STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 19-156)

ORDER

An order of the Controlled Substances Board **to amend** CSB 4.11 (9) and **to create** CSB 4.04 (2) (gb) and (gd), 4.09 (1) (c) and (d) and 4.093 (2m), relating to operation of prescription drug monitoring program.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.385, Stats.

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

Explanation of agency authority:

The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs. The section goes on to state several items the board shall do, including defining what constitutes suspicious or critically dangerous conduct or practices for purposes of the rules promulgated under s. 961.385 (2) (c), Stats.

Related statute or rule: s. 961.385, Stats.

Plain language analysis:

Section 1 requires the drug dosage units and partial fill indicator to be submitted to the prescription drug monitoring program.

Section 2 clarifies that healthcare professionals may access monitored prescription drug history reports about a patient for scientific research purposes if the patient is a direct patient of the healthcare professional and the patient has given informed consent. In addition, the proposed rule clarifies that a healthcare professional may access monitored prescription drug history reports about a patient for purposes of conducting an overdose fatality review.

Section 3 allows department staff who are charged with investigations to be able to access audit trails related to the log of monitored prescription drug history reports and prescription drug monitoring program data disclosed and a log of requests for prescription drug monitoring program data or monitored prescription drug history reports even when no information was disclosed.

Section 4 clarifies research purposes to be for scientific research purposes and that the Controlled Substances Board may require evidence of institutional review board approval for the research.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not require submission of the drug dosage unit or partial fill indicator. Illinois does not authorize access for practitioner scientific research.

Iowa: Iowa does not require submission of the drug dosage unit or partial fill indicator. Iowa does not authorize access for practitioner scientific research. Summary, statistical, or aggregate data to public or private entities for statistical, public research, public policy, or educational purposes.

Michigan: Michigan does not require submission of drug dosage units or partial fill indicator. Data may be provided to employees or agents of the Department of Licensing and Regulatory Affairs. Michigan does not authorize access for scientific research.

Minnesota: Minnesota requires the submission of drug dosage units and partial fill indicator. Personnel of the Minnesota Board of Pharmacy may have access to audit trails. Minnesota does not authorize access for scientific research.

Summary of factual data and analytical methodologies:

The Controlled Substances Board reviewed the rule to make clarifications and updates based upon stakeholder feedback.

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

This rule was posted for economic comments and none 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

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TEXT OF RULE

SECTION 1. CSB 4.04 (2) (gb) and (gd) is created to read:

CSB 4.04 (2) (gb) The drug dosage units.
(gd) The partial fill indicator.

SECTION 2. CSB 4.09 (1) (c) and (d) are created to read:

CSB 4.09 (1) (c) Scientific research purposes if all of the following requirements are met:

1. The patient is a direct patient of the healthcare professional.
2. The healthcare professional has obtained informed consent from the patient to access monitored prescription drug history reports for scientific research purposes.

(d) Purposes of conducting an overdose fatality review.

SECTION 3. CSB 4.093 (2m) is created to read:

CSB 4.093 (2m) Department staff who are charged with investigating dispensers, dispenser delegates, pharmacists, pharmacist delegates, practitioners, and practitioner delegates may access the audit trails related to s. CSB 4.12 (3) (f) and (g).

SECTION 4. CSB 4.11 (9) is amended to read:

CSB 4.11 (9) The board may disclose PDMP data without personally identifiable information that could be reasonably used to identify any patient, healthcare professional, practitioner delegate, pharmacist delegate, or dispenser for public health and scientific research purposes. The board may require evidence of institutional review board approval.

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)

Dated July 10, 2020 Agency

Chair
Controlled Substances Board