

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 19-156**

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 proposed rule will clarify and update minor provisions based upon stakeholder feedback including the following: requires drug dosage units and partial fill indicator to be submitted to the PDMP, clarifying disclosure of PDMP data for public health and research purposes, and creating a provision to allow for disclosure of audit trails to designated staff of a federal or state governmental agency.

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 January 10, 2020. The following people either testified at the hearing, or submitted written comments:

William Peppard, PharmD, BCPS, FCCM

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

A request for the Controlled Substances Board to expand the policy in the proposed rule to allow researchers to access patient identified data without patient informed consent following Institutional Review Board protocol.

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

Declined to allow researchers to access patient identified data without patient informed consent due to patient privacy concerns and the ability for researchers to obtain nonidentified data for scientific research purposes.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

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

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

There is no economic impact on small business.