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
12/09/24

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 15

4. Subject
Compounding Pharmaceuticals

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

6. Chapter 20, Stats. Appropriations Affected
s20.165 (1) (hg)

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 Pharmacy Examining Board recently completed a revision to Wisconsin Administrative Code Chapter Phar 15 which became effective on August 1, 2022. The objective of this rule is to repeal and recreate the recent version of Phar 15 to incorporate by reference United States Pharmaceopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020

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 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. 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)
DSPS estimates a total of $5,955.00 in one-time costs for implementing this rule. The one-time staff costs support 0.1 limited term employee to undertake tasks such as rule drafting, regal review, training on new rules, and updating forms and website.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is that there will be clear and up to date standards fo pharmaceutical compounding, safe handling of hazardous drugs, and radiopharmaceuticals in Pharmacy practice.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are increased safety in pharmacy practice in Wisconsin .

17. Compare With Approaches Being Used by Federal Government

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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.The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, labeling requirements and may distribute compounded drugs in response to an order that is not patient specific. The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions..

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

Illinois: For patient-specific prescriptions, sterile and unsterile pharmaceutical compounding is governed by the USP 42-NF 37 from the 2019 USP Compounding Compendium, except for USP Chapter 800. Additionally, all pharmacies that compound drugs must maintain a set of minimum standards and equipment. These requirements include a specific area for compounding materials, accurate scales or measuring equipment, a separate area for compounding, a record keeping system for tracking compounded drugs, drug distribution procedures, and labelling. Additional requirements for sterile compounding include current reference materials, pharmacist availability at all times to answer patient and health care professional questions, and emergency medications for adverse drug reactions to compounded sterile drugs. [Illinois Administrative Code s. 1330.640]. In Illinois, the definition of "compounding" excludes flavorings [225 Illinois Compiled Statutes 85 s. 3 (o)].

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. Additionally, Iowa includes requirements for the use of flavoring agents. These requirements include that pharmacist may add flavoring in the amount of not more than percent of the total volume of the drug. The beyond-use date of the flavored drug must be no greater than 14 days and the pharmacist must document that a flavoring agent was added ot a drug. Compliance with USP Chapter 825 is not required, however Iowa does have its own rules for radiopharmaceuticals and nuclear pharmacy [Iowa Administrative Code ss.657.16 and 657.20].

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 through a national accrediting organization and be in compliance with USP standards [Michigan Compiled Laws s. 333.17748a to c]. In Michigan, the definition of "compounding" does not include flavoring agents that are nonallergenic, inert, and not more than 5% of the drug's total volume [Michigan Administrative Rules R 338.501 (1) (e)].

Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow USP chapter 795 standards. Pharmacies compounding sterile drug preparations are required to follow USP chapter 797 standards. [Minnesota Administrative Rules s.6800.3300]

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