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
09/01/21

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 8

4. Subject
Requirements for Controlled Substances

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

6. Chapter 20, Stats. Appropriations Affected
20.165(1)(g)

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 objective of the proposed rule is to complete a comprehensive review of Phar 8, Requirements for Controlled Substances and make revisions to ensure the chapter is statutorily compliant with state and federal law and are current with professional standards and practices.

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 for 14 days on the Department of Safety and Professional Services' website to solicit comments on the potential economic impact. 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)
No econonmic or fiscal impacts are anticipated for specific businesses, business sectors, public utility rate payers, local governmental units, or the state's economy as a whole. A total of $1,107.54 in one time costs are anticipated to be absorbed within the operating budget of the Department of Safety and Professional Services.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The Board intends to modernize Phar 8 to bring it in line with current pharmacy standards and practices. The Board will evaluate reducing the regulatory impact on pharmacies without negatively impacting public safety. The board will also incorporate minimum standards to prevent controlled substance diversion.

16. Long Range Implications of Implementing the Rule
This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. The rule project simplifies recordkeeping requirements for controlled substances, removes restrictions on receipt of prescriptions via facsimile machine, partial dispensing, renewals, labeling, and emergency kits in long-term care facilities.

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.

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

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.600 to 68/1330.800 outlines requirements for pharmacy standards and pharmacy operations. Illinois law requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA (IL 68/1330.710). Illinois administrative rule requires that inventory of controlled substances be done annually, with an exact count for Schedule II drugs and an approximation for Schedule III and IV. Illinois also requires that a record of all written prescription orders received and verbal prescriptions filled, compounded or dispensed for controlled substances be retained for at least 5 years (IAC 3100.360). Illinois also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. There does not appear to be a requirement that the prescriber follow up with a written prescription (IAC 3100.400).

Iowa: The Iowa Pharmacy Board requires a pharmacy to maintain controlled substance records for at least 2 years and to segregate Schedule I and II drug records from other controlled substance records (Iowa Admin. Code 657-10.36). Iowa also requires that pharmacies keep a perpetual inventory of all Schedule II drugs on hand (Iowa Admin. Code 657-10.18). Iowa only requires a pharmacist to report theft or loss of controlled substances to the Pharmacy Board if there is reason to believe that the theft was committed by a pharmacy board licensee, otherwise it is sufficient to merely report to the DEA (Iowa Admin. Code 657-10.21). Iowa also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Iowa Admin. Code 657-10.26).

Michigan: Michigan requires theft or diversion of a controlled substance to be reported to the DEA within 10 days. There does not appear to be a separate requirement to report it to the Pharmacy Board (Mich. R 338.3141). Inventory must be taken of all controlled substances at least annually (Mich. R 338.3151 and 338.3152). Controlled substance records must be retained for at least 5 years, with the first 3 in hard copy form and in the last 2 may be kept electronically. Michigan also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Michigan R 338.3164 and 338.3165).

Minnesota: Minnesota requires a perpetual inventory of Schedule II substances which must be reconciled monthly (Minn. Admin. Code 6800.4600). Pharmacists must report loss or theft of controlled substances to the DEA immediately. There is no requirement that a separate report be made to the state (Minn. Admin. Code 6800.4800). All prescription information must be maintained for at least 2 years (Minn. Admin. Code 6800.3100).

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	608-267-7139

This document can be made available in alternate formats to individuals with disabilities upon request.

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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