

**STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD**

**IN THE MATTER OF RULEMAKING :
PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE
CONTROLLED SUBSTANCES BOARD : CR 24-033**

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:

Wisconsin Administrative Code Chapter CSB 4 currently outlines requirements for methods of obtaining monitored prescription drug history reports. Patients are allowed to request their own history reports either in person at the Department of Safety and Professional Services or via a mailed request on a form provided by the Board. A person authorized by the patient may only request copies of those same reports in person. Without making changes under the proposed rule, a person authorized by the patient will continue to only be able to make such requests in person at the Department.

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 May 10, 2024. No public comments were received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

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

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

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	CONTROLLED SUBSTANCES
CONTROLLED SUBSTANCES BOARD	:	BOARD
	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 24-033)

PROPOSED ORDER

An order of the Controlled Substances Board to amend CSB 4.11 (2) (a) and (c), relating to monitored prescription drug history reports.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss 146.82 and 961.385 (2) (c), Stats.

Statutory authority: ss. 146.82 and 961.385 (2) (c), Stats.

Explanation of agency authority:

Section 146.82 of Wisconsin Statutes includes the requirements for confidentiality of patient health records, while section 961.385 (2) (c), Stats., states that the board shall establish by rule and have the prescription drug monitoring program “specify the persons whom a record may be disclosed and the circumstances under which the disclosure may occur. Except as otherwise provided under this section, the rule promulgated under this paragraph shall comply with s. 146.82.” Therefore, the Controlled Substances Board has the authority to specify who has access to reports from the prescription drug monitoring program as long as those reports and the restrictions specified comply with the confidentiality of patient health care records under s. 146.82, Stats.

Related statute or rule: None.

Plain language analysis: Wisconsin Administrative Code Chapter CSB 4 currently outlines requirements for methods of obtaining monitored prescription drug history reports. Patients are allowed to request their own history reports either in person at the Department of Safety and Professional Services or via a mailed request on a form provided by the Board. A person authorized by the patient may only request copies of those same reports in person. Without making changes under the proposed rule, a person authorized by the patient will continue to only be able to make such requests in person at the Department.

Summary of, and comparison with, existing or proposed federal regulation: None.

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: The Illinois Prescription Monitoring Program allows patients access to their personal prescription history based on a validation process established by administrative rules [720 Illinois Compiled Statutes Chapter 570 Section 318 (m)]. The administrative rules governing patient access to their prescription history require that the patient, parent, or guardian complete a notarized request for a personal information report of a patient's prescription history, and submit it by mail to the Illinois Prescription Monitoring Program [Illinois Administrative Code Title 77 Chapter X Subchapter e Part 2050 Section 2080.190 (a)].

Iowa: The Iowa Prescription Monitoring Program allows patients or a patient's agent to request that patient's own prescription history report by submitting a request form. Request forms may be submitted in-person with a government issued photo identification or via mail if the request form is notarized and sent with a certified copy of the patient's government issued identification. A patient's agent may sign the request form in lieu of the patient if a copy the legal document establishing the agency relationship is provided. The patient's agent must also present a government issued identification for in-person requests or a certified copy of a government issued identification for mailed requests. [657 Iowa Administrative Code Chapter 37 Section 37.16 (7)].

Michigan: The administrative rules that govern the Michigan Automated Prescription System, the state's electronic system for monitoring schedule II to V controlled substances, does not specify whether a report of a patient's prescription history can be disclosed, nor how a report may be obtained by a patient. [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program allows a patient who has been prescribed a controlled substance to access the program's database to obtain information on users who have access to that patient's data records. A patient may submit a request for this information on a notarized form from the Minnesota State Board of Pharmacy's website.[Minnesota Statutes Chapter 152 Section 152.126 Subdivision 11].

Summary of factual data and analytical methodologies: The Board reviewed Wisconsin Administrative Code Chapter CSB 4 and made updates as needed.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The proposed rule was posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department’s Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

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, held on May 10, 2024, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 4.11 (2) (a) and (c) are amended to read:

CSB 4.11 (2) (a) Appears in person at the department with two forms of valid proof of identity, one of which is a valid government-issued photographic identification or mails to the department copies of two forms of valid proof of identity, one of which is a valid government-issued photographic identification.

(c) Makes a request for the monitored prescription drug history report on a form provided by the board. If the request is mailed, the form shall be notarized.

SECTION 2. 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 Controlled Substances Board is approved for submission to the Governor and Legislature.

Dated 06/17/2024

Agency *Douglas Englebort*
Chairperson
Controlled Substances Board

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

<p>1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected</p>	<p>2. Date 3/28/24</p>
<p>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 4</p>	
<p>4. Subject Monitored Prescription Drug History Reports</p>	
<p>5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S</p>	<p>6. Chapter 20, Stats. Appropriations Affected s. 20.165 (1) (hg)</p>
<p>7. Fiscal Effect of Implementing the Rule <input type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input checked="" type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input checked="" type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget</p>	
<p>8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)</p>	
<p>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0</p>	
<p>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)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>11. Policy Problem Addressed by the Rule The objective of the proposed rule is to allow an authorized patient representative to request monitored prescription drug history reports on behalf of a patient both in person and via mail.</p>	
<p>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 rule was posted on the Department of Safety and Professional Service's (DSPS) website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.</p>	
<p>13. Identify the Local Governmental Units that Participated in the Development of this EIA. None.</p>	
<p>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) DSPS estimates a total of \$3,200 in one-time costs for implementing the provisions of this rule to support the equivalent of a 0.1 limited term employee for activities including rulemaking and coordination with PDMP program staff. The one-time costs cannot be absorbed in the currently appropriated agency budget.</p>	
<p>15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit of implementing the rule is that patients authorized representatives will have the option to request monitored prescription drug history reports via mail, in addition to in-person requests.</p>	
<p>16. Long Range Implications of Implementing the Rule The long range implications of implementing this rule is greater patient and customer satisfaction with the Prescription Drug Monitoring Program (PDMP) through increased accessibility to monitored prescription drug history reports where allowed by law.</p>	
<p>17. Compare With Approaches Being Used by Federal Government None.</p>	

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois: The Illinois Prescription Monitoring Program allows patients access to their personal prescription history based on a validation process established by administrative rules [720 Illinois Compiled Statutes Chapter 570 Section 318 (m)]. The administrative rules governing patient access to their prescription history require that the patient, parent, or guardian complete a notarized request for a personal information report of a patient's prescription history, and submit it by mail to the Illinois Prescription Monitoring Program [Illinois Administrative Coder Title 77 Chapter X Subchapter e Part 2050 Section 2080.190 (a)].

Iowa: The Iowa Prescription Monitoring Program allows patients or a patient's agent to request that individual patient's own prescription history report by submitting a request form. Request forms may be submitted in-person with a government issued photo identification or via mail if the request form is notarized and sent with a certified copy of the patient's government issued identification. A patient's agent may sign the request form in lieu of the patient if a copy the legal document establishing the agency relationship is provided. The patient's agent must also present a government issued identification for in-person requests or a certified copy of a government issued identification for mailed requests. [657 Iowa Administrative Code Chapter 37 Section 37.16 (7)].

Michigan: The administrative rules that govern the Michigan Automated Prescription System, the states electronic system for monitoring schedule II to V controlled substances, does not specify whether a report of a patient's prescription history can be disclosed, nor how a report may be obtained by a patient. [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program allows a patient who has been prescribed a controlled substance to access the program's database to obtain information on users who have access to that patient's data records. A patient may submit a request for this information on a notarized form from the Minnesota State Board of Pharmacy's website.[Minnesota Statutes Chapter 152 Section 152.126 Subdivision 11].

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.

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
-