**STATE OF WISCONSIN**
**CONTROLLED SUBSTANCES BOARD**

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| **IN THE MATTER OF RULEMAKING** | **:** | |
| **PROCEEDINGS BEFORE THE** | **:** | **REPORT TO THE LEGISLATURE** |
| **CONTROLLED SUBSTANCES BOARD** | **:** | **CR 17-028** |

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## 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 statutes directs the Controlled Substances Board to establish by rule a prescription drug monitoring program and lists several requirements for the program 2015 Acts 266, 267 and 268 amended these requirements , specifically the requirements related to reporting, disclosure, and practitioner review. This rule amends the rule to implement these Acts and make other necessary changes resulting from the implementation.

## 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 May 12, 2017. The following people either testified at the hearing, or submitted written comments:**

Mark Grapentine, representing Wisconsin Medical Society
Matthew Stanford, representing Wisconsin Hospital Association
Joe Kachelski, representing Wisconsin Statewide Health Information Network
Brad Bekkum, representing Marshfield Clinic Health System
David Rushlow and Donn Dexter, representing Mayo Clinic Health System
Michael Richards, representing Gundersen Health System

**The Controlled Substances Board summarizes the comments received either by hearing testimony or by written submission as follows:**

Everyone who testified at the hearing or submitted comments were overall supportive of the rule. Multiple people providing comments made the following recommendations:

- Amend the language to explicitly recognize the medical principle of agency and delegation applies to the mandated physician review of the record.

- Designate the data elements which must be contained in a record to satisfy the practitioner's review obligation.
- Maintain the prohibition on a vendor simply providing a summary of PDMP data or a snapshot of PDMP data as a means for practitioners to meet the PDMP review mandate. However, amend the language to allow for integration efforts with third party vendors.
- Require registration with the ePDMP for receipt of notifications and law enforcement alerts if contracting with a third party vendor.
- Create language to authorize access to the PDMP by a practitioner's vendor provided the vendor enters into a data use agreement approved by the Department of Safety and Professional Services.
- Amend the language in CSB 4.105 (3) to clarify that mere non-compliance with the practitioner review mandate cannot be referred to the law enforcement.

In addition to the above recommendations, the following comments were made:

- Gundersen Health Systems requested practitioners working at skilled nursing facilities to be exempt from the required practitioner PDMP review.
- Marshfield Clinic Health System requested the requirement for a practitioner notify the Board when the practitioner is unable to review a patient record because the PDMP system is not operational or due to other technological failures.
- Marshfield Clinic Health System also recommended the rule allow PDMP integration access through Appriss, a third party vendor.

**The Controlled Substances Board explains modifications to its rule-making proposal prompted by public comments as follows:**

The Controlled Substances Board modified the rule to allow practitioners to delegate review following standards of practice and clarified language regarding referrals to law enforcement by limiting such reports to situations in which dangerous practice or criminal activity may have occurred.

The Controlled Substances Board recognizes the value of PDMP being integrated into a patient's electronic health record and is working to better facilitate health system and prescriber adoption of the ePDMP integration. However, the Controlled Substances Board believes it would be in the interest of public safety to provide the data directly through the PDMP system itself without using a third party vendor entity. This relieves significant concerns a third party vendor would receive the confidential patient health information, remove the encryption, manipulate the data and then transmit to the electronic health record. The Controlled Substances Board would have no control over what the third party does with sensitive patient health information nor be able to protect the confidentiality of patient health information. In addition, a practitioner would not receive any of the notifications or law enforcement alerts which are required features of the PDMP and valuable information to the decision making process of a practitioner prior to prescribing a controlled substance.

The Controlled Substances Board declined to define practitioner review beyond what is currently defined in s. CSB 4.02 (12m). Section 961.385 (2) (cs), Stats. requires the

program to require a practitioner to review a patient's records under the program before the practitioner issues a prescription order for the patient. The statute does not limit the monitored prescription drug history report of a patient to a subset of patient information and the Controlled Substances Board's position is the entire patient record has pertinent data for the practitioner to review prior to prescribing a controlled substance.

The Controlled Substances Board declined to exempt practitioners working at skilled nursing facilities to be exempt from the required practitioner PDMP review. Section 961.385 (2) (cs) 2., Stats recreates exemptions to the practitioner review requirement and practitioner working in a skilled nursing facility does not fall under one of those exemptions, therefore, the Controlled Substances Board does not have the authority to make that exemption.

The Controlled Substances Board declined to remove the requirement for a practitioner to report to the Board when the practitioner is unable to review the patient's records because the PDMP system is not operational or due to other technological failure. The program is required to have this requirement in place per s. 961.385 (2) (cs) 2. e., Stats.

## VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

**Comment 2b:** In the rule summary's explanation of agency authority, consider providing a brief plain language description of the authority, rather than repeating the statutory text. Likewise, in the plain language analysis, consider providing a brief description of the changes effected by the enactment of the cited Acts, rather than simply citing the Acts.

**Response**: The Controlled Substances Board chose to keep the statutory language in the explanation of agency authority. While the statutory authority is lengthy it does list all of the items which are required to be a part of the prescription drug monitoring program.

**Comment 2e:** In s. CSB 4.02 (15g) and (17), the amended definitions for "pharmacist" and "practitioner" are phrased in a substantive rather than descriptive manner, and are unnecessary because the cited definitions under current law already include pharmacists and practitioners licensed in another state. Consider removing those changes.

**Response**: The amended definitions clarify that those licensed in another state but are working in Wisconsin (under another state's license) are included in the definition. This is a clarification for those working in federal facilities or working under the nurse licensure compact.

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:

This rule does not have an impact on small business.

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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| IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD | : | PROPOSED ORDER OF THE CONTROLELD SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 17-028) |

## PROPOSED ORDER

An order of the Controlled Substances Board to repeal CSB 4.02 (14), and (15)(b), 4.03 (2), 4.04 (1) (b), (d) and (e), 4.05 (2) and (3), 4.10 (1) (a), 4.11 (10) (c) (note), 4.12 (2), (4), (4g), (4r) and (5); to renumber and amend CSB 4.05 (1); to consolidate, renumber and amend CSB (15) (intro.) and (a); to amend CSB 4.01, 4.02 (1), (2), (7), (11r), (12) (a) 1., (13), (15g), (15r), (16), (17) and (18), 4.04 (2) (b), (e) and (i) and (4), 4.06 (1), (2), (3) and (5), 4.10 (1) (intro), and (c), (2) (intro) and (a), (3), (6), and (7), 4.11 (title), (1), (2) (intro) and (c), (5) (intro.), (a) and (c), (6) (intro.), (a) and (c), (7) (intro.), (a) and (c), (8) (intro.), (a) and (c), (9), and (10), 4.12 (title) and (1), 4.12 (6) (intro.) and (a), and (6) (c), 4.13, 4.14 (title) and (1) (intro.), and 4.15 (1) and (5) (intro.); to repeal and recreate CSB 4.05 (1) (note), 4.05 (4), 4.07, 4.09, and 4.12 (3); to create CSB 4.02 (2m), (3s), (4m), (5m), (11c), (11n), (11w), (12m), (15b), (15e), (18m) and (21m), 4.05 (1) (a) and (b), 4.08 (2m), 4.093, 4.097, 4.105, 4.11 (5) (d), 4.12 (2m), (6) (am), and (6) (cg) and (cr) 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:** s. 961.385 (2), Stats.

**Explanation of agency authority:**

961.385 (2) The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs. The program shall do all of the following:

(a) 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 a 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, except that the program may not require the generation of a record in any of the following circumstances:

1. A monitored prescription drug is administered directly to a patient.

2. A monitored prescription drug is compounded, packaged, or labeled in preparation for delivery but is not delivered.

3. The prescription order is for a monitored prescription drug that is a substance listed in the schedule in s. 961.22 and is not a narcotic drug, and the prescription order is for a number of doses that is intended to last the patient 7 days or less.

(b) 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. 450.11 (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.

(c) Specify the persons to whom a record may be disclosed and the circumstances under which the disclosure may occur. Except as otherwise provided under this section, the rule promulgated under this paragraph shall comply with s. 146.82.

(cm) Permit the board to disclose a record generated by the program to any of the following:

1. A practitioner, pharmacist, registered nurse licensed under s. 441.06, substance abuse counselor, as defined in s. 440.88 (1) (b), or individual authorized under s. 457.02 (5m) to treat alcohol or substance dependency or abuse as a specialty if any of the following is applicable:

a. The practitioner, pharmacist, registered nurse, substance abuse counselor, or individual is directly treating or rendering assistance to the patient.

b. The practitioner, pharmacist, registered nurse, substance abuse counselor, or individual is being consulted regarding the health of the patient by an individual who is directly treating or rendering assistance to the patient.

2. A person who medically coordinates, directs, or supervises, or establishes standard operating procedures for, a practitioner, pharmacist, registered nurse, substance abuse counselor, or individual authorized under s. 457.02 (5m) to treat alcohol or substance dependency or abuse as a specialty to whom records may be disclosed under subd. 1., if the person is evaluating the job performance of the practitioner, pharmacist, registered nurse, substance abuse counselor, or individual, or is performing quality assessment and improvement activities, including outcomes evaluation or development of clinical guidelines, and if the disclosure does not contain personally identifiable information, as defined in s. 19.62 (5), of a patient and is limited to only those records about the practitioner, pharmacist, registered nurse, substance abuse counselor, or individual the person medically coordinates, directs, or supervises, or for whom the person establishes standard operating procedures.

3. Relevant state boards and agencies, relevant agencies of other states, relevant law enforcement agencies, as defined in s. 165.77 (1) (b), and relevant prosecutorial units, as defined in s. 978.001 (2), if any of the following is true:

a. The state board or agency, agency of another state, law enforcement agency, or prosecutorial unit makes a written request for the record and is engaged in an active and specific investigation or prosecution of a violation of any state or federal law involving a monitored prescription drug, and the record being requested is reasonably related to that investigation or prosecution.

b. The state board or agency, agency of another state, law enforcement agency, or prosecutorial unit makes a written request for the record and is monitoring the patient as part of a drug court, as defined in s. 165.955 (1).

c. The circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner, or patient. The board shall define what constitutes suspicious or critically dangerous conduct or practices for purposes of this subd. 3. c.

4. An agent of a practitioner or pharmacist if disclosure to the practitioner or pharmacist is authorized subject to subd. 1.

(cs) 1. Require a practitioner to review a patient's records under the program before the practitioner issues a prescription order for the patient. This subdivision does not apply after April 1, 2020 or 3 years after the 30th day after the date of publication in the Wisconsin Administrative Register of the notice under 2015 Wisconsin Act 266, section 17 (2g), whichever is later.

2. The requirement under subd. 1. that a practitioner review a patient's records under the program before the practitioner issues a prescription order for the patient does not apply if any of the following is true:

a. The patient is receiving hospice care, as defined in s. 50.94 (1) (a).

b. The prescription order is for a number of doses that is intended to last the patient 3 days or less and is not subject to refill.

c. The monitored prescription drug is lawfully administered to the patient.

d. Due to emergency, it is not possible for the practitioner to review the patient's records under the program before the practitioner issues a prescription order for the patient.

e. The practitioner is unable to review the patient's records under the program because the digital platform for the program is not operational or due to other technological failure if the practitioner reports that failure to the board.

(d) Specify a secure electronic format for submittal of a record generated under the program and authorize the board to grant a pharmacy or practitioner a waiver of the specified format.

(e) Specify a deadline for the submittal of a record to the board.

(f) Permit the board to refer to the appropriate licensing or regulatory board for discipline, or the appropriate law enforcement agency for investigation and possible prosecution, a pharmacist, pharmacy, or practitioner that fails to comply with rules promulgated under this subsection, including by failure to generate a record that is required by the program.

(g) Maximize the potential for funding the operation of the program with available federal funding sources.

(h) Ensure that the program complies with s. 146.82, except as otherwise provided in this section, and 45 CFR part 164, subpart E.

(i) Disclose information submitted to the program by a law enforcement agency under s. 961.37 (3) (a) to relevant practitioners, pharmacists, and others to whom the board may make disclosures under par. (c).

**Related statute or rule: N/A**

**Plain language analysis:**

This rule implements 2015 Wisconsin Acts 266, 267 and 268.

Section 1 updates the authority and scope to reflect the disclosure of information and the dispensing of monitored prescription drugs.

Section 2 updates the definition of "access" to reflect the ability to view monitored prescription drug history reports, audit trails and PDMP data. The definition of administer is updated to reflect the new statutory definition.

Section 3 creates new definitions for “agent”, “audit trail”, “business day” and “deliver or delivery”. “Agent”, “business day” and “deliver or delivery” have the same definitions as the statutes. “Audit trail” is a log of each time the PDMP system discloses information and the type of information disclosed.

Section 4 updates the statutory reference in the definition of “dispense”.

Section 5 creates definitions of “healthcare professional”, which is a pharmacist, practitioner, registered nurse, substance abuse counselor or an individual credentialed by the Marriage and Family Therapy, Professional Counseling and Social Work Examining Board with the substance use disorder specialty, and “law enforcement agency” which has the meaning given in statutes.

Section 6 amends the definition of “managing pharmacist” as a pharmacist who has responsibility and direct control of the pharmaceutical operations in a pharmacy.

Section 7 creates definitions for “medical coordinator” and “monitored prescription drug history report”. A medical coordinator is the person responsible for the operating procedures for a healthcare professional. Monitored prescription drug history report includes the PDMP data, required reports, information submitted to the program and the information form the analytics platform.

Section 8 updates the statutory reference in the patient definition.

Section 9 repeals the definition for person authorized by the patient.

Section 10 updates the definition of “PDMP data” as the information compiled and analyzed by the system based upon data submitted by dispensers.

Section 11 repeals the portion of the “PDMP information” definition because it no longer is applicable.

Section 12 creates definitions for “PDMP system” and “personally identifiable information”. The PDMP system is the entire hardware and software of the systems. Personally identifiable information is information which identifies a person.

Section 13 updates the definitions of “pharmacist”, “pharmacist delegate”, “pharmacy”, “practitioner” and “practitioner delegate”. “Pharmacist” is updated to recognize pharmacists who are licensed in another state but engage in practice in Wisconsin or at a pharmacy licensed as an out-of-state pharmacy. “Pharmacist delegate” and “practitioner delegate” are updated to reflect the change in terminology from PDMP information to monitored prescription drug history reports. The “pharmacy” definition has an updated statutory reference. “Practitioner” definition adds people who are licensed in another state but can legally engage in practice in our state without a Wisconsin license.

Section 14 creates a definition of “prescribing metrics report” which includes PDMP data, audit trails, reports about a patient submitted to the program and information from the analytics platform. It also creates a definition for “prosecutorial unit” citing the definition in statute.

Section 15 repeals from the drugs that have a substantial potential for abuse, those substances which are identified in schedule IV or V in the Wisconsin controlled substances schedules due to these substances are monitored drugs and no longer need the separate identification.

Section 16 repeals the definitions for “dispenser identifier”, “NPI number” and “practitioner identifier” as they are no longer utilized.

Section 17 removes dispenser identifier and practitioner identifier and replaces with the DEA registration number; removes the name and strength of the monitored prescription drug. It also clarifies the language that the board may refer a dispenser and dispenser delegate for failing to comply the dispensing data to the appropriate licensing board for discipline.

Section 18 updates that dispensing data may be transmitted in multiple ways.

Section 19 creates that dispensing data may be submitted as a file that complies with the data standards identified in the implementation guide. Or by using the prescription record entry functions of the system.

Section 20 recreates the note for how the data standards in version 4 release 2 of the ASAP implementation guide for prescription monitoring programs may be obtained.

Section 21 repeals two portions of electronic submission of dispensing data which are no longer methods of submission.

Section 22 indicates that the board may refer a dispenser or delegate that fail to submit data to the licensing board for discipline.

Section 23 requires submission of dispensing data to the PDMP no later than 11:59 p.m. the next business day after the monitored prescription drug is dispensed. If no monitored prescription drug is dispensed during that business day, the dispenser shall submit a zero report. If a report is unable to be submitted due to circumstances beyond the control of the dispenser, the dispenser may request an emergency waiver from the board. The board may refer a dispenser or delegate that fail to submit data to the licensing board for discipline.

Section 24 creates provisions for correcting dispensing data within 5 business days of discovering the error. The board may refer a dispenser or delegate that fails to correct data to the licensing board for discipline or to law enforcement for possible prosecution.

Section 25 creates a provision that a dispenser is not required to submit dispensing data when a drug is prepared for delivery but not yet delivered.

Section 26 repeals and recreates the provisions relating to access to monitored prescription drug history reports and PDMP data to reflect updated terminology and requirements as a result of

Acts 266, 267 and 268. Monitored prescription drug history reports may be accessed by healthcare professionals, pharmacists and pharmacist delegates if the individual is treating or rendering assistance to the patient or the individual is being consulted regarding the health of the patient. Healthcare professionals, pharmacists and pharmacist delegates may only disclose monitored prescription drug history reports to the patient, to another healthcare professional or medical coordinator for consultation, to the pharmacist or practitioner who is directly treating or rendering assistance or to a law enforcement agency.

Section 27 creates a section regarding monitored prescription drug history reports and audit trails about healthcare professions. Healthcare professionals may access audit trails about themselves and their delegates. A practitioner may access the audit trails accessible to healthcare professionals and a prescribing metrics report about themselves. Medical coordinators may access prescribing metrics reports and audit trails about individuals they direct or supervise or if they are evaluating the job performance or performing quality assessment and improvement activities.

Section 28 provides grounds for denying, suspending, revoking or restricting or limiting access to the PDMP.

Section 29 updates to include healthcare professional and medical coordinator.

Section 30 repeals a no longer valid cross reference.

Section 31 updates the section to include healthcare professional and medical coordinator.

Section 32 creates the provision that the practitioner or practitioner delegate assisting the practitioner in accordance with the standards of practice, review PDMP before prescribing unless the patient is receiving hospice care, the prescription is for 3 days or less, the drug is administered to the patient, the practitioner is unable to review the PDMP due to an emergency or because the PDMP is not operation or other technological failure that is reported to the board. The board may refer a practitioner that fails to review the PDMP to the licensing board for discipline.

Section 33 updates terminology. It also clarifies if a patient is requesting data by mail that copies of two forms of identity must be included with the request.

Section 34 creates a provision the board may disclose the minimum necessary amount of information to designated staff of a federal or state governmental agency that cites the agency's authorization to similar confidential patient care records.

Section 35 updates terminology.

Section 36 repeals an obsolete note.

Section 37 updates that the PDMP database is to store dispensing data and is in a secure environment and encrypted format.

Section 38 repeals the separate provision that is unnecessary due to the update in section 37.

Section 39 creates a requirement for the board to develop and maintain PDMP to facilitate the submission of dispensing data, creation of monitored prescription drug history reports about patients, practitioners and dispensers and access to the monitored prescription drug history reports, prescribing metrics reports and audit trails.

Section 40 creates the description of audit trails which includes logs of dispensing data, persons who have access to the PDMP, prescription monitoring programs in other states which shares data, pharmacies and hospitals which are determined to have the equivalent capability to maintain the confidentiality of monitored prescription drug history reports and a log of each time a person accesses PDMP, monitored prescription drug history reports and PDMP data disclosed pursuant to CSB 4.11 and requests for PDMP data or monitored prescription drug history reports even when no information was disclosed.

Section 41 repeals the separate provisions regarding logs which must be maintained due to the creation of section 40.

Section 42 updates terminology.

Section 43 creates provision regarding the operation of the analytics platform.

Section 44 updates terminology from PDMP information to monitored prescription drug history reports, audit trails and PDMP data.

Section 45 creates the requirement for preparing monitored prescription drug history reports, audit trails and PDMP data for the board to review in determining whether suspicious or critically dangerous conduct or practices took place.

Section 46 updates terminology regarding the confidentiality of PDMP records. It clarifies that a person who discloses PDMP data may be referred for discipline or prosecution.

Section 47 updates terminology from information to monitored prescription drug history reports and data.

Section 48 amends the information being reviewed and disclosed by the board when determining suspicious or critically dangerous conduct to include dispensing data, monitored prescription drug history reports, and PDMP data.

Section 49 creates the provision to allow the board to refer a pharmacist, pharmacy, or practitioner to law enforcement agency for investigation and possible prosecution if the board determines tat a criminal violation may have occurred. As part of the referral, the board may disclose monitored prescription drug history reports, audit trails and PDMP data.

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

**Comparison with rules in adjacent states:**

**Illinois**: Illinois requires reporting to the drug monitoring program within one day. Illinois does not require mandatory use of the drug monitoring program. Illinois does not provide access to mental health, substance abuse professionals or law enforcement.

**Iowa**: Iowa requires reporting to the drug monitoring program within one week. Iowa does not require mandatory use of the drug monitoring program. Iowa does not provide access to mental health, substance abuse professionals or law enforcement.

**Michigan**: Michigan requires reporting to the drug monitoring program within one day if reporting online and within one week if reporting by mail. Michigan does not require mandatory use of the drug monitoring program. Michigan does not provide access to mental health, substance abuse professionals or law enforcement.

**Minnesota:** Minnesota requires reporting to the drug monitoring program within one day. Minnesota does require mandatory use of the drug monitoring program. Minnesota does provide access to mental health and substance abuse professionals. Minnesota does not provide access to law enforcement.

**Summary of factual data and analytical methodologies:**

This rule updates terminology and requirements resulting from 2015 Wisconsin Acts 266, 267 and 268.

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

This rule was posted on website for the solicitation of 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 Kirsten.Reader@wisconsin.gov, or by calling (608) 267-2435.

**Agency contact person**:

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

**Place where comments are to be submitted and deadline for submission**:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on May 12, 2017 to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. CSB 4.01 is amended to read:

**CSB 4.01 Authority and scope.** The rules in this chapter are adopted under authority in ss. 227.11 (2) (a) and 961.385, Stats., for the purpose of creating a prescription drug monitoring program to collect and ~~maintain~~ disclose information relating to the prescribing and dispensing of monitored prescription drugs.

SECTION 2. CSB 4.02 (1) and (2) are amended to read:

**CSB 4.02 (1)** "Access" means to have the ability to view ~~PDMP information through an account established with the board~~ monitored prescription drug history reports, audit trails, and PDMP data as authorized by s. CSB 4.09.

**(2)** "Administer" has the meaning given in s. ~~450.01 (1)~~ 961.385 (1) (a), Stats.

SECTION 3. CSB 4.02 (2m), (3s), (4m) and (5m) are created to read:

**CSB 4.02 (2m)** "Agent" has the meaning given in s. 961.385 (1) (ab), Stats.

**(3s)** "Audit trail" means the log that contains information about each time the PDMP system discloses PDMP data, monitored prescription drug history reports, and prescribing metrics reports.

**(4m)** "Business day" has the meaning given in s. 961.385 (1) (ad), Stats.

**(5m)** "Deliver" or "delivery" has the meaning in s. 961.385 (1) (ae), Stats.

SECTION 4. CSB 4.02 (7) is amended to read:

**CSB 4.02 (7)** "Dispense" has the meaning given in s. ~~450.01 (7)~~ 961.385 (1) (af), Stats.

SECTION 5. CSB 4.02 (11c) and (11n) are created to read:

**CSB 4.02 (11c)** "Healthcare Professional" means a pharmacist, practitioner, registered nurse licensed under s. 441.06, Stats., substance abuse counselor, as defined in s. 440.88 (1) (b), Stats. or individual authorized under s. 457.02 (5m), Stats. to treat alcohol or substance dependency or abuse as a specialty.

**(11n)** "Law enforcement agency" has the meaning given in s. 165.77 (1) (b), Stats.

SECTION 6. CSB 4.02 (11r) and (12) (a) 1. are amended to read:

**CSB 4.02 (11r**) "Managing pharmacist" ~~has the meaning given in s. Phar 1.02 (6)~~ means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

**4.02 (12)** (a) 1. A controlled substance included in s. ~~961.385 (1)~~ 961.385 (1) (ag), Stats.

SECTION 7. CSB 4.02 (11w) and (12m) are created to read:

**CSB 4.02 (11w)** "Medical coordinator" means a person who medically coordinates, directs, supervises, or establishes standard operating procedures for a healthcare professional.

**(12m)** "Monitored prescription drug history report" means all of the following information about a patient, patient address, practitioner, or dispenser compiled by the PDMP system and disclosed as authorized in ss. CSB 4.09 and 4.11:

(a) PDMP data.
(b) Reports submitted to the program pursuant to s. 961.37, Stats.
(c) Information submitted to the program by a healthcare professional.
(d) Information from the analytics platform.

SECTION 8. CSB 4.02 (13) is amended to read:

**CSB 4.02 (13)** "Patient" has the meaning given in s. ~~450.01 (14)~~ 961.385 (1) (aj), Stats.

SECTION 9. CSB 4.02 (14) is repealed.

SECTION 10. CSB 4.02 (15) (intro.) and (a) are consolidated, renumbered CSB 4.01 (15) and amended to read:

**CSB 4.02 (15)** "PDMP ~~information~~ data" means ~~any of the following: The data~~ the information compiled and ~~stored~~ analyzed by the ~~board~~ PDMP system from dispensing data submitted to it by dispensers.

SECTION 11. CSB 4.02 (15) (b) is repealed.

SECTION 12. CSB 4.02 (15b) and (15e) are created to read:

**CSB 4.02 (15b)** "PDMP system" means the web-based application, analytics platform, and all related hardware and software that facilitates the submission of dispensing data and the access to

and disclosure of PDMP data, monitored prescription drug history reports, audit trails, and prescribing metrics reports.

**(15e)** "Personally identifiable information" means information that can be associated with a particular person through one or more identifiers or other information or circumstances.

SECTION 13. CSB 4.02 (15g), (15r), (16), (17) and (18) are amended to read:

**CSB 4.02 (15g)** "Pharmacist" has the meaning given in s. 961.385 (1) (aL), Stats. For the purposes of this program, the board recognizes a pharmacist licensed by another state that engages in the practice of pharmacy within the contiguous borders of this state or who practices at a pharmacy licensed under s. 450.065, Stats. as a person authorized to engage in the practice of pharmacy.

**(15r)** "Pharmacist delegate" means an agent of a pharmacist to whom the pharmacist has delegated the task of accessing ~~PDMP information~~ monitored prescription drug history reports.

**(16)** "Pharmacy" ~~means any place of practice licensed by~~ has the ~~board under ss. 450.06 or 450.065~~ meaning given in s. 961.385 (1) (an), Stats., including a pharmacy that chooses to solely dispense to animal patients.

**(17)** "Practitioner" has the meaning given in s. 961.385 (1) (ar), Stats. For the purposes of this program, the board recognizes a practitioner licensed by another state that engages in the practice of their credentialed profession within the contiguous borders of this state as a person authorized to prescribe and administer drugs.

**(18)** "Practitioner delegate" means an agent ~~or employee~~ of a practitioner to whom the practitioner has delegated the task of accessing ~~PDMP information~~ monitored prescription drug history reports.

SECTION 14. CSB 4.02 (18m) and (21m) are created to read:

**CSB 4.02 (18m)** "Prescribing metrics report" means all of the following information about a practitioner compiled by the PDMP system and disclosed as authorized in s. CSB 4.09:

(a) PDMP data.
(b) Audit trails.
(c) Reports submitted to the program pursuant to s. 961.37, Stats. about a patient to whom the practitioner has issued a prescription order.
(d) Information from the analytics platform.

**(21m) "**Prosecutorial unit" has the meaning given in s. 978.001 (2), Stats.

SECTION 15. CSB 4.03 (2) is repealed.

SECTION 16. CSB 4.04 (1) (b), (d) and (e) are repealed.

SECTION 17. CSB 4.04 (2) (b),(e) and (i) and (4) are amended to read:

**CSB 4.04 (2)** (b) The ~~dispenser identifier, if available~~ dispenser's DEA registration number.

(e) The NDC number ~~or the name and strength~~ of the monitored prescription drug.

(i) The ~~practitioner identifier, if available~~ practitioner's DEA registration number.

**(4)** ~~A~~ The board may refer a dispenser and dispenser delegate~~, if applicable, who~~ that fail to compile dispensing data as required by sub. (2) ~~may be subject~~ to ~~disciplinary action by~~ the appropriate licensing or regulatory board ~~that issued the license under which the dispenser is authorized to dispense monitored prescription drugs~~ for discipline.

SECTION 18. CSB 4.05 (1) (intro) is renumbered CSB 4.05 (1) (intro.) and amended to read:

**CSB 4.05 (1)** Unless exempt under s. CSB 4.08, a dispenser shall electronically submit dispensing data ~~through an account with the board.~~ to the PDMP in any of the following ways:

SECTION 19. CSB 4.05 (1) (a) and (b) are created to read:

**CSB 4.05 (1)** (a) As a file that complies with the data standards identified in version 4 and release 2 of ASAP implementation guide for prescription monitoring programs.

(b) Using the prescription record entry functions of the PDMP system.

SECTION 20. CSB 4.05 (1) (note) is repealed and recreated to read:

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, P.O. Box 8366, Madison, WI 53708.

SECTION 21. CSB 4.05 (2) and (3) are repealed.

SECTION 22. CSB 4.05 (4) is repealed and recreated to read:

**CSB 4.05 (4)** The board may refer a dispenser and dispenser delegate that fail to submit dispensing data as required by sub. (1) to the appropriate licensing or regulatory board for discipline.

SECTION 23. CSB 4.06 (1), (2), (3) and (5) are amended to read:

**CSB 4.06 (1)** A dispenser shall submit dispensing data to the ~~board within 7 days~~ PDMP no later than 11:59 p.m. of ~~dispensing a~~ the next business day after the monitored prescription drug is dispensed.

**(2)** If a dispenser does not dispense a monitored prescription drug ~~for 7 days~~ on a business day, the dispenser shall submit no later than 11:59 p.m. of the next business day a zero report to the ~~board~~ PDMP that accounts for each ~~7-day period during~~ business day on which the dispenser did not dispense a monitored prescription drug.

**(3)** If a dispenser is not able to submit dispensing data ~~within 7 days of dispensing~~ or a ~~monitored prescription drug~~ zero report before 11:59 p.m. of the next business day as required by ~~sub.~~ subs. (1) or (2), the board may grant an emergency waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser is not able to submit dispensing data or a zero report because of circumstances beyond its control.

(b) The dispenser files with the board a written application for an emergency waiver on a form provided by the board prior to the required submission of dispensing data or zero report.

**(5)** ~~A~~ The board may refer a dispenser and dispenser delegate~~, if applicable, who~~ that fail to submit dispensing data or a zero report as required by subs. (1) and (2), or be granted an emergency waiver under sub. (3), or a dispenser and a dispenser delegate~~, if applicable, who~~ that submit false information to the ~~board may be subject~~ PDMP to ~~disciplinary action by~~ the appropriate licensing or regulatory board ~~that issued the license under which the dispenser is authorized to dispense monitored prescription drugs~~ for discipline.

SECTION 24. CSB 4.07 is repealed and recreated to read:

**CSB 4.07 Correction of dispensing data. (1)** A dispenser shall electronically correct dispensing data in the PDMP system within 5 business days of discovering an omission, error, or inaccuracy in previously submitted dispensing data.

**(2)** The board may refer a dispenser and dispenser delegate that fail to correct dispensing data as required by sub. (1) to the appropriate licensing or regulatory board for discipline.

SECTION 25. CSB 4.08 (2m) is created to read:

**CSB 4.08 (2m)** A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is compounded, packaged or labeled in preparation for delivery but is not delivered.

SECTION 26. CSB 4.09 is repealed and recreated to read:

**CSB 4.09 Access to monitored prescription drug history reports and PDMP data about a patient.**

**(1)** Healthcare professionals may access monitored prescription drug history reports about a patient for any of the following reasons:

(a) The healthcare professional is directly treating or rendering assistance to the patient.

(b) The healthcare professional is being consulted regarding the health of the patient by an individual who is directly treating or rendering assistance to the patient.

**(2)** Pharmacist delegates and practitioner delegates may access monitored prescription drug history reports about a patient for any of the following reasons:

(a) A pharmacist or practitioner who is directly treating or rendering assistance to the patient has delegated the task of obtaining monitored prescription drug history reports about the patient to the pharmacist delegate or practitioner delegate.

(b) A pharmacist or practitioner who is being consulted regarding the health of the patient by an individual who is directly treating or rendering assistance to the patient has delegated the task of obtaining monitored prescription drug history reports about the patient to the pharmacist delegate or practitioner delegate.

**(3)** Healthcare professionals, pharmacist delegates and practitioner delegates may only disclose a monitored prescription drug history report about a patient obtained pursuant to subs. (1) or (2) in the following situations:

(a) To the patient as part of treating or rendering assistance to the patient.

(b) To another healthcare professional or a medical coordinator for consultation about the health of the patient or as part of treating or rendering assistance to the patient.

(c) To the pharmacist or practitioner who is directly treating or rendering assistance to the patient.

(d) To a law enforcement agency as required by s. 146.82, Stats.

**(4)** To obtain access to monitored prescription drug history reports as authorized in sub. (1) and (2), healthcare professionals, pharmacist delegates, and practitioner delegates shall do one of the following:

(a) Create an account with the PDMP system.

(b) Create an account with a prescription monitoring program operated by a relevant agency in another jurisdiction with which the board exchanges monitored prescription drug history reports or PDMP data pursuant to s. CSB 4.14.

(c) Create an account with a pharmacy or other entity at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports or that is connected to and lawfully obtains data from the state-designated entity under ch. 153, Stats.

(d) Create an account with a hospital or other entity at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports or that is connected to and lawfully obtains data from the state-designated entity under ch. 153, Stats.

SECTION 27. CSB 4.093 is created to read:

**CSB 4.093 Monitored prescription drug history reports, and audit trails about healthcare professionals.**

**(1)** Healthcare professionals may access audit trails about themselves and their practitioner delegates or pharmacist delegates.

**(2)** A practitioner may access the audit trails accessible to healthcare professionals and a prescribing metrics report about themself.

**(3)** Medical coordinators may access prescribing metrics reports, and audit trails about a healthcare professional whom the medical coordinator coordinates, directs, or supervises or for

whom the medical coordinator establishes standard operating procedures that contain no personally identifiable information about a patient if the medical coordinator is conducting any of the following activities:

(a) Evaluating the job performance of the healthcare professional.

(b) Performing quality assessment and improvement activities, including outcomes evaluation or development of clinical guidelines for the healthcare professional.

**(4)** To obtain access to prescribing metrics reports, and audit trails as authorized in sub. (1) and (2), healthcare professionals, pharmacist delegates, and practitioner delegates shall create an account with the PDMP system.

**(5)** To obtain access to prescribing metrics reports, and audit trails about a healthcare professional, a medical coordinator shall create an account with the PDMP system.

SECTION 28. CSB 4.097 is created to read:

**CSB 4.097 Deny, suspend, revoke or otherwise restrict or limit access.**

**(1)** The board may deny, suspend, revoke or otherwise restrict or limit a healthcare professional's, pharmacist delegate's, practitioner delegate's, or medical coordinator's access to monitored prescription drug history reports, prescribing metrics reports, PDMP data, and audit tails for any of the following reasons:

(a) The healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator is suspected of attempting to access, accessing, or disclosing a monitored prescription drug history report, prescribing metrics report, PDMP data, or audit trail in violation of s. 146.82 or 961.385, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records.

(b) The healthcare professional is no longer licensed in this state or in another state and recognized by this state as a person to whom the board may grant access pursuant to s. CSB 4.09 or 4.093.

(c) The board, or other licensing board, or regulatory agency takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.

(d) A licensing board or equivalent regulatory agency in another jurisdiction takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.

(e) The federal department of justice, drug enforcement administration takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.

(f) The healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator is convicted of a crime substantially related to the prescribing, administering, or dispensing of a monitored prescription drug.

(g) The pharmacist delegate or practitioner delegate is no longer delegated the task of accessing monitored prescription drug history reports.

(h) The medical coordinator no longer coordinates, directs, supervises, or establishes standard operating procedures for a healthcare professional.

**(2)** The board may temporarily suspend access to monitored prescription drug history reports, prescribing metrics reports, PDMP data, and audit trails upon discovering circumstances that indicate a healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator has performed any of the actions identified in sub. (1) (a).

SECTION 29. CSB 4.10 (1) (intro) is amended to read:

**CSB 4.10 (1)** A ~~pharmacist~~ dispenser, healthcare professional, pharmacist delegate, ~~practitioner, or~~ practitioner delegate, or medical coordinator may request that the board review any of the following:

SECTION 30. CSB 4.10 (1) (a) is repealed.

SECTION 31. CSB 4.10 (1) (c), (2) (intro) and (a), (3), (6), and (7) is amended to read:

**CSB 4.10 (1)** (c) The denial, suspension, revocation or other restriction or limitation imposed on the ~~pharmacist's~~, healthcare professional's, pharmacist delegate's, ~~practitioner's, or~~ practitioner delegate's, or medical coordinator's account pursuant to s. CSB ~~4.09 (3)~~ 4.09 (5).

**(2)** To request a review, the ~~pharmacist~~ dispenser, health care professional, pharmacist delegate, ~~practitioner, or~~ practitioner delegate, or medical coordinator shall file a written request with the board within 20 days after the mailing of the notice of the action in sub. (1). The request shall be in writing and include all of the following:

(a) The ~~pharmacist's~~ dispenser's, healthcare professional's, pharmacist delegate's, ~~practitioner's, or~~ practitioner delegate's, or medical coordinator's name and address, including street address, city, state and ZIP code.

**(3)** The board shall conduct the review at its next regularly scheduled meeting and notify the ~~pharmacist~~ dispenser, healthcare professional, pharmacist delegate, ~~practitioner, or~~ practitioner delegate, or medical coordinator of the time and place of the review.

**(6)** The board shall provide the ~~pharmacist~~ dispenser, healthcare professional, pharmacist delegate, ~~practitioner, or~~ practitioner delegate, or medical coordinator with an opportunity to submit written documentation, make a personal appearance before the board and present a statement. The board may establish a time limit for making a presentation. Unless otherwise determined by the board, the time for making a personal appearance shall be 20 minutes.

**(7)** If the ~~pharmacist~~ dispenser, healthcare professional, pharmacist delegate, ~~practitioner, or~~ practitioner delegate, or medical coordinator fails to appear for a review, or withdraws the request for a review, the board may note the failure to appear in the minutes and affirm its original decision without further action.

SECTION 32. CSB 4.105 is created to read:

**CSB 4.105 Practitioners' requirement to review monitored prescription drug history reports. (1)** A practitioner, or a practitioner delegate assisting the practitioner in accordance with the standards of practice for the practitioner's profession, shall review the monitored prescription drug history report about a patient before the practitioner issues a prescription order for the patient unless any of the following conditions are met:

(a) The patient is receiving hospice care, as defined in s. 50.94 (1) (a).

(b) The prescription order is for a number of doses that is intended to last the patient 3 days or less and is not subject to refill.

(c) The monitored prescription drug is lawfully administered to the patient.

(d) The practitioner is unable to review the patient's monitored prescription drug history reports before issuing a prescription order for the patient due to an emergency.

(e) The practitioner is unable to review the patient's records under their program because the PDMP system is not operational or due to other technological failure that the practitioner reports to the board.

**(2)** Reviews of reports or other information not provided by the board as part of the program that summarize or analyze PDMP data do not satisfy the requirement to review a monitored prescription drug history report under sub. (1).

**(3)** The board may refer a practitioner that fails to review a monitored prescription drug history report about a patient prior to issuing a prescription order for that patient to the appropriate licensing or regulatory board for discipline.

SECTION 33. CSB 4.11 (title), (1) and (2) (intro) and (c), and (5) (intro), (a) and (c), are amended to read:

**CSB 4.11 Methods of obtaining ~~PDMP information~~ monitored prescription drug history reports.**

**(1)** The board shall disclose ~~dispensing data~~ the monitored prescription drug history report about a patient to the patient if he or she does all of the following:

(a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government-issued photographic identification or mails to the department copies of two forms of valid proof of identity, one of which is valid government-issued photographic identification.

(b) Makes a request for the ~~dispensing data~~ monitored prescription drug history reports about the patient on a form provided by the board. If the request is mailed, the form shall be notarized.

**(2)** The board shall disclose ~~dispensing data~~ the monitored prescription drug history report about a patient to a person authorized by the patient if the person authorized by the patient does all of the following:

(c) Makes a request for the ~~dispensing data~~ monitored prescription drug history report on a form provided by the board.

**(5)** The board shall disclose the minimum necessary amount of ~~PDMP~~ information ~~necessary~~ in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of a federal or state governmental agency 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 designated staff does all of the following:

(a) Creates an account with the ~~board on a form provided by the board~~ PDMP system.

(c) Makes a request for the ~~PDMP information~~ monitored prescription drug history report through its PDMP system account ~~with the board~~.

SECTION 34. CSB 4.11(5) (d) is created to read:

**CSB 4.11 (5)** (d) If the PDMP system is unable to fulfill a request from designated staff through their account with the PDMP system, the board may disclose the minimum necessary amount of information necessary to designated staff of a federal or state governmental agency upon written request that cites the agency's specific authorization 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.

SECTION 35. CSB 4.11 (6) (intro), (a) and (c), (7) (intro), (a) and (c), (8) (intro), (a) and (c), (9), and (10) are amended to read:

**(6)** The board shall disclose the minimum necessary amount of PDMP data or information ~~necessary~~ in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of the department who is charged with investigating dispensers, dispenser delegates, pharmacists, pharmacist delegates, practitioners, and practitioner delegates 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 designated staff does all of the following:

(a) Creates an account with the ~~board on a form provided by the board~~ PDMP system.

(c) Makes a request for the ~~PDMP information~~ monitored prescription drug history report through its PDMP system account ~~with the board~~.

**(7)** The board shall disclose the minimum necessary amount of ~~dispensing data necessary~~ information in a monitored prescription drug history report about a patient or patient address 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:

(a) Creates an account with the ~~board on a form provided by the board~~ PDMP system.

(c) Makes a request for the ~~dispensing data~~ monitored prescription drug history report through its PDMP system account ~~with the board~~.

**(8)** The board shall disclose the minimum necessary amount of ~~dispensing data necessary~~ information in a monitored prescription drug history report about a patient 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:

(a) Creates an account with the ~~board on a form provided by the board~~ PDMP system.

(c) Makes a request for the ~~dispensing data~~ monitored prescription drug history report through its PDMP system account with the board.

**(9)** The board may disclose ~~de-identified~~ PDMP data without personally identifiable information ~~which does not and cannot~~ that could be reasonably used to identify any ~~patient upon written request~~ patient, healthcare professional, practitioner delegate, pharmacist delegate, or dispenser for public health and research purposes.

**(10)** The board shall disclose the minimum necessary amount of ~~PDMP~~ information in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of a law enforcement ~~authority 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~~ agency or prosecutorial unit if the designated staff does all of the following:

(a) Creates an account with the ~~board on a form provided by the board~~ PDMP system.

(b) Provides ~~a lawful order of a court of record under s. 146.82 (2) (a) 4., Stats., or provides evidence satisfactory to the board that~~ documentation demonstrating the law enforcement agency or prosecutorial unit is ~~entitled to the information under s. 146.82 (2) (a) 11., Stats~~ engaged in one of the following activities:

1. An active and specific investigation or prosecution of a violation of any state or federal law involving a monitored prescription drug and that the ~~PDMP data~~ information being requested is reasonably related to that investigation or prosecution.

2. The monitoring of a patient as part of a drug court, as defined in s. 165.955 (1).

(c) Makes a request for ~~PDMP information~~ the monitored prescription drug history report through its account with the ~~board~~ PDMP system.

SECTION 36. CSB 4.11 (10) (c) (note) is repealed.

SECTION 37. CSB 4.12 (title) and (1) are amended to read:

**CSB 4.12 Use of PDMP ~~information~~ data by the board and department.**

**(1)** The board shall develop and maintain a PDMP database to store dispensing data and PDMP ~~information~~ data in a secure environment and an encrypted format.

SECTION 38. CSB 4.12 (2) is repealed.

SECTION 39. CSB 4.12 (2m) is created to read:

**CSB 4.12 (2m)** The board shall develop and maintain a PDMP system to facilitate all of the following:

(a) The submission of dispensing data to the PDMP database.

(b) The creation of monitored prescription drug history reports about specific patients, practitioners, and dispensers.
(c) The access to and the obtaining of monitored prescription drug history reports, prescribing metrics reports and audit trails.

SECTION 40. CSB 4.12 (3) is repealed and recreated to read:

**CSB 4.12 (3)** The board shall maintain audit trails that contain all of the following information:
(a) A log of dispensing data submitted to the PDMP database by each dispenser.
(b) A log of persons to whom the Board has granted direct access to the PDMP system under s. CSB 4.093 (4) (a) and a log of each time a person attempts to access PDMP data or a monitored prescription drug history report.
(c) A log of prescription monitoring programs operated by a relevant agency in another jurisdiction with which the board exchanges PDMP data pursuant to s. CSB 4.14 and a log of each time a person from another jurisdiction attempts to access PDMP data.
(d) A log of pharmacies or other entities at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports and a log of each time a person from a pharmacy or other entity attempts to access PDMP data or a monitored prescription drug history report.
(e) A log of hospitals or other entities at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports and a log of each time a person from a hospital or other entity attempts to access PDMP data or a monitored prescription drug history report.
(f) A log of monitored prescription drug history reports and PDMP data disclosed pursuant to s. CSB 4.11, including the name of the person to whom the information was disclosed.
(g) A log of requests for PDMP data or monitored prescription drug history reports even when no information was disclosed.

SECTION 41. CSB 4.12 (4), (4g), (4r), and (5) are repealed.

SECTION 42. CSB 4.12 (6) (intro) and (a) are amended to read:

**CSB 4.12(6)** ~~Board and department staff~~ Staff assigned administrative duties over the PDMP, vendors, contractors, and other agents of the board shall only have access to the minimum amount of PDMP ~~information~~ data necessary for all of the following purposes:
(a) The design, implementation, operation, and maintenance of the program, including the PDMP database, PDMP system, the disclosure of information via other entities pursuant to s. CSB 4.09 (4), and the exchange of information pursuant to s. CSB 4.15 as part of the assigned duties and responsibilities of their employment.

SECTION 43. CSB 4.12 (6) (am) is created to read:

**CSB 4.12 (6)** (am) The operation of an analytics platform that provides data cleansing and standardization, data integration, advanced analytics, and alert management capabilities as part of the PDMP database and PDMP system.

SECTION 44. CSB 4.12 (6) (c) is amended to read:

**CSB 4.12 (6)** (c) Evaluating and responding to legitimate requests for ~~PDMP information~~ monitored prescription drug history reports, audit trails, and PDMP data.

SECTION 45. CSB 4.12 (6) (cg) and (cr) are created to read:

**CSB 4.12 (6)** (cg) Preparing monitored prescription drug history reports, audit trails, and PDMP data for the board to determine whether suspicious or critically dangerous conduct or practices has occurred or is occurring pursuant to s. CSB 4.15.

(cr) Conducting a review of the program as required by s. 961.385 (5), Stats.

SECTION 46. CSB 4.13 is amended to read:

**CSB 4.13 Confidentiality of PDMP ~~information~~ records. (1)** The dispensing data, PDMP ~~information~~ data, audit trails, monitored prescription drug history reports, and prescribing metrics reports maintained, ~~by the board, department or a vendor contracting with the department which is submitted to, maintained~~ created, or stored as a part of the program ~~is~~ are not subject to inspection or copying under s. 19.35, Stats.

**(2)** A person who discloses or a person whose delegate discloses dispensing data, PDMP ~~information~~ data, audit trails, monitored prescription drug history reports, or prescribing metrics reports in violation of s. 146.82 or 961.385, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records, may be ~~subject to disciplinary action by~~ referred to the appropriate licensing or regulatory board ~~that issued the license under which the person is authorized to prescribe or dispense monitored prescription drugs and all appropriate civil and criminal penalties~~ for discipline, or the appropriate law enforcement agency for investigation and possible prosecution if the board determines that a criminal violation may have occurred.

SECTION 47. CSB 4.14 (title) and (1) (intro) are amended to read:

**CSB 4.14 Exchange of PDMP ~~information~~ data. (1)** The board may exchange monitored prescription drug history reports and PDMP ~~information~~ data with a prescription monitoring program operated by a relevant agency in another state or jurisdiction if the prescription monitoring program satisfies all of the following conditions:

SECTION 48. CSB 4.15 (1) and (5) (intro) are amended to read:

**CSB 4.15 (1)** The board may review dispensing data, monitored prescription drug history reports, PDMP ~~information~~ data, and data compiled pursuant to s. CSB 4.12 to determine

whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist, pharmacy, practitioner, or patient.

**(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~~ monitored prescription drug history reports, audit trails, and PDMP data to any of the following:

SECTION 49. CSB 4.15 (6) is created to read:

**CSB 4.15 (6)** Upon determining that a criminal violation may have occurred, the board may refer a pharmacist, pharmacy, or practitioner to the appropriate law enforcement agency for investigation and possible prosecution. The board may disclose monitored prescription drug history reports, audit trails, and PDMP data to the law enforcement agency as part of the referral.

SECTION 50. 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.

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(END OF TEXT OF RULE)

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This Proposed Order of the Controlled Substances Board is approved for submission to the Governor and Legislature.

Dated August 3, 2017

Chair
Controlled Substances Board

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R03/2012)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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# ADMINISTRATIVE RULES
## Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Administrative Rule Chapter, Title and Number
CSB 4

3. Subject
Operation of Prescription Drug Monitoring Program

4. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

5. Chapter 20, Stats. Appropriations Affected
20.165(1)(g) and (1)(hg)

6. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget
☐ Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

8. Would Implementation and Compliance Costs Be Greater Than $20 million?
☐ Yes ☒ No

9. Policy Problem Addressed by the Rule
This rule implements Acts 266, 267 and 268 and makes other changes resulting from the implementation of those acts.

10. 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.
This rule was posted for economic comments and none were received.

11. Identify the local governmental units that participated in the development of this EIA.
None

12. 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)
Any economic impact resulting from the requirements are a result of the statutory requirements created by 2015 Acts 266, 267 and 268 and not the impact of the rule.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The rule modifies the operation of the prescription drug monitoring program (PDMP) as directed by the legislature in Acts 266, 267 and 268. The benefit is the PDMP containing the mandated statutory requirements implemented into the program.

14. Long Range Implications of Implementing the Rule
The long range implication is practitioners and dispensers having current and complete knowledge of the controlled substances being prescribed and dispensed which will result in better and safer health care for Wisconsin citizens.

15. Compare With Approaches Being Used by Federal Government
None

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
**Illinois**: Illinois requires reporting to the drug monitoring program within one day. Illinois does not require mandatory use of the drug monitoring program. Illinois does not provide access to mental health, substance abuse professionals or law enforcement.

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## ADMINISTRATIVE RULES
## Fiscal Estimate & Economic Impact Analysis

**Iowa**: Iowa requires reporting to the drug monitoring program within one week. Iowa does not require mandatory use of the drug monitoring program. Iowa does not provide access to mental health, substance abuse professionals or law enforcement.
**Michigan**: Michigan requires reporting to the drug monitoring program within one day if reporting online and within one week if reporting by mail. Michigan does not require mandatory use of the drug monitoring program. Michigan does not provide access to mental health, substance abuse professionals or law enforcement.
**Minnesota:** Minnesota requires reporting to the drug monitoring program within one day. Minnesota does require mandatory use of the drug monitoring program. Minnesota does provide access to mental health and substance abuse professionals. Minnesota does not provide access to law enforcement.

| 17. Contact Name | 18. Contact Phone Number |
|---|---|
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This document can be made available in alternate formats to individuals with disabilities upon request.