

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)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 4.02 (12s), 4.04 (2) (bm) and (im), 4.04 (5), and 4.097 (1) (i), and amend CSB 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) (im), and 4.04 (5). The Board also repealed the exemption requirement under CSB 4.08 (4) that allowed dispensers to be exempt from reporting Gabapentin prescribing if they do not have a DEA number.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 an NPI number. 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), 4.04 (2) (bm) and (im), and 4.04 (5) are created to read:

CSB 4.02 (12s) “NPI number” means national provider identifier number, the unique number used in the U.S. to identify each health care provider.

CSB 4.04 (2) (bm) The dispenser’s NPI number.

CSB 4.04 (2) (im) The prescriber’s NPI number.

CSB 4.04 (5) Beginning December 1, 2024, all healthcare professionals and pharmacies shall comply with the application of an NPI number to each prescription record required to be reported to the PDMP.

SECTION 2. 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 Avenue~~ 4822 Madison Yards Way, P.O. Box 8366, Madison, WI ~~53708~~ 53705.

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 ~~53708~~ 53705.

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 ~~53708~~53705.

CSB 4.08 (1) (b) (Note) The application for an exemption may be obtained online at www.dsp.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 ~~53708~~53705. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

SECTION 3. CSB 4.08 (4) is repealed.

SECTION 4. CSB 4.097 (1) (i) is created to read:

CSB 4.097 (1) (i) Beginning December 1, 2024, the board may temporarily suspend access to monitored prescription drug history reports when the healthcare professional fails to enter an NPI number into the PDMP system where required.

SECTION 5. 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)