. The Board primarily utilized the United States Pharmaceopeia chapters 795 and 797 which are the recognized pharmacopeial standards. The Board also reviewed several other states which have updated their compounding rules since the New England Compounding Center meningitis outbreak in 2012.
The alternative to the rule is to maintain the current rules which do not adequately protect the public from harm.

14. Long Range Implications of Implementing the Rule
The long range benefit is the safe compounded pharmaceutical products.

15. Compare With Approaches Being Used by Federal Government
None. The federal government does regulate outsourcing facilities.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Illinois: Illinois requires a specific area for compounding; records to be kept of each compounded prescription and the

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components; reference books; and a pharmacy operations manual with policies and procedures pertinent to the complexity and size of the compounding operations. The pharmacy may compound drug products to be sued by practitioners in their office for administration to patients. Sterile compounding requires: a designated area of sufficient size to accommodate a laminar airflow hood, barrier isolation chamber and proper storage of drugs and supplies; the laminar airflow hood shall be certified annually; sink with hot and cold water; refrigerator and/or freezer with a thermometer or temperature recording device; current resource materials and texts; patient profile or medication system; specific labeling requirements including beyond use date and time; and compounding records are to be maintained for 5 years.

Iowa: Iowa requires compliance with United States Pharmacopeia, Chapters 795 and 797. In addition, an FDA registered outsourcing facility must be licensed as a pharmacy in Iowa.

Michigan: Michigan requires a pharmacy that provides compounding services to be licensed as a pharmacy and authorized to provide compounding services. The pharmacy must be accredited by the Pharmacy Compounding Accreditation Board and be in compliance with United States Pharmacopeia standards. In addition, any outsourcing facility must be licensed as a pharmacy in Michigan.

Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow United States Pharmacopeia, chapter 795 standards and pharmacies compounding sterile drug preparations to follow United States Pharmacopeia, chapter 797 standards.

17. Contact Name	18. 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