STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	**:**	**REPORT TO THE LEGISLATURE CR 22-007**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

The objective of the rule is to review the updated United States Pharmacopeia (USP) 795 and 797 standards, which originally had a publication date of June 1, 2019 with an anticipated official date of December 1, 2019. However, due to appeals filed, the 2019 revisions of the USP are currently on hold. The 2008 USP 795 and 797 are the current standard for pharmacy compounding until those 2019 standards are published and effective.

Even though the Board will not be moving forward with the 2019 revisions at this time, there are still updates that need to be made to Phar 15 to align it with the 2008 USP 795 and 797 chapters that are currently in effect. It is the Board's intent to amend Phar 15 without creating an unnecessary burden on Wisconsin pharmacies, while still aligning it with the current USP chapters. When new updated standards are available, the Board will consider opening a new scope statement to address any further changes if applicable.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Pharmacy Examining Board held a public hearing on February 14, 2022. The following people either testified at the hearing, or submitted written comments:

- Richard L. Green, BS Pharm, R.Ph., BCNP, FAPhA, Director of Radiopharmacy Practice, Cardinal Health Nuclear & Precision Health Solutions
- John Long, R.Ph., MBA, Director Regulatory Affairs, CVS Health
- Danielle Womack, Vice President of Public Affairs, Pharmacy Society of Wisconsin

- Brian L. Koenig, PE, MBA, CNBT, Technical Safety Services

The Pharmacy Examining Board summarizes the comments received either by hearing testimony or by written submission as follows:

- Cardinal Health Nuclear & Precision Health Solutions provided a summary of the practice of nuclear pharmacy in Wisconsin. They also highlighted the recent addition of USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging, which outlines nuclear pharmacy standards for compounding previously covered in USP General Chapter <797>. Finally, they encouraged the Board to write regulations requiring that Wisconsin nuclear pharmacists follow USP General Chapter <825>.
- CVS Health provided comments that there is confusion over the objective of the rule change, as well as the mix of terminology between the currently effective 2008 USP General Chapter <797>, the 2019 version that was never published, and the recently released version from 2021. They therefore requested further clarification on the rule.
- The Pharmacy Society of Wisconsin made two recommendations. The first, was a request for the Board to be consistent throughout the rule with its use of terms such as "stored in a refrigerator" or "stored in a freezer" versus providing specific temperatures for refrigerated or frozen products. The second recommendation was that the Board consider using the term "products" instead of "packages" in Phar 15.34 to align with the proposed revisions of the USP General Chapter <797>.
- Brian Koenig provided comments requesting clarification from the Board on whether they intend to add to the current Phar 15 or adopt the future version of USP General Chapter <797> instead. Mr. Koenig also recommended that the Board consider adopting USP General Chapter <797> and then add additional statements that the Board feels are necessary.

The Department explains modifications to its rule-making proposal prompted by public comments as follows:

- Phar 15.30 (11), (13), and (17) amended to include equivalent Celsius temperature ranges
- Phar 15.37 (5), (6), and (7) Celsius temperature ranges updated to "Controlled room temperature", "freezer", or "refrigerator" to be consistent with use of these terms in other rule sections
- Phar 15.34 updated the term "packages" to "products" to be consistent with USP language

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

All of the recommendations suggested in the Clearinghouse Report have been accepted in whole. After consideration of all of the recommendations, the Pharmacy Examining Board notes here that the language laid out in Phar 15.34 for Immediate-use compounded sterile preparations is, in their opinion, necessary to clarify the requirements for this specific type of compounding.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS:

A report from the Small Business Regulatory Review Board was requested on December 16, 2021. No report has been received.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 22-007)

PROPOSED ORDER

An order of the Pharmacy Examining Board to amend Phar 15.30 (11), (13), and (17), 15.33 (10), and 15.37 (1) (intro.), (c), and (d); create Phar 15.30 (10m), (14g) and (14r), and 15.37 (5), (6), and (7); and repeal and recreate Phar 15.34, relating to compounding pharmaceuticals.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.01 (16)

Statutory authority: ss. 15.08 (5) (b), and 450.02 (3) (d) and (e), Stats.

Explanation of agency authority:

The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession. [s. 15.08 (5) (b), Stats.]

The board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961 and establish minimum standards for the practice of pharmacy. [s. 450.02 (3) (d) and (e), Stats.]

Related statute or rule: N/A

Plain language analysis:

The objective of the rule is to review the updated United States Pharmacopeia (USP) 795 and 797 standards, which originally had a publication date of June 1, 2019 with an anticipated official date of December 1, 2019. However, due to appeals filed, the 2019 revisions of the USP are currently on hold. The 2008 USP 795 and 797 are the current standard for pharmacy compounding until those 2019 standards are published and effective.

Even though the Board will not be moving forward with the 2019 revisions at this time, there are still updates that need to be made to Phar 15 to align it with the 2008 USP 795 and 797 chapters that are currently in effect. It is the Board's intent to amend Phar 15 without creating an unnecessary burden on Wisconsin pharmacies, while still aligning it with the current USP chapters. When new updated standards are available, the Board will consider opening a new scope statement to address any further changes if applicable.

Summary of, and comparison with, existing or proposed federal regulation:

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.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:

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. For non-patient specific or "office use" of non-sterile compounded drugs, additional requirements apply. Among them, retrievable records must be maintained for at least 5 years and specific labelling requirements for office use. 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]

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. In addition, an FDA registered outsourcing facility must be licensed as a pharmacy in Iowa. [Iowa Administrative Code ss. 657.20.3, 657.20.4, and 657.20.6]

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. 333.17748]

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]

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board primarily utilized United States Pharmacopeia chapters 795 and 797 which are the recognized pharmacopeia standards.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The proposed rules were posted for a period of 30 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No economic impact comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis are attached.

Effect on small business:

These proposed rules do have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. and were submitted to the Small Business Regulatory Review Board for a determination on whether the rules will have a significant economic impact on a substantial number of small businesses. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing on February 14, 2022 at 11:00 a.m., to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1 Phar 15.30 (10m), (14g), and (14r) are created to read:

Phar 15.30 (10m) "High-risk level compounded sterile preparations" means preparations compounded from non-sterile ingredients or from ingredients that are incorporated using non-sterile equipment before terminal sterilization, or from commercially manufactured sterile products that lack effective antimicrobial preservatives and whose preparation, transfer, sterilization, and packaging is performed in air quality worse than ISO class 5 for more than one hour. High-risk level compounded sterile preparations include water containing preparations that are stored for more than six hours before terminal sterilization.

(14g) "Low-risk level compounded sterile preparations" means preparations compounded with aseptic manipulations entirely within ISO class 5 or better air quality using only sterile ingredients, products, components, and devices. The low-risk level sterile compounding process involves only transfer, measuring, and mixing, using no more than three commercially manufactured sterile products, and not more than two entries into one sterile container or package to make the compounded sterile preparations.

(14r) "Medium-risk level compounded sterile preparations" means preparations compounded under low-risk level conditions but which require multiple individual or small doses of sterile products to be combined or pooled to prepare compounded sterile preparations that will be administered either to multiple patients or to one patient on multiple occasions. The medium-risk level sterile compounding process includes complex aseptic manipulations other than single volume transfer, and requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

SECTION 2 Phar 15.30 (11), (13), and (17) are amended to read:

Phar 15.30 (11) "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 68 degrees to 77 degrees Fahrenheit or 20 degrees to 25 degrees Celsius.

(13) "Freezer" means a place in which the temperature is maintained between -13 degrees and 14 degrees Fahrenheit or -25 degrees and -10 degrees Celsius.

(17) "Refrigerator" means a cold place in which the temperature is maintained between 36 degrees and 46 degrees Fahrenheit or 2 degrees and 8 degrees Celsius.

SECTION 3 Phar 15.33 (10) is amended to read:

Phar 15.33 (10) Entry points on bags and vials shall be wiped with small sterile 70% isopropyl alcohol swabs or comparable method for disinfecting, allowing the isopropyl alcohol to dry before piercing stoppers with sterile needles and breaking necks of ~~ampuls~~

ampules. The surface of the sterile 70% isopropyl alcohol swabs used for disinfecting entry points of sterile package and devices may not contact any other object before contacting the surface of the entry point. Particle generating material may not be used to disinfect the sterile entry points of packages and devices.

SECTION 4 Phar 15.34 is repealed and recreated to read:

Phar 15.34 Immediate-use compounded sterile preparations. Immediate-use compounded sterile preparations are exempt from the requirements described for low-risk level, Category 1, and Category 2 compounding sterile preparations only when all the following criteria are met:
(1) The compounding process involves simple transfer of not more than three commercially manufactured sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or product of sterile infusion solution or administration container or device.
(2) Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.
(3) During preparation, aseptic technique is followed and, if not immediately administered, the finished compound sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compound sterile preparations, and direct contact of outside surfaces.
(4) Administration begins not later than 4 hours following the start of the preparation.
(5) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared it, and the exact 4-hour BUD and time.
(6) If administration of the compounded sterile preparation has not begun within 4 hours following the start of preparation, it shall be promptly, properly, and safely discarded.

SECTION 5 Phar 15.37 (1) (intro.), (c), and (d) are amended to read:

Phar 15.37 (1) Sterility and stability considerations shall be taken into account when establishing a BUD. Either Category 1 and 2, or low, medium, and high-risk compounding preparation standards may be used, but not a combination of the two within the same pharmacy. The following dates and times for storage and initiation of administration of the compounded sterile preparations shall apply:

(c) For aseptically processed Category 2 ~~compounded~~ processed sterile preparations, one of the following:

1. ~~Prepared~~ No sterility testing performed or sterility testing not passed, and prepared with one or more nonsterile ~~ingredients~~ starting components, ~~which are sterilized with a validated sterilization procedure prior to compounding no preservative added and no sterility testing performed~~ one of the following:

a. Within ~~4 days~~ 1 day when the preparation is stored at controlled room temperature.

b. Within ~~7~~ 4 days when the preparation is stored in a refrigerator.
c. Within 45 days when the preparation is stored in a freezer.

2. ~~Prepared only with sterile ingredients, no preservative added and no~~ No sterility testing performed or sterility testing not passed, and prepared with only sterile starting components, one of the following:
a. Within ~~6~~ 4 days when the preparation is stored at controlled room temperature.
b. Within ~~9~~ 10 days when the preparation is stored in a refrigerator.
c. Within 45 days when the preparation is stored in a freezer.

3. ~~Prepared only with sterile ingredients, preservative added and no sterility~~ Sterility testing performed and passed, one of the following:
a. Within ~~28~~ 30 days when the preparation is stored at controlled room temperature.
b. Within ~~42~~ 45 days when the preparation is stored in a refrigerator.
c. Within ~~45~~ 60 days when the preparation is stored in a freezer.

~~4. Prepared only with sterile ingredients, no preservative added and sterility testing, one of the following:~~
~~a. Within 28 days when the preparation is stored at controlled room temperature.~~
~~b. Within 42 days when the preparation is stored in a refrigerator.~~
~~c. Within 45 days when the preparation is stored in a freezer.~~

~~5. Prepared only with sterile ingredients, preservative added and sterility testing, one of the following:~~
~~a. Within 42 days when the preparation is stored at controlled room temperature.~~
~~b. Within 42 days when the preparation is stored in a refrigerator.~~
~~c. Within 45 days when the preparation is stored in a freezer.~~

(d) For Category 2 compounded sterile preparations, terminally sterilized by a validated procedure, one of the following:

1. ~~Prepared with no preservative and no~~ No sterility testing performed or sterility testing not passed, one of the following:
a. Within 14 days when the preparation is stored at controlled room temperature.
b. Within 28 days when the preparation is stored in a refrigerator.
c. Within 45 days when the preparation is stored in a freezer.

2. ~~Prepared with no preservative added and sterility~~ Sterility testing performed and passed, one of the following:
a. Within ~~28~~ 45 days when the preparation is stored at controlled room temperature.
b. Within ~~42~~ 60 days when the preparation is stored in a refrigerator.
c. Within ~~45~~ 90 days when the preparation is stored in a freezer.

~~3. Prepared with preservative added and no sterility testing performed, one of the following:~~
~~a. Within 28 days when the preparation is stored at controlled room temperature.~~
~~b. Within 42 days when the preparation is stored in a refrigerator.~~
~~c. Within 45 days when the preparation is stored in a freezer.~~

~~4. Prepared with preservative added and sterility testing performed, one of the following:~~
~~a. Within 42 days when the preparation is stored at controlled room temperature.~~

~~b. Within 42 days when the preparation is stored in a refrigerator.~~
~~c. Within 45 days when the preparation is stored in a freezer.~~

SECTION 6 Phar 15.37 (5), (6), and (7) are created to read:

Phar 15.37 (5) For low-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 48 hours when the preparation is stored at controlled room temperature.

(b) Within 14 days when the preparation is stored in a refrigerator.

(c) Within 45 days when the preparation is stored in a freezer.

(d) For products prepared in an airflow workbench not located in a buffer area, administration shall begin within 12 hours or less of preparation.

(6) For medium-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) within 30 hours when the preparation is stored at controlled room temperature.

(b) within nine days when the preparation is stored in a refrigerator.

(c) within 45 days when the preparation is stored in a freezer.

(7) For high-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 24 hours when the preparation is stored at controlled room temperature.

(b) Within three days when the preparation is stored in a refrigerator.

(c) Within 45 days when the preparation is stored in a freezer.

SECTION 7 EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Dated 02/25/2022 Agency _____

Secretary
Pharmacy Examining Board

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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

2. Date
January 18, 2022

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
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 this rule amend Phar 15 without creating an unnecessary burden on Wisconsin pharmacies, while still aligning it with the current 795 and 797 USP chapters.

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 proposed rules were posted for a period of 30 days on the Department of Safety and Professional Services' website to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No economic impact 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 economic or fiscal impacts are anticipated for specific businesses, sectors, ratepayers, local governments, or the state's economy as a whole. A total of $650.00 in one time costs are anticpated to be absorobed 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 benefits of implementing this rule is clear standards for the practice of pharmaceutical compounding until the next revision of USP chapters 795 and 797 occur. The alternative to implementing the rule is that Wisconsin Administrative Code Chapter Phar 15 would remain in conflict with current USP standards.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are clear standards for pharmaceutical compounding in Wiscsonsin.

17. Compare With Approaches Being Used by Federal Government

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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. For non-patient specific or "office use" of non-sterile compounded drugs, additional requirements apply. Among them, retrievable records must be maintained for at least 5 years and specific labelling requirements for office use. 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]

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. In addition, an FDA registered outsourcing facility must be licensed as a pharmacy in Iowa. [Iowa Administrative Code ss. 657.20.3, 657.20.4, and 657.20.6]

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. 333.17748]

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
Nilajah Hardin, Administrative Rules Coordinator	608-267-7139

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

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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