

Clearinghouse Rule 24-060

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 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)
