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 15-101)

ORDER

An order of the Controlled Substances Board to repeal 4.03 (3); to amend CSB 4.02 (4), 4.08 (1), 4.10 (1) (c), 4.10 (2) (a), 4.11 (1), 4.11 (1) (b), 4.11 (2), 4.11 (2) (c), 4.11 (7), 4.11 (7) (c), 4.11 (8) and 4.11 (8) (c); to create 4. 15 relating to the operation of the prescription drug monitoring program.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.385, Stats.

Statutory authority: ss. 961.385 (2)

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:

Plain language analysis:

Section 1 indicates Board means the Controlled Substances Board. 2015 Act 55 changed the jurisdiction of the prescription drug monitoring program from the Pharmacy Examining Board to the Controlled Substances Board.

Section 2 repeals Tramadol from the list of monitored prescription drugs, because Tramadol is now identified as a controlled substance by both federal and Wisconsin law.

Section 3 changes the "his or her" to its to be consistent with the language throughout this chapter.

Sections 4 and 5 update dispenser and dispenser delegate to pharmacist and pharmacist delegate. This change was done for clarity in CR 14-003, and there were two instances of these words that were inadvertently missed.

Sections 6, 7, 8, 9, 10, 11, 12 and 13 replace the references to PDMP information with references to dispensing data. This change is to create clarity between the situations in which the Board may disclose dispensing data and when the Board may disclose other PDMP information. There are situations in which it may be inappropriate and contradictory to the purpose of the program to disclose PDMP information when dispensing data would be more appropriate. The change clearly delineates when the Board may release dispensing data and PDMP information.

Section 14 creates a section on disclosure of PDMP information when the Board identifies suspicious or critically dangerous conduct or practices in PDMP data. 2015 Act 55 directs the board to include provisions in the rules governing the Board's disclosure of PDMP information that allow the Board to disclose information to relevant state boards and agencies, agencies of other states and law enforcement agencies under circumstances that indicate suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner or patient. This rule defines the factors that the Board will use to determine whether the conduct or practices of a pharmacy, pharmacist, practitioner or patient are suspicious or critically dangerous.

When looking at the pharmacist's or pharmacy's practice, the factors will include: practice which deviates from accepted practice, unusual patterns in payment, history of actions taken against the pharmacist or pharmacy, type and number of monitored prescription drugs dispensed, forged prescription orders for a monitored prescription that have been dispensed, the distance patients travel to have monitored prescription drugs dispensed and the number of patients dispensed monitored prescription drugs who meet the criteria of patients engaging in suspicious or critically dangerous conduct.

When looking at the practitioner's practice, the factors will include: prescribing practices which deviate from accepted prescribing practices, prescribing potentially dangerous combinations of monitored prescription drugs to the same patient, the type and number of monitored prescription drugs prescribed by the practitioner, history of actions taken against the practitioner, the distance patients travel to obtain monitored prescription drug prescriptions and the number of patients to

whom the practitioner prescribes monitored prescriptions who meet the criteria of patients engaging in suspicious or critically dangerous conduct.

When looking at a patient, the factors will include: the number of practitioners from whom the patient has obtained a prescription for a monitored prescription drug, number of pharmacies from where the patient was dispensed a monitored prescription drug, the number of prescriptions for monitored drug obtained by the patient, the number of monitored prescription drug doses dispensed to the patient, the monitored prescription drugs dispensed to a patient which include dangerous levels of any drug, the number of times the patient is prescribed or dispensed a monitored drug before the previously dispensed amount of the same or a similar monitored prescription drug would be expected to end and the payment methodology used by the patient to obtain controlled substances.

Upon determining that there are circumstances indicating suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner or patient, the Board may disclose PDMP information to a relevant patient, pharmacist, practitioner, state board or agency, agency of another state or law enforcement agency.

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

Comparison with rules in adjacent states:

Illinois: Illinois' prescription monitoring program does not address proactive disclosure of suspicious or critically dangerous conduct or practices.

Iowa: Iowa does not have rules which allow for disclosure to regulatory agencies or law enforcement without an order, subpoena or other means of legal compulsion relating to a specific investigation of a specific individual and supported by a determination of probable cause.

Michigan: Michigan's prescription monitoring program does not address proactive disclosure of suspicious or critically dangerous conduct or practices to entities.

Minnesota: The Minnesota Board of Pharmacy is required by statute to review the data submitted to the prescription monitoring program on at least a quarterly basis to determine if a patient meets criteria defined by the Board in consultation with an advisory task force. If the Board determines that a patient meets the criteria, the Board may disclose information about the patient to prescribers and pharmacists who have treated the patient. The prescription monitoring program may be used by permissible users for the identification of individuals receiving prescriptions for controlled substances from prescribers who subsequently obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards of use for those controlled substances and individuals presenting forged or otherwise false or altered prescriptions for controlled substances to dispensers. Minnesota does not allow accessing the database for the sole purpose of identifying prescribers of controlled substances for unusual or excessive prescribing patterns without a valid search warrant or court

order. No licensing board or agency may access the database for the purpose of obtaining information to be used to initiate or substantiate a disciplinary action against a prescriber.

Summary of factual data and analytical methodologies:

In order to define what factors to evaluate to determine what constitutes suspicious or critically dangerous conduct or practices the Board consulted the following sources:

Prescription Drug Monitoring Program Center of Excellence at Brandeis University, *Using PDMP Data to Guide Interventions with Possible At-Risk Prescribers*, Oct. 2014.

Prescription Drug Monitoring Program Center of Excellence at Brandeis University, *Guidance on PDMP Best Practices: Options for Unsolicited Reporting*, Jan. 2014.

Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach*, Nov. 2015.

Haegerich, et al., *What We Know, and Don't Know, About the Impact of State Policy and Systems-Level Interventions on Prescriptions Drug Overdose*, Drug and Alcohol Dependence: An International Journal on Biomedical and Psychosocial Approaches, Oct. 2014.
WCMR 14-118-011 Rules Governing The Controlled Substances Prescription Monitoring Program.

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 Eric.Esser@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 4.02 (4) is amended to read:

CSB 4.02 (4) "Board" ~~has the meaning given in s. 450.01 (2), Stats.~~ means the Controlled Substances Board.

SECTION 2. CSB 4.03 (3) is repealed.

SECTION 3. CSB 4.08 (1) is amended to read:

CSB 4.08 (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew ~~his or her~~ its license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

SECTION 4. CSB 4.10 (1) (c) is amended to read:

CSB 4.10 (1) (c) The denial, suspension, revocation or other restriction or limitation imposed on the ~~dispenser's,~~ ~~dispenser~~ pharmacist's, pharmacist delegate's, practitioner's, or practitioner delegate's account pursuant to s. CSB 18.09 (3).

SECTION 5. CSB 4.10 (2) (a) is amended to read:

CSB 4.10 (2) (a) The ~~dispenser's,~~ ~~dispenser~~ pharmacist's, pharmacist delegate's, practitioner's, or practitioner delegate's name and address, including street address, city, state and ZIP code.

SECTION 6. CSB 4.11 (1) is amended to read:

CSB 4.11 **(1)** The board shall disclose ~~PDMP information~~ dispensing data about a patient to the patient if he or she does all of the following:

SECTION 7. CSB 4.11 (1) (b) is amended to read:

CSB 4.11 (1) (b) Makes a request for the ~~PDMP information~~ dispensing data on a form provided by the board.

SECTION 8. CSB 4.11 (2) is amended to read:

CSB 4.11 (2) The board shall disclose ~~PDMP information~~ dispensing data about a patient to a person authorized by the patient if the person authorized by the patient does all of the following:

SECTION 9. CSB 4.11 (2) (c) is amended to read:

CSB 4.11 (2) (c) Makes a request for the ~~PDMP information~~ dispensing data on a form provided by the board.

SECTION 10. CSB 4.11 (7) is amended to read:

CSB 4.11 (7) The board shall disclose the minimum amount of ~~PDMP information~~ dispensing data necessary to a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

SECTION 11. CSB 4.11 (7) (c) is amended to read:

CSB 4.11 (7) (c) Makes a request for the ~~PDMP information~~ dispensing data through its account with the board.

SECTION 12. CSB 4.11 (8) is amended to read:

CSB 4.11 (8) The board shall disclose the minimum amount of ~~PDMP information~~ dispensing data necessary to a coroner, deputy coroner, medical examiner, or medical examiner's assistant following the death of a patient in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

SECTION 13. CSB 4.11 (8) (c) is amended to read:

CSB 4.11 (8) (c) Makes a request for the ~~PDMP information~~ dispensing data through its account with the board.

SECTION 14. CSB 4.15 is created to read:

CSB 4.15 **Disclosure of suspicious or critically dangerous conduct or practices.**
(1) The board may review PDMP information to determine whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist, pharmacy, practitioner, or patient.
(2) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist or pharmacy:

(a) The pharmacist or pharmacy's monitored prescription drug dispensing practices deviate from accepted pharmacist or pharmacy practices.

(b) There are unusual patterns in the payment methodology used by patients to whom monitored prescription drugs are dispensed by the pharmacist or pharmacy.

(c) The history of actions taken against the pharmacist or pharmacy by other state agencies, agencies of another state, or law enforcement.

(d) The type and number of monitored prescription drugs dispensed by the pharmacist or at the pharmacy.

(e) The pharmacist or pharmacy has dispensed forged prescription orders for a monitored prescription drug.

(f) The distance patients travel to have monitored prescription drugs dispensed at the pharmacy.

(g) The number of patients dispensed monitored prescription drugs at the pharmacy or by the pharmacist who satisfy any of the criteria identified in sub. (4).

(3) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a practitioner:

(a) The practitioner's monitored prescription drug prescribing practices deviate from accepted prescribing practices.

(b) The practitioner prescribes potentially dangerous combinations of monitored prescription drugs to the same patient.

(c) The type and number of monitored prescription drugs prescribed by the practitioner.

(d) The history of actions taken against the practitioner by other state agencies, agencies of another state, or law enforcement.

(e) The distance patients travel to obtain monitored prescription drug prescriptions from the practitioner.

(f) The number of patients to whom the practitioner prescribed a monitored prescription who satisfy any of the criteria identified in sub. (4).

(4) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a patient:

(a) The number of practitioners from whom the patient has obtained a prescription for a monitored prescription drug.

(b) The number of pharmacies from where the patient was dispensed a monitored prescription drug.

(c) The number of prescriptions for a monitored prescription drug obtained by the patient.

(d) The number of monitored prescription drug doses dispensed to the patient.

(e) Whether the monitored prescription drugs dispensed to the patient include dangerous levels of any drug.

(f) The number of times the patient is prescribed or dispensed a monitored prescription drug before the previously dispensed amount of the same or a similar monitored prescription drug would be expected to end.

(g) The payment methodology used by the patient to obtain controlled substances at a pharmacy.

(5) Upon determining that circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacy, practitioner, or patient, the Board may disclose PDMP information to any of the following:

(a) A relevant patient.

(b) A relevant pharmacist or practitioner.

(c) A relevant state board or agency.
(d) A relevant agency of another state.
(e) A relevant law enforcement agency.

SECTION 15. 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)
