STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING:

PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE

CONTROLLED SUBSTANCES BOARD: CR 24-013

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 objective of the proposed rule is to add the National Provider Identifier (NPI) for all dispensing and prescribing Prescription Drug Monitoring Program (PDMP) records by creating CSB 4.02 (12s), 4.04 (2) (bm) and (im). Sections CSB 4.04 (2) (b) and (i) were also updated to reflect that a DEA number is only required if applicable. The Board also repealed the exemption requirement under CSB 4.08 (4) that allowed dispensers to be exempt from reporting Gabapentin prescribing if they do not have a DEA number. Section CSB 4.097 (1) (i) was created to reflect that access to the PDMP can be restricted for failure to provide any of the data from CSB 4.04 (2) when required. Updates were also made to the mailing address for the Department in ss CSB 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), and 4.08 (1) (b) (Note).

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 March 8, 2024. No public comments were received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment: "5a. As created by the proposed rule s. CSB 4.097 (1) (i) specifies the consequences for failure to enter other data into the PDMP system as required under s. CSB 4.04 (2)?"

Response: The Board accepts this comment and agrees that the requirement in s. CSB 4.097 (1) (i) should apply to all data outlined in s. CSB 4.04 (2). Section CSB 4.097 (1) (i) has been updated accordingly.

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

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 24-013)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 4.02 (12s), 4.04 (2) (bm) and (im), and 4.097 (1) (i), and amend CSB 4.04 (2) (b) and (i), 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), and 4.08 (1) (b) (Note), and repeal CSB 4.08 (4), relating to national provider identifier requirement.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 961.385 (2) (b) and (7s), Stats.

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

Explanation of agency authority:

961.385 (2) (b) states that the board shall establish by rule and have the prescription drug monitoring program "Identify specific data elements to be contained in a record documenting the dispensing of a monitored prescription drug, including the method of payment and, subject to sub. (2m), the name recorded under s. 450.44 (1b) (bm). In identifying specific data elements, the board shall consider data elements identified by similar programs in other states and shall ensure, to the extent possible, that records generated by the program are easily shared with other states."

Related statute or rule: None.

Plain language analysis:

The objective of the proposed rule is to add the National Provider Identifier (NPI) for all dispensing and prescribing Prescription Drug Monitoring Program (PDMP) records by creating CSB 4.02 (12s), 4.04 (2) (bm) and (im). Sections CSB 4.04 (2) (b) and (i) were also updated to reflect that a DEA number is only required if applicable. The Board also repealed the exemption requirement under CSB 4.08 (4) that allowed dispensers to be exempt from reporting Gabapentin prescribing if they do not have a DEA number. Section CSB 4.097 (1) (i) was created to reflect that access to the PDMP can be restricted for failure to provide any of the data from CSB 4.04 (2) when required. Updates were also made to the mailing address for the Department in ss CSB 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), and 4.08 (1) (b) (Note).

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: No comments were received.

Comparison with rules in adjacent states:

Illinois: The Illinois Prescription Monitoring Program does not require an NPI number to be reported [720 Illinois Compiled Statutes Chapter 570 Section 316].

Iowa: The Iowa Prescription Monitoring Program does not require an NPI number to be reported [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 require an NPI number to be reported [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program requires the NPI number of the prescriber and the NPI number of the dispenser to be reported for all controlled substances dispensed in the state [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 in consultation with Wisconsin Prescription Drug Monitoring Program staff to determine where the NPI number requirement can be added and if updates to other sections in the chapter were needed.

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; 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 March 8, 2024, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 4.02 (12s) is created to read:

CSB 4.02 (12s) "NPI number" means national provider identifier number, the unique number issued by the National Plan and Provider Enumeration System of the federal Centers for Medicare and Medicaid Services used in the U.S. to identify each health care provider.

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

CSB 4.04 (2) (b) The dispenser's DEA registration number, if applicable.

SECTION 3. CSB 4.04 (2) (bm) is created to read:

CSB 4.04 (2) (bm) Beginning December 1, 2025, the dispenser's NPI number.

SECTION 4. CSB 4.04 (2) (i) is amended to read:

CSB 4.04 (2) (i) The practitioner's DEA registration number, if applicable.

SECTION 5. CSB 4.04 (2) (im) is created to read:

CSB 4.04 (2) (im) Beginning December 1, 2025, the prescriber's NPI number.

SECTION 6. CSB 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), and 4.08 (1) (b) (Note) are amended to read:

CSB 4.05 (1) (b) (Note) The guide for dispensers which specifies the data standards in version 4 release 2 of the ASAP implementation guide for prescription monitoring programs and other electronic formats identified by the board may be obtained online at https://pdmp.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue4822 Madison Yards Way, P.O. Box 8366, Madison, WI 5370853705.

CSB 4.06 (3) (b) (Note) The application for an emergency waiver may be obtained online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 5370853705.

CSB 4.07 (2) (Note) The written notice to the board may be submitted through an account with the board, sent by electronic mail or sent by U.S. mail to the Department of Safety and Professional Services 1400 East Washington Avenue, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 5370853705.

CSB 4.08 (1) (b) (Note) The application for an exemption may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services 1400 East Washington Avenue,4822 Madison Yards Way, P.O. Box 8366, Madison, WI 5370853705. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

SECTION 7. CSB 4.08 (4) is repealed.

SECTION 8. CSB 4.097 (1) (i) is created to read:

CSB 4.097 (1) (i) Beginning December 1, 2025, the board may temporarily suspend access to monitored prescription drug history reports when the healthcare professional fails to enter any of the data under s. CSB 4.04 (2) where required.

SECTION 9. 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 05/13/2024 Agency Douglas Inglebert Chairperson

Controlled Substances Board

STATE OF WISCONSIN DEPARTMENT OF ADMINISTRATION DOA-2049 (R09/2016) DIVISION OF EXECUTIVE BUDGET AND FINANCE 101 EAST WILSON STREET, 10TH FLOOR P.O. BOX 7864 MADISON, WI 53707-7864 FAX: (608) 267-0372

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

Type of Estimate and Analysis Original ☐ Updated ☐ Corrected	2. Date February 5, 2024	
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 4		
4. Subject National Provider Identifier Requirement		
5. Fund Sources Affected ☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S	6. Chapter 20, Stats. Appropriations Affected s. 20.165 (1) (g)	
7. Fiscal Effect of Implementing the Rule ☑ No Fiscal Effect ☐ Increase Existing Revenues ☐ Indeterminate ☐ Decrease Existing Revenues	☐ Increase Costs ☐ Decrease Costs ☐ Could Absorb Within Agency's Budget	
☐ Local Government Units ☐ Publi	c Utility Rate Payers 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).		
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)? ☐ Yes ☑ No		
11. Policy Problem Addressed by the Rule The objective of the proposed rule is to add the National Provider Identifier (NPI) for all dispensing and prescribing Prescription Drug Monitoring Program (PDMP) records.		
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. N/A		
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 no one-time or annual costs to implement this rule.		
15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit of implementing the rule is increased accuracy and reporting on the prescribing of Gabapentin and any other monitored drug reported to the PDMP which does not require a DEA number to be prescribed and dispensed. All individual HIPAA-covered healthcare providers are required to have an individual NPI number and therefore NPI numbers can be reported by providers to the PDMP for monitored drugs in lieu of a DEA number. The alternative to implementing this rule is that Gabapentin, and any other future monitored drug that is not a controlled substance, will continue to be inconsistently reported in the PDMP system.		
16. Long Range Implications of Implementing the Rule The long range implications of implementing the rule are accruate reporting and tracking of Gabapentin and any other future monitored drug that is not a controlled substance in the PDMP		

17. Compare With Approaches Being Used by Federal Government

STATE OF WISCONSIN DEPARTMENT OF ADMINISTRATION DOA-2049 (R09/2016) DIVISION OF EXECUTIVE BUDGET AND FINANCE 101 EAST WILSON STREET, 10TH FLOOR P.O. BOX 7864 MADISON, WI 53707-7864 FAX: (608) 267-0372

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

None.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota) Illinois: The Illinois Prescription Monitoring Program does not require an NPI number to be reported [720 Illinois Compiled Statutes Chapter 570 Section 316].

Iowa: The Iowa Prescription Monitoring Program does not require an NPI number to be reported [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 require an NPI number to be reported [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program requires the NPI number of the prescriber and the NPI number of the dispenser to be reported for all controlled substances dispensed in the state [Minnesota Statutes Chapter 152 Section 152.126 Subdivision 4].

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.

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ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

 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