Report From Agency

STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING : PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE CONTROLLED SUBSTANCES BOARD : CR 15-070

I. THE PROPOSED RULE:

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

II. REFERENCE TO APPLICABLE FORMS:

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:

This rule implements 2013 Act 199 requiring the name of the person, either from on the id presented or known by the pharmacist, to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

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

The Controlled Substances Board held a public hearing on October 6, 2015. The following people either testified at the hearing, or submitted written comments:

Pharmacy Examining Board Joel Kurzman, Regional Director, National Association of Chain Drug Stores Anna Legreid Dopp, Pharmacy Society of Wisconsin Matthew Mabie, Hometown Pharmacy Thad Schumacher, Hometown Pharmacy Susan Kleppin, Chartwell Midwest Wisconsin

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

All the testimony received was against the effective date of April 9, 2016. The people who testified indicated: the statute places a substantial cost to pharmacies (estimates

\$8000 to \$15000 per pharmacy) to change software to allow the point of sale software system to work with the pharmacy filling software system (which are two separate systems); increased costs due to changes in data collection workflow averaging 2-5 minutes per data collection and entry; and the date does not provide enough time for vendors to develop software resulting in paper submissions.

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

2013 Act 199 requires rules to be promulgated requiring the name of the person the drug is dispensed or delivered to be submitted to the prescription drug monitoring system. 2013 Act 199 indicates the rules promulgated to require this data submission may not require this submission until April 9, 2016 and after consultation with representatives of licensed pharmacists and pharmacies and subject to the approval of the Secretary of the Department of Safety and Professional Services, the board may delay the requirement for an additional period. The prescription drug monitoring program came under the jurisdiction of the Controlled Substances Board as a result of 2015 Act 55. The Board is requested and obtained approval of the Secretary to delay the requirement to April 9, 2017 as a result of the public hearing comments.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 5: In the Note provided under the caption for the proposed order, a period should be added to the end of the following sentence: "This proposed rule references the new numbering."

Response: The preliminary rule draft contained a note which read "Chapter Phar 18 will become Chapter CSB 4 effective October 1, 2015. This proposed rule references the new numbering." This note was provided to minimize confusion as to the reference to CSB 4 at the time it was submitted to Clearinghouse and the public hearing notice was published due to the chapter in effect at that time was still Phar 18. The note is no longer required as the chapter being amended is currently CSB 4.

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:

N/A