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 15-068**

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 purpose of the proposed rule is to exclude naloxegol from schedule II controlled substances. On January 23, 2015, a final rule was published in the Federal Register removing naloxegol from schedule II of the federal Controlled Substances Act effective that day. The Controlled Substances Board took Affirmative Action on March 25, 2015 to similarly exclude naloxegol under chapter 961 effective April 1, 2015 and expires upon promulgation of a final rule.

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

Per s. 961.11(4), Stats., if no objection is made, the board shall promulgate a final rule for which notice of proposed rulemaking is omitted. Therefore, the Board did not hold a public hearing.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 4: It appears that 21 C.F.R. s. 1308.12 (b) (1) is the federal rule that was used as authority to promulgate this proposed rule. If so, this federal administrative rule should be referenced in the rule summary's section entitled, "Related statute or rule".

Response: There is not a Wisconsin related statute or rule. The rulemaking order addresses federal regulation in a separate section.

Comment 5a: The rule summary's section entitled, "Explanation of agency authority", appears to be a direct quote from s. 961.11 (4), Stats. If so, this section should be amended to clarify that it is quoting a statute. For example, the statute should be cited as s. 961.11 (4), Stats., and quotation marks should be placed around the quoted text. Preferably, the section would provide a plain language explanation of the pertinent parts of the statute.

Response: The "Explanation of agency authority" clearly provides a citation and the statutory language. A plain language explanation would be a summary and the Board prefers to utilize the exact language when providing agency authority. The entire statute cited is pertinent to the authority of the Board in this matter.

Comment 5b: The rule summary's section entitled, "Summary of, and comparison with, existing or proposed federal regulation", includes a summary of federal action to remove naloxegol from being listed as a Schedule II substance under the federal Controlled Substances Act. However, this section does not include a discussion on how the proposed rule compares with federal law. Also, it would be helpful to provide citations to the applicable federal code referenced and the Federal Register where this final rule order was published (i.e., 90 F.R. 3468).

Response: The section explains the United States Department of Justice removed naloxegol from Schedule II of the Controlled Substances Act. Therefore, naloxegol is no longer federally scheduled. This proposed rule excludes naloxegol from scheduling.

Comment 5c: The rule summary's section entitled, "Plain language analysis", should begin with an analysis of what the proposed rule does and then continue with the background of the history of the Affirmative Action order.

Response: The Affirmative Action order leading to this proposed rule is a relevant fact in the analysis. It is important to provide a chronological history of the facts in discussing what the proposed rule does.

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:

This rule does not have an impact on small business.