

**STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD**

**IN THE MATTER OF RULEMAKING :
PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE
CONTROLLED SUBSTANCES BOARD : CR 24-060**

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 what data should be entered into the Wisconsin Prescription Drug Monitoring Program (PDMP) for each reportable prescription. Pursuant to s. 450.11 (1) (f), Stats., the Pharmacy Examining Board has written an exception, outlined in s. Phar 8.06 (2), that applies to the name required under s. CSB 4.04 (2) (p) when the prescription is delivered to the patient via common carrier or delivery services. As currently written, s. CSB 4.04 (2) (p) does not allow for a practitioner to make this exception. Therefore, the Controlled Substances Board has updated the requirement so that this exception can occur without causing data entry issues for the PDMP. Without making changes under the proposed rule, there will continue to be a lack of clarity and around the name that needs to be entered into the PDMP per s. CSB 4.04 (2) (p).

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 September 20, 2024. No public comments were received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:
Legislative Council Staff did not make any recommendations.

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 24-060)

PROPOSED ORDER

An order of the Controlled Substances Board to amend CSB 4.04 (2) (p), relating to mail delivered prescriptions.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.11 (1b)(f) and 961.385 (2) (b), Stats.

Statutory authority: s. 961.385 (2) (a), Stats.

Explanation of agency authority:

961.385 (2) (a), Stats. states that the board shall establish by rule and have the prescription drug monitoring program “require a pharmacy or a practitioner to generate a record documenting each dispensing of a monitored prescription drug at the pharmacy, or if the monitored prescription drug is not dispensed at the pharmacy, by the practitioner and to submit the record to the board no later than 11:59 p.m. of the next business day after the monitored prescription drug is dispensed...”

Related statute or rule: Wisconsin Administrative Code Chapter Phar 8

Plain language analysis: Wisconsin Administrative Code Chapter CSB 4 currently outlines requirements for what data should be entered into the Wisconsin Prescription Drug Monitoring Program (PDMP) for each reportable prescription. Pursuant to s. 450.11 (1) (f), Stats., the Pharmacy Examining Board has written an exception, outlined in s. Phar 8.06 (2), that applies to the name required under s. CSB 4.04 (2) (p) when the prescription is delivered to the patient via common carrier or delivery services. As currently written, s. CSB 4.04 (2) (p) does not allow for a practitioner to make this exception. Therefore, the Controlled Substances Board has updated the requirement so that this exception can occur without causing data entry issues for the PDMP. Without making changes under the proposed rule, there will continue to be a lack of clarity and around the name that needs to be entered into the PDMP per s. CSB 4.04 (2) (p).

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: The Controlled Substances Board held a Preliminary Hearing on Statement of Scope for this project on March 8, 2024. No public comments were received.

Comparison with rules in adjacent states:

Illinois: The Illinois Prescription Monitoring Program does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There also does not appear to be an exception to data entry when a prescription is delivered via mail. However, the recipient's name, address, date of birth, and gender are required for each reportable prescription [720 Illinois Compiled Statutes Chapter 570 Section 316].

Iowa: The Iowa Prescription Monitoring Program does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There also does not appear to be an exception to data entry when a prescription is delivered via mail. Outside of the prescriber's name and Drug Enforcement Administration (DEA) registration number, only the patient's name and various pieces of information are required for each reportable prescription [657 Iowa Administrative Code Chapter 37 Section 12].

Michigan: The Michigan Automated Prescription System, the states electronic system for monitoring schedule II to V controlled substances, does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There also does not appear to be an exception to data entry when a prescription is delivered via mail. However, there is a provision that allows for the dispensing prescriber to presume that the identification provided by the patient or their representative is correct [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There is an exception where the dispenser is not required to submit data to the program for a prescription that is mailed or delivered from Minnesota to another state, as long as the data is reported to the prescription drug monitoring program of that state. Various pieces of dispenser, patient, and prescriber data are required for each reportable prescription [Minnesota Statutes Chapter 152 Section 152.126 Subdivision 4].

Summary of factual data and analytical methodologies: The Board reviewed Wisconsin Administrative Code Chapter CSB 4 and made updates as needed based on a recommendation from the Wisconsin Pharmacy Examining Board.

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

The proposed rules were 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; 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 September 20, 2024, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 4.04 (2) (p) is amended to read:

CSB 4.04 (2) (p) The name recorded under s. 450.11 (1b) (bm), Stats., unless exempted pursuant to s. Phar 8.06 (2).

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 10/30/2024

Agency *Douglas Englebert*
Chairperson
Controlled Substances Board

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	2. Date 08/09/24
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 4	
4. Subject Mail Delivered Prescriptions	
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	6. Chapter 20, Stats. Appropriations Affected s. 20.165 (1) (hg)
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 type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget	
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)	
9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0	
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	
11. Policy Problem Addressed by the Rule Wisconsin Administrative Code Chapter CSB 4 currently outlines requirements for what data should be entered into the Wisconsin Prescription Drug Monitoring Program (PDMP) for each reportable prescription. Pursuant to s. 450.11 (1) (f), Stats., the Pharmacy Examining Board has written an exception, outlined in s. Phar 8.06 (2), that applies to the name required under s. CSB 4.04 (2) (p) when the prescription is delivered to the patient via common carrier or delivery services. As currently written, s. CSB 4.04 (2) (p) does not allow for a practitioner to make this exception. Therefore, the Controlled Substances Board has updated the requirement so that this exception can occur without causing data entry issues for the PDMP. Without making changes under the proposed rule, there will continue to be a lack of clarity and around the name that needs to be entered into the PDMP per s. CSB 4.04 (2) (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.	
13. Identify the Local Governmental Units that Participated in the Development of this EIA. None.	
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 \$3,700 in one time costs. The one-time staff costs support 0.1 limited term employee to undertake such tasks as rule drafting, providing legal counsel and review, updating forms, work guides and providing team training and review updates, as well as provide support the increased demand for customer service in the form of phone calls, chats and emails. The one-time costs cannot be absorbed in the currently appropriated agency budget.	
15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule	

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

The benefit of implementing the rule is conformity of requirements in CSB 4.04 (2) (p) and Phar 8.06 (2) regarding mail delivered prescriptions. The alternative to implementing this rule is that there will continue to be a discrepancy between two areas of the administrative code.

16. Long Range Implications of Implementing the Rule

The long range implications of implementing the rule are consistent references to an exemption to a statutory requirement in the administrative code.

17. Compare With Approaches Being Used by Federal Government

None.

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

Illinois: The Illinois Prescription Monitoring Program does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There also does not appear to be an exception to data entry when a prescription is delivered via mail. However, the recipient's name, address, date of birth, and gender are required for each reportable prescription [720 Illinois Compiled Statutes Chapter 570 Section 316].

Iowa: The Iowa Prescription Monitoring Program does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There also does not appear to be an exception to data entry when a prescription is delivered via mail. Outside of the prescriber's name and Drug Enforcement Administration (DEA) registration number, only the patient's name and various pieces of information are required for each reportable prescription [657 Iowa Administrative Code Chapter 37 Section 12].

Michigan: The Michigan Automated Prescription System, the states electronic system for monitoring schedule II to V controlled substances, does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There also does not appear to be an exception to data entry when a prescription is delivered via mail. However, there is a provision that allows for the dispensing prescriber to presume that the identification provided by the patient or their representative is correct [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program does not specify that the person to whom the drug was dispensed must provide identification and that the name on the identification must be recorded into the system. There is an exception where the dispenser is not required to submit data to the program for a prescription that is mailed or delivered from Minnesota to another state, as long as the data is reported to the prescription drug monitoring program of that state. Various pieces of dispenser, patient, and prescriber data are required for each reportable prescription [Minnesota Statutes Chapter 152 Section 152.126 Subdivision 4].

19. Contact Name

Nilajah Hardin, Administrative Rules Coordinator

20. Contact Phone Number

(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
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