Report From Agency

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
PHARMACY EXAMINING BOARD	**:**	**CR 16-085**

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 basis and purpose of the proposed rule is to update the non-sterile and sterile compounding rules. Following the New England Compounding Center meningitis outbreak in 2012 which affected 753 patients (64 patient deaths), the Pharmacy Examining Board recognized that Wisconsin's current rules have not been updated since 2000 and did not adequately address current practice or safety standards for compounding non-sterile and sterile pharmaceuticals.

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 January 17, 2017. The following people either testified at the hearing, or submitted written comments:

Danielle Laurent representing Pharmacy Society of Wisconsin
Jeremy Levin representing Rural Wisconsin Health Cooperative
Aaron Webb, Pharmacy Manager, University of Wisconsin Hospital and Clinics
Dawn Wypiszynski representing Morton LTC
Susan Kleppin representing Chartwell Midwest Wisconsin
Michelle Violi representing Women's International Pharmacy
Ronald Phillips representing Animal Health Institute
Jennifer Hoppe representing The Joint Commission

Jordan Lamb of DeWitt, Ross & Stevens representing Wisconsin Veterinary Medical Association

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

Several people recommended the Pharmacy Examining Board adopt U. S. Pharmacopeia chapters 795 and 797. The Board in formulating the rule considered the draft of the new chapter USP 797 and Phar 15 may contain items which will not be adopted in the final revision of chapter USP 797. Hospitals are required to meet USP chapters 795 and 797 to maintain accreditation.

There were comments submitted indicating that Phar 15 should only apply to bulk compounding pharmacies who sell their product to other pharmacies. Similar comments were made to exempt retail or hospitals from Phar 15 because those entities do not manufacture drugs.

Comments related solely to compounding for animal patients were received. The Animal Health Institute requested that Phar 15 not exempt compounding for animal patients from the non-patient specific compounding requirements in the proposed Phar 15.17 raising safety concerns, including food safety implications for food animals. The Wisconsin Veterinary Medical Association requested an exemption to the proposed Phar 15.17 to allow a veterinarian to dispense a non-patient specific compounded drug to a patient for a period of time not to exceed 10 days.

The Joint Commission provided information related to their new Medication Compounding certification program for the Board's consideration in reliance on their program to ensure that pharmacies providing compounding pharmaceuticals are complaint with the requirements contained in the proposed rules.

Please see the attached Appendix A for specific line item comments not addressed as general comments in this section.

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

The Pharmacy Examining Board is not adopting U.S. Pharmacopeia chapters 795 and 797 due to the difficulties associated with enforcing standards which are not itemized and read as recommendations or best practices. The Pharmacy Examining Board recognizes that the U.S. Pharmacopeial Convention is in the process of updating the U.S. Pharmacopeia chapter 797. The Board balanced safety concerns with the burden regulations place on pharmacies while creating the minimum standards in Phar 15 recognizing that other entities may require higher standards.

Pharmacies are not allowed to compound bulk pharmaceuticals and sell to other pharmacies. Outsourcing facilities are not required to be a licensed pharmacy and may or may not obtain prescriptions for individual patients (if dispensing to a patient than a prescription is required). Outsourcing facilities are required to register with the federal

government and meet Current Good Manufacturing Practices. Outsourcing facilities currently are not licensed in Wisconsin and Phar 15 does not apply.

The Pharmacy Examining Board did not make any changes to the proposed Phar 15 for animal patients. The Pharmacy Examining Board based the decision on regardless of whether the patient is a human or animal, there are patient safety concerns as it relates to compounding pharmaceuticals.

Please see the attached Appendix A for modifications as a result of specific line item comments.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 5i: In s. Phar 15.20 (3), the board should review the provision for clarity and its relationship to other provisions in s. Phar 15.20. For example, in what circumstances may components be transferred to other containers? How does the transfer of components relate to the timeliness of usage of those components and the requirement that a component be stored in is original container under s. Phar 15.20(1).

Response: The Pharmacy Examining Board reviewed the provision and believes it is clear. There is no conflict with s. Phar 15.20 (1) and (3). If a component is transferred, it needs to be stored in a container providing a minimally equivalent integrity and an expiration date will need to be identified. The expiration date from the manufacturer or distributor as provided for in sub. (1) will no longer be automatically once the component has been transferred and will need an expiration assigned.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

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

The Small Business Regulatory Review Board provided a verbal statement that the rule will not have a significant economic impact on a substantial number of small businesses.

APPENDIX A

Comment: In Phar 15.01 (9) (c) clarify reconstituting versus compounding. Also clarify this relates to only non-sterile preparations.

Response: The Pharmacy Examining Board modified the paragraph to include these clarifications.

Comment: In Phar 15.11, the "equipment surfaces that contact components" is unnecessary and should be removed.

Response: The Pharmacy Examining Board removed this phrase.

Comment: The record for mixing instructions does not require all of the listed requirements, particularly in non-sterile compounding.

Response: The Pharmacy Examining Board removed the list and added to Phar 15.12 (5) the phrase, "pertinent to the replication of the preparation as compounded".

Comment: In Phar 15.13, clarify who conducts the final check verification.

Response: The Pharmacy Examining Board modified this section to read, "One or more pharmacists shall complete a verification of all of the following before dispensing." to allow for the multiple pharmacists in the process to complete the various verifications after each step. The Pharmacy Examining Board also clarified that if any discrepancy is found during any of the verifications the appropriate corrective action shall be taken before dispensing.

Comment: In Phar 15.14 (2) (d), the items listed as included in environmental monitoring are unnecessary. In Phar 15.14 (2) (m), there needs to be clarification.

Response: The Pharmacy Examining Board removed the list of items in Phar 15.14 (2) (d) and simplified Phar 15.14(2) (m) to "maintaining the integrity of any classified work area".

Comment: Recommend the label includes notification that the pharmaceutical was compounded.

Response: The Pharmacy Examining Board added a paragraph, "Indication that the preparation is compounded unless administered by health care personnel."

Comment: Recommend adding a provision to Phar 15.16 (2) about using professional judgement if USP or NF grade is not available.

Response: The Pharmacy Examining Board made this addition.

Comment: Several comments regarding clarification of Phar 15.17.

Response: The Pharmacy Examining Board clarified the introduction paragraph to address the non-patient specific compounding is pursuant to a non-patient specific order to be administered by the practitioner or practitioner's agent. In addition, the Pharmacy Examining Board removed the requirement that the order include the name of the compounded preparation's name due to lack of clarity as to what the name would be and added strength of the compounded preparation. The label should indicate "For Practitioner Administration Only – Not for Dispensing or Distribution" which replaced the word "use" with "administration". Lastly the Pharmacy Examining Board moved the provision related to recall to Phar 15.14 (2)(o) requiring there to be a policy for recall of any compounded preparation.

Comment: Recommend the primary engineering control be certified by the Controlled Environment Testing Association's national Board of Testing.

Response: The Pharmacy Examining Board included this entity but also created a provision allowing a different entity to be approved by the Board.

Comment: Recommend combining the donning of protective clothing and the hand hygiene procedure for clarity purposes.

Response: The Pharmacy Examining Board accepted the recommendation and made the clarification that sterile gloves shall be donned over the RABS gloves. In addition, the Pharmacy Examining Board made other clarifications as to clothing.

Comment: Several comments requesting clarification of the cleaning and disinfecting the compounding area and supplies.

Response: The Pharmacy Examining Board created definitions for cleaning and disinfecting and simplified the frequency and need to clean/disinfect the various areas.

Comment: Recommend adding to Phar 15.26 (3) a clarification regarding a preservative added by the compounder versus the vial already containing a preservative.

Response: The Pharmacy Examining Board added the phrase "added by the compounder".

Comment: Recommend adding to Phar 15.37 a provision relating to compounded sterile formulations with a preservative passing an antimicrobial effectiveness testing before dispensing.

Response: The Pharmacy Examining Board added Phar 15.37 (4).

Comment: Recommend clarification as to the compounding personnel required to complete training.

Response: The Pharmacy Examining Board revised Phar 15.38 (1) (intro) to include a listing of the compounding personnel required to complete training.