



CONTROLLED SUBSTANCES BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison
Contact: Andrea Magermans (608) 266-2112
January 11, 2019

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions and deliberations of the Board.

AGENDA

9:30 A.M.

OPEN SESSION - CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1-4)**
- B. Approval of Minutes of November 9, 2018 (5-6)**
- C. Administrative Matters - Discussion and Consideration (7-9)**
 - 1. Election of Officers
 - 2. Appointment of Liaisons and Alternates
 - 3. Delegation of Authorities
 - 4. Staff Updates
 - 5. Board Members
 - a. Yvonne Bellay – Dept. of Agriculture, Trade, and Consumer Protection Designee
 - b. Alan Bloom – Pharmacologist
 - c. Doug Englebert – Dept. of Health Services Designee
 - d. Philip Trapskin – Pharmacy Examining Board Designee
 - e. Subhadeep Barman – Psychiatrist
 - f. Peter Kallio – Board of Nursing Designee
 - g. Leonardo Huck – Dentistry Examining Board Designee
 - h. Tina Virgil – Attorney General Designee
 - i. Timothy Westlake – Medical Examining Board Designee
- D. APPEARANCE – WISHIN: WISHIN’S Integration of PDMP Data – Discussion and Consideration (10-24)**

E. Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration (25)

1. **WI ePDMP Operations Update**
 - a. 2018 Statistics
 - b. Recent and Upcoming Releases **(26-27)**
 - c. Interstate Data Sharing
 - d. Status of Grants
 1. User Survey/Focus Groups
 - e. Electronic Health Record (EHR) Integration Status
 - f. Status of User Led Enhancement Report
 - g. Status of RxCheck
2. **Outreach**
 - a. December Newsletter **(28-31)**
 - b. Communication Plan
 - c. Outreach Calendar **(32-33)**
3. **Quarterly Report Update**
 - a. Q4 2018 Report Status Update
4. **Referral Workgroup**
 - a. Board of Nursing Letter **(34-35)**
 - b. Referral Process/Frequency
 - c. Past Referral Status
 - d. New Entries to Referral Reports Based on Previous Thresholds
 - e. Pharmacy Compliance
5. **Dispenser Compliance Audit Update (36)**
6. **Legislative Concerns**

F. Legislative and Administrative Rule Matters – Discussion and Consideration (37)

1. CSB 2.63, Relating to Scheduling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA **(38-41)**
2. CSB 2.64, Relating to Scheduling N-Ethylpentylone **(42-44)**
3. CSB 2.65, Relating to Scheduling FDA Approved Cannabidiol Drugs **(45-47)**
4. Affirmative Action Relating to Excluding from Scheduling Industrial Hemp Cannabidiol
5. Affirmative Action Relating to Scheduling 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 **(48-49)**
6. CSB 3, Relating to Special Use Authorization **(50-51)**
7. CSB 5, Relating to Pharmacies and Physicians Dispensing Cannabidiol
8. CSB 4, Relating to Operation of Prescription Drug Monitoring Program **(52-58)**
9. Follow Up on Law Enforcement Hearing – Discussion on Emerging Threats
10. Update on Legislation and Pending or Possible Rulemaking Projects

G. Controlled Substances Board Annual Report – Discussion and Consideration

H. Board Member Reports

1. Governor’s Task Force on Opioid Abuse – Timothy Westlake
2. Medical Examining Board – Timothy Westlake
3. Dentistry Examining Board – Leonardo Huck
4. Board of Nursing – Peter Kallio
5. Pharmacy Examining Board – Philip Trapskin

I. Liaison Reports

1. SCAODA Liaison – Subhadeep Barman
2. SUA Liaisons – Yvonne Bellay and Alan Bloom

J. Special Use Authorizations – Discussion and Consideration

K. Discussion and Consideration of Items Received After Preparation of the Agenda:

1. Introductions, Announcements, and Recognition
2. Administrative Matters
3. Election of Officers
4. Appointment of Liaisons and Alternates
5. Delegation of Authorities
6. Informational Items
7. Division of Legal Services and Compliance (DLSC) Matters
8. Education and Examination Matters
9. Credentialing Matters
10. Practice Matters
11. Legislative and Administrative Rule Matters
12. Liaison Reports
13. Appearances from Requests Received or Renewed
14. Speaking Engagements, Travel, or Public Relations Requests, and Reports
15. Consulting with Legal Counsel

L. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), 440.205 and 961.385(2)(c) Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

M. Deliberation on DLSC Matters

1. Case Closings

- a. **APPEARANCE: DLSC Investigator Kyle Heller and DLSC Attorney Carley Peich Kiesling – 17 CSB 001 – W. #06132 & G.S.D. (59-64)**

N. Special Use Authorizations – Discussion and Consideration

O. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

P. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate

Q. Open Session Items Noticed Above Not Completed in the Initial Open Session

ADJOURNMENT

NEXT MEETING: MARCH 15, 2019

MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

**CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
NOVEMBER 9, 2018**

PRESENT: Subhadeep Barman, Yvonne Bellay, Alan Bloom, Doug Englebert, Leonardo Huck, Peter Kallio, Philip Trapskin, Tina Virgil, Timothy Westlake

STAFF: Erin Karow, Executive Director; Sharon Henes, Administrative Rules Coordinator; Kimberly Wood, Program Assistant Supervisor-Adv.; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chair, called the meeting to order at 9:35 a.m. A quorum of seven (7) members was confirmed.

ADOPTION OF AGENDA

MOTION: Leonardo Huck moved, seconded by Yvonne Bellay, to adopt the agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES

MOTION: Timothy Westlake moved, seconded by Peter Kallio, to approve the minutes of September 14, 2018 and October 9, 2018 as published. Motion carried unanimously.

LEGISLATION AND RULE MATTERS

CSB 2.61 Relating to Scheduling MT-45 – Review Clearinghouse Comments

MOTION: Alan Bloom moved, seconded by Timothy Westlake, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule CSB 2.61 relating to scheduling MT-45, for submission to the Governor's Office and Legislature. Motion carried unanimously.

CSB 2.62 Relating to Scheduling Parachloroisobutyryl Fentanyl – Review of Clearinghouse Comments

MOTION: Alan Bloom moved, seconded by Timothy Westlake, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse CSB 2.62 relating to scheduling Parachloroisobutyryl Fentanyl, for submission to the Governor's Office and Legislature. Motion carried unanimously.

CSB 2.64 Scope Relating to Scheduling N-Ethylpentylone

MOTION: Peter Kallio moved, seconded by Leonardo Huck, to approve the Scope Statement revising CSB 2.64, relating to scheduling N-Ethylpentylone, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chair to approve the Scope Statement for implementation no less than 10 days after publication. Motion carried unanimously.

CSB 2.65 Scope Relating to Scheduling FDA Approved Cannabidiol Drugs

MOTION: Peter Kallio moved, seconded by Leonardo Huck, to approve the Scope Statement revising CSB 2.65, relating to scheduling FDA approved cannabidiol drugs, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chair to approve the Scope Statement for implementation no less than 10 days after publication. Motion carried unanimously.

ADJOURNMENT

MOTION: Alan Bloom moved, seconded by Timothy Westlake, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 12:10 p.m.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Maximilian Turner, Bureau Assistant		2) Date When Request Submitted: 12/21/18 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 1/11/2019	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Administrative Matters 1) Election of Officers 2) Appointment of Liaisons and Alternates 3) Delegation of Authorities	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: 1) The Board should conduct Election of its Officers for 2019 2) The new Chairperson should review and appoint/reappoint Liaisons and Alternates as appropriate 3) The Board should review and then consider continuation or modification of previously delegated authorities			
11) Authorization			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)			
Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

CONTROLLED SUBSTANCES BOARD

2018 Elections and Liaison Appointments

Elections and liaison appointments external of the Board were made in January 2018.

****Denotes Liaison Appointments added at the 3/9/2018 meeting.**

2018 OFFICER ELECTION RESULTS	
Board Chair	Doug Englebert
Vice Chair	Alan Bloom
Secretary	Yvonne Bellay
2018 LIAISON APPOINTMENTS	
SUA Liaison(s)	Alan Bloom, Yvonne Bellay
SCAODA Liaison	Subhadeep Barman
Legislative Liaison	Timothy Westlake Alternate – Doug Englebert
PDMP Liaison	Timothy Westlake Alternate – Subhadeep Barman
**Referral Criteria Workgroup	Doug Englebert, Peter Kallio, Timothy Westlake, Philip Trapskin

DELEGATION MOTIONS

Document Signature Delegation

MOTION: Philip Trapskin moved, seconded by Peter Kallio, to delegate authority to the Chair or chief presiding officer, or longest serving member of the Board, by order of succession, to sign documents on behalf of the Board. In order to carry out duties of the Board, the Chair, chief presiding officer, or longest serving member of the Board, has the ability to delegate this signature authority for purposes of facilitating the completion of assignments during or between meetings. The Chair, chief presiding officer, or longest serving member of the Board delegates the authority to Executive Director, or designee, to sign the name of any Board member on documents as necessary and appropriate. Motion carried unanimously.

Delegated Authority for Urgent Matters

MOTION: Philip Trapskin moved, seconded by Peter Kallio, that, in order to facilitate the completion of urgent matters between meetings, the Board delegates its authority to the Chair (or, in the absence of the Chair, the highest-ranking officer or longest serving board member in that succession), to appoint liaisons to the Department to act in urgent matters. Motion carried unanimously.

Special Use Authorization Liaison Delegation

MOTION: Philip Trapskin moved, seconded by Peter Kallio, to authorize the Special Use Authorization (SUA) liaison(s) to review and make approval decisions regarding SUA applications and approve required training or credentialing on behalf of the Board. Furthermore, the Board authorizes DSPS staff to sign SUA permits on behalf of the Board. Motion carried unanimously.

MOTION: Peter Kallio moved, seconded by Jason Smith, to authorize the Special Use Authorization (SUA) liaison(s) to make all decisions related to Special Use Authorizations. Motion carried unanimously. (Added at 3/9/18 Meeting)

Quarterly Report Delegation (Added at 2/21/18 Meeting)

MOTION: Yvonne Bellay moved, seconded by Jason Smith, to authorize the Chair to approve all PDMP Quarterly Reports. Motion carried unanimously.

Legislative Liaison Delegation

MOTION: Philip Trapskin moved, seconded by Peter Kallio, to delegate authority to the Legislative Liaison(s) to address Board issues related to legislative matters excluding media requests. Motion carried unanimously.

SCAODA Liaison Delegation

MOTION: Philip Trapskin moved, seconded by Peter Kallio, to authorize the SCAODA liaison to vote on behalf of the Board at the State Council on Alcohol and Other Drug Abuse meetings. Motion carried unanimously.

PDMP Liaison Delegation

MOTION: Philip Trapskin moved, seconded by Peter Kallio, to authorize PDMP Liaisons to make individual decisions on behalf of the Board when waiting for a Board meeting would unreasonably delay the development, testing, deployment, or operation of the PDMP. The Board also grants the PDMP liaison the authority to suspend access to the PDMP pursuant to CSB § 4.09 (3). Motion carried unanimously.

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Andrea Magermans		2) Date When Request Submitted: 12/20/2018 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 1/11/19	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? APPEARANCE by WISHIN: WISHIN's Integration of PDMP Data – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input checked="" type="checkbox"/> Yes, by Steve Rottmann <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: <p style="text-align: center;">Presentation by Steve Rottmann, COO of Wisconsin Statewide Health Information Network (WISHIN), about WISHIN's Integration of PDMP data</p>			
11) Signature of person making this request Andrea Magermans 12/20/18		Authorization	Date
Supervisor (if required)			Date
Executive Director signature (indicates approval to add post agenda deadline item to agenda)			Date
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WISHIN'S INTEGRATION OF ePDMP DATA

January 11, 2019



WISHIN

OUTLINE

- WISHIN Overview
- Current ePDMP integration
- Proposed Solution
- Compliance with Current Legislation
- Value proposition
- Questions

INTRODUCTION

- WISHIN is the state-designated entity for health information exchange in Wisconsin
- WISHIN is pleased to be a partner of DSPS and the CSB in delivering ePDMP reports to clinicians.
- Our users derive value from the ePDMP integration. We want to continue to ensure they can do so in compliance with the law, and appropriately access the data in the context of the community health record

- Pulse is a community health record:
 - An EHR agnostic aggregated summary of patient information from multiple organizations.
 - A longitudinal, patient-centric view of patient health information, rather than a series of separate encounter summaries.
- Pulse can include the following data:
 - ADT (problem list, allergies, diagnoses, etc.)
 - Laboratory results
 - Radiology results
 - Pathology results
 - Transcription reports
 - C-CDAs – electronic care summaries
 - ePDMP integration/Medicaid Prescription Fills/WIR integration

CURRENT ePDMP INTEGRATION

- Natural partnership as ePDMP is a specialized HIE
- SSO from client EHRs to WISHIN and seamless access to ePDMP
- 32 organizations and 5,000 WISHIN Pulse users are contracted to use ePDMP

Limitation of the current implementation

- Limited view-only access to ePDMP reports with ability to print
- Provides only a portion of the patient's history, but providers could better use the discrete data

WISHIN'S SECURITY CONTROLS

- Security is paramount to WISHIN's success and an obligation to all WISHIN Participants
- WISHIN's technical vendor is HITRUST CSF Certified
 - Complies with all federal health IT security standards
 - Validated by third-party audits
 - Monthly vulnerability scans
 - Annual penetration tests
 - Annual DR tests
- WISHIN performs annual HIPAA security assessments by an external vendor
 - Monthly vulnerability scans
 - Annual penetration tests

PROPOSED SOLUTION

- Discrete and actionable data will populate WISHIN as medication information within clinical workflows to improve decision-making
- Proposed functionality:
 - Report will be presented in accordance with CSB 4.105 and CSB 4.09
 - Performs a full query of the patient and pulls data from the state ePDMP for the patient
 - Discrete data would be stored in WISHIN for purposes of:
 - Context of ePDMP data and broader clinical history
 - Medication reconciliation
 - Transitions of care



Home > Search Results > Medications

**TEST, THOMAS**

Male Age 51 DOB 1/1/1965

MRN
1000005
< 30[Profile & Face Sheets](#)

Print

Patient Summary

Encounters

Results

Medications

Documents

Immunizations

Medications

Allergies

Click column titles to sort

View By: 10 All

<input type="button" value="+"/>	Date	Allergen	Reaction	Severity
----------------------------------	------	----------	----------	----------

No records to display

Showing:

Medication Alerts

Click column titles to sort

View By: 10 All

Type	Alert Information
------	-------------------

No records to display

Medication History

Medication Orders

Prescription Monitoring Program

Start Date:



End Date:



	Rx Number	Date Filled	Date Written	Refill Number	Authorized Refills	Quantity	Medication	Prescriber	Dispenser
<input type="button" value="+"/>	1000001	06/25/2015	01/30/2015	3	5	60.0	CLONAZEPAM 1 MG TABLET 1 MG	DOCTOR, DIANNE	WALGREEN CO.
<input type="button" value="+"/>	1000002	11/04/2015	08/31/2015	2	5	90.0	LYRICA 100 MG CAPSULE 100 MG	DOCTOR, DIANNE	WALGREEN CO.
	1000003	08/21/2015	08/21/2015	0	0	40.0	OXYCODONE HCL 5 MG TABLET 5 MG	DOCTOR, DIANNE	WALGREEN CO.
<input type="button" value="+"/>	1000004	05/08/2015	05/08/2015	0	0	40.0	OXYCODONE HCL 15 MG TABLET 15 MG	DOCTOR, DIANNE	WALGREEN CO.

COMPLIANCE WITH CURRENT LEGISLATION

- Access to WISHIN Pulse and ePDMP report and data is controlled by specific roles, and further associated with valid ePDMP user credentials
 - In accordance with SS CSB4-Emergency Rule 4.09 (3) to disclose the patient history report
 - (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*
- Roles apply to practitioners, pharmacists or delegates (agents) that access the PDMP via WISHIN
 - In accordance with §961.385
 - Required to sign a WISHIN data sharing participation agreement acknowledging they will use the system in accordance with CSB 4.09
 - Must be registered users of the state ePDMP
 - All queries and activity is logged in accordance with CSB 4.093
- Once ePDMP data is placed into WISHIN, access rules and state policies will be supported:
 - WI Admin Code Ch. 4.09
 - Access and use of the PDMP data
 - WISHIN aligns with these requirements and has already had many conversations with all parties to ensure WISHIN does meet those requirements.

VALUE PROPOSITION – PRACTITIONERS & PHARMACISTS

- Prescribers can assess the appropriateness of a prescription in the context of overall clinical history:
 - Past and current diagnosis
 - Care plan instruction
 - Radiology reports & Lab results
 - Pharmacy and broader provider utilization
- Supports real-time pharmacy and provider medication reconciliation
 - Enables real-time reconciliation
 - Avoid chart chasing
 - Medicaid fill history
 - Fill history from payers
- Comprehensive discharge summaries & transitions of care:
 - Improve transitions or referrals to all sites of care (LTPAC, home health, BH, etc.)
 - Ability to integrate PDMP and clinical data into EHRs and CM systems
- Cost-effective integration from client EHRs for all care settings

20

VALUE PROPOSITION – STATE/DSPS/CSB

- Turn data into actionable insight – using clinical data in conjunction with ePDMP data – subject to WISHIN Board approval
 - Opioid use, risk and cost presented along with Dx, encounters, LOS, community readmit, etc.
 - Predictive movement of high utilizers (pattern recognition)
 - Establish risk scores to support decision-making or interventions
- Ensure the same level of data security as required by CSB
 - Available only to users with authorized role
 - Eliminates need for delegates to print and compromising the integrity of PDMP data
- SUPPORT Act – Opioid abuse
 - WISHIN and DHS working to align on many opportunities to share data across the state and across state borders
 - Augment PMP Interconnect with cross-state patient information
 - Reuse existing technology to enhance the activities CSB desires to use in addressing the opioid epidemic
- CMS approved funding is available for the project to integrate ePDMP data into WISHIN Pulse

21







APPENDIX

WISHIN PULSE DASHBOARD



5,971,309
Unique Patients

Unique patients in the
WISHIN Pulse Master
Patient Index

1,460
Client Sites

Hospitals, Clinics, FQHCs,
Home Health, and SNFs

5,583,686
Care Summaries

Care summaries in the
form of CCDAs documents

5,585,919
Transcriptions

Transcribed reports

499,479,598
ADT Transactions

Admit, discharge, transfer,
diagnosis, allergies,
problem lists, and patient
demographic data

179,637
EKG Reports

Electrocardiogram final
reports

115,583,019
Lab & Path Results

Laboratory and pathology
final results

3,483,289
Radiology Reports

Radiology transcribed
reports

197,227,772
PHSS

Public health syndromic
surveillance data
submission to the State of
Wisconsin in support of
Meaningful Use

Updated November 30, 2018



AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Andrea Magermans and Sarah Bradley		2) Date When Request Submitted: 12/20/2018 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting																			
3) Name of Board, Committee, Council, Sections: Controlled Substances Board																					
4) Meeting Date: 1/11/19	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration																			
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input checked="" type="checkbox"/> Yes, by PDMP Staff <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:																			
10) Describe the issue and action that should be addressed: <ol style="list-style-type: none"> 1. WI ePDMP Operations Update <ol style="list-style-type: none"> a. 2018 stats b. Recent and Upcoming Releases c. Interstate data sharing d. Status of Grants <ol style="list-style-type: none"> i. User survey/focus groups e. EHR Integration Status 2. Outreach <ol style="list-style-type: none"> a. December newsletter b. Communication plan c. Outreach calendar 3. Quarterly Report Update (Q4 2018) 4. Referral update <ol style="list-style-type: none"> a. Board of Nursing letter b. Referral process/frequency 5. Dispenser Compliance Audit Update 																					
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">11) Signature of person making this request</td> <td style="width: 20%; text-align: center;">Authorization</td> <td style="width: 20%; text-align: right;">Date</td> </tr> <tr> <td>Andrea Magermans 12/20/18</td> <td></td> <td></td> </tr> <tr> <td>Supervisor (if required)</td> <td></td> <td style="text-align: right;">Date</td> </tr> <tr> <td></td> <td></td> <td></td> </tr> <tr> <td colspan="3">Executive Director signature (indicates approval to add post agenda deadline item to agenda)</td> </tr> <tr> <td></td> <td></td> <td style="text-align: right;">Date</td> </tr> </table>				11) Signature of person making this request	Authorization	Date	Andrea Magermans 12/20/18			Supervisor (if required)		Date				Executive Director signature (indicates approval to add post agenda deadline item to agenda)					Date
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Release Summary

Wisconsin ePDMP

updated 12.18.2018

Release	Description
<p>2019 Development Considerations (pending cost and prioritization by user of the PDMP)</p>	<p><i>Healthcare Prescriber User</i></p> <ul style="list-style-type: none"> • Addition of RxCheck for interstate data sharing • Improved ability to manage delegate users <p><i>All User</i></p> <ul style="list-style-type: none"> • Improved layout and design of Patient Report including alerts and dispensing details • Improved patient searching for hyphenated names <p><i>Pharmacy User</i></p> <ul style="list-style-type: none"> • Additional data validations on ASAP submission • Optional submission of Date Sold <p><i>Law Enforcement User</i></p> <ul style="list-style-type: none"> • Ability to bulk upload alerts
<p>R10.2 December 2018</p>	<p><i>Healthcare Prescriber User</i></p> <ul style="list-style-type: none"> • WI Addiction Resource Tab (Project ECHO, UW Addiction Consultation Hotline and WI Addiction Recovery Helpline) <p><i>Law Enforcement/Government Employee Users</i></p> <ul style="list-style-type: none"> • Permission to view Data Driven Alerts on Patient Report
<p>R10.1 September 2018</p>	<p><i>Medical Coordinator Assistant User</i></p> <ul style="list-style-type: none"> • New ePDMP role • Allows management of DEA list for Medical Coordinator by assistant <p><i>Healthcare Prescriber User</i></p> <ul style="list-style-type: none"> • Improved workflow for printing the Patient History Report
<p>R10.0 August 2018</p>	<p><i>Medical Coordinator User</i></p> <ul style="list-style-type: none"> • Metrics detail added to prescriber grid • Improved functionality for managing DEA list <p><i>Healthcare Prescriber User</i></p> <ul style="list-style-type: none"> • Improved communication for pending MC request
<p>R9.0 June 2018</p>	<p><i>Healthcare Prescriber User</i></p> <ul style="list-style-type: none"> • New Features for Prescriber Metrics Report <ul style="list-style-type: none"> ○ Map of distance travelled by patient ○ Graphic of payment type for dispensing ○ Drill down patient list for patient alert counts • Improved messaging for patient search results • Improved messaging for EHR related to interstate data <p><i>Pharmacy Submitter User</i></p> <ul style="list-style-type: none"> • Removal of zip code to city validation in ASAP file <p><i>Public Statistics</i></p> <ul style="list-style-type: none"> • Addition of MME per script graphic
<p>R8.5 March 2018</p>	<p><i>Healthcare Prescriber User</i></p> <ul style="list-style-type: none"> • Implement Password Expiration • Addition of audit log of Medical Coordinator view of Prescriber Metrics <p><i>Pharmacy Submitter User</i></p> <ul style="list-style-type: none"> • Improved messaging for fatal errors in ASAP processing <p><i>Law Enforcement User</i></p> <ul style="list-style-type: none"> • Addition of log of submitted alerts <p><i>Public Statistics</i></p> <ul style="list-style-type: none"> • Addition of raw data export

Release Summary

Wisconsin ePDMP

updated 12.18.2018

Release	Description
R8.0 January 2018	Healthcare Prescriber User <ul style="list-style-type: none">• Addition of Prescriber Led Alert• Limit patient query results to 2 years of data• Prescriber Metrics Report comparison to others in specialty

Magermans, Andrea L - DSPS

From: Wisconsin Department of Safety and Professional Services <WIDSPS@public.govdelivery.com>
Sent: Monday, December 17, 2018 4:00 PM
To: Predaina, Jelena - DSPS; Predaina, Jelena - DSPS; Censky, Matt - DSPS; Nartowicz, Joseph III - DSPS; Magermans, Andrea L - DSPS
Subject: Courtesy Copy: WI ePDMP News

This is a courtesy copy of an email bulletin sent by Andrea Magermans.

This bulletin was sent to the following groups of people:

Subscribers of PDMP Updates (45290 recipients)

Having trouble viewing this email? [View it as a Web page.](#)



WISCONSIN | ePDMP



December 17, 2018

2018 has been another important year for the development and utilization of the Wisconsin Enhanced Prescription Drug Monitoring Program (WI ePDMP). There are now regularly close to 600,000 patient queries performed on a monthly basis, and dispensing data indicate a 32% decrease in opioid prescriptions dispensed since 2015.

Read below for information about:

- WI ePDMP Features for Prescribers
- What's in store for 2019

Patient Report Feature Spotlight

Addiction Resources

WI ePDMP patient reports for prescribers now link to information about Wisconsin addiction resources for healthcare professionals, as well as patients and their families.



Clicking on "Learn More About Addiction Resources" provides information about the following resources from the Wisconsin Department of Health Services:

- **The University of Wisconsin Addiction Consultation Hotline**, providing real-time support for healthcare professionals from specialists in addiction medicine, addiction psychiatry, psychology, and AODA counseling.
- **Project ECHO® (Extension for Community Healthcare Outcomes)**, a statewide initiative connecting clinical experts with primary care providers and medication assisted treatment prescribers across Wisconsin.
- **The Wisconsin Addiction Recovery Helpline**, available to connect people with resources to overcome dependence on opioids or other substances.

Prescriber Led Alerts

The "Add Prescriber Alert" button allows prescribers to place alerts on WI ePDMP patient reports in order to inform other healthcare users about the following patient events:

1. Treatment Agreement
2. Violation of Treatment Agreement
3. Overdose Incident

Alerts created for purposes other than the patient events listed above are not allowed and will be removed by PDMP administrators.

Prescriber Metrics Reports

Prescribers can access valuable information about their own prescribing practice by clicking on the "Prescribing Practice Metrics" icon when logged in to the WI ePDMP. This feature is not available to users who access patient reports from a single-sign-on within their EHR.



In addition to a complete list of dispensings associated with their DEA numbers, prescribers can view a summary of their controlled substances prescribing volume compared to peers of the same specialty, as well as an indication of their patients with alerts, the distance their patients travel for controlled substance prescriptions, and an estimation of their WI ePDMP usage.

Coming in 2019

Additional enhancements are in store for the WI ePDMP in 2019, in an effort to make sure it continues to meet its users' needs. The 2018 user satisfaction survey showed a high satisfaction rate with the WI ePDMP and helped identify many of the upcoming enhancements. Your feedback is valuable to the continued success of the WI ePDMP!

- Additional user surveys and online focus groups will be conducted to gather and refine ideas for priority enhancements.
 - If you do not receive a survey but are interested in providing feedback, contact PDMP staff to be included in the focus groups.
-

Stay Informed

To receive future updates about the WI ePDMP, make sure you are subscribed to PDMP Updates: [Manage Subscriptions](#).

You can also "Like" our Facebook page to keep informed about enhancements to the WI ePDMP: <https://pdmp.wi.gov/news>.



Questions?

Please contact us at pdmp@wisconsin.gov.

CONTACT US

Email: pdmp@wisconsin.gov | Phone: (608) 266-0011

The mission of the Department of Safety and Professional Services is to promote economic growth and stability while protecting the citizens of Wisconsin as designated by statute.

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2018 – WI ePDMP Outreach Calendar

OCTOBER		NOVEMBER		DECEMBER	
1		1		1	
2		2		2	
3		3		3	
4	Greater Milwaukee Dental Association	4		4	
5		5		5	
6		6		6	
7		7		7	
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9		9		9	
10		10	Waukesha County Chapter of Medical Assistants	10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	WI Assoc. of Local Health Departments and Boards
15		15		15	
16	1. PDMP North Regional Meeting 2. DHS Tribal Consult	16		16	
17	PDMP North Regional Meeting	17		17	
18		18		18	
19		19		19	
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23	WI DOJ Opioid/Meth Forum	23		23	
24		24		24	
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31				31	

2019 - WI ePDMP Outreach Calendar

JANUARY		FEBRUARY		MARCH	
1		1		1	
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4		4		4	
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14	Platteville Roundtable	14		14	
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30				30	
31				31	



December 20, 2018

[NAME]
Address 1
Address 2
Address 3

Dear [NAME]:

This letter serves as a reminder of the requirement under Wis. Stat. § 961.385 for practitioners to review patient records in the Wisconsin Enhanced Prescription Drug Monitoring Program (WI ePDMP) prior to issuing a prescription order for a controlled substance. You have been identified as a prescriber with an estimated WI ePDMP usage of less than 50%. This estimation considers the number of patient queries that you and your linked delegates have performed compared to the number of controlled substance prescription order dispensings of over three days that are associated with your DEA number.

The Wisconsin Department of Safety and Professional Services (DSPS) would like to take this opportunity to highlight some of the features of the WI ePDMP, a valuable tool to address prescription drug abuse by helping healthcare professionals evaluate their patients' use of controlled substance prescription drugs to make more informed prescribing, treatment, and dispensing decisions.

Patient Reports

WI ePDMP patient reports contain two years of a patient's controlled substance prescription history and include a chart indicating the patient's opioid and benzodiazepine prescriptions over time. Each patient report shows a map that acts as a quick snapshot to help a provider identify a patient who obtains controlled substance prescriptions from multiple prescribers or pharmacies or who travels long distances to obtain controlled substance prescriptions. When logged in to the WI ePDMP website, dispensing data can also be requested from the PDMP of neighboring states.

Alerts

Alerts on the patient report inform prescribers of concerning prescription patterns or potential harmful interactions. Some alerts are based on analytics of the dispensing detail, such as indicating when there is a daily opioid dose over 90 morphine milligram equivalents or concurrent opioid and benzodiazepine prescriptions, both of which increase the risk of an overdose event. Other alerts are entered by law enforcement as a mechanism for notifying providers of suspected opioid overdose events, controlled substance violations, and stolen controlled substance prescriptions.

Alerts may also be entered by prescribers in order to inform other healthcare users of the WI ePDMP about the following patient events:

- 1) Treatment Agreement
- 2) Violation of Treatment Agreement
- 3) Overdose Incident

Prescribing Practice Assessment

Beyond the clinical decision support tool in the patient reports, the WI ePDMP provides valuable prescribing practice assessment tools for prescribers of controlled substances and those who oversee them. These tools include the Patients Panel and the Prescriber Metrics Report, which are accessible by logging in to the WI ePDMP website at <https://pdmp.wi.gov/> and clicking on the appropriate icon. These features are currently not available via single-sign-on EHR integration.

Patients Panel

The Patients Panel displays a summary of information about patients to whom a prescriber has recently prescribed a controlled substance, including whether the patients have any data-driven or law-enforcement-reported alerts. The Patients Panel also provides one-click access to view a patient report.

Prescriber Metrics Report

This self-assessment tool for prescribers contains an individual prescriber's metrics for the last 100 days in comparison to other prescribers of the same specialty. The report provides a summary of prescription orders dispensed, estimated WI ePDMP usage, and number of patients with concerning patient history alerts, including the ability for prescribers to view the patient names associated with data-driven and law-enforcement-entered alerts. A map plots the home address of patients, allowing prescribers to see the distance their patients travel to receive controlled substance prescriptions. The report contains a full list of controlled substance prescription orders associated with the prescriber's DEA number, which can be useful for identifying fraudulent use of a prescriber's credentials.

Medical Coordinator Role

The Medical Coordinator role allows staff who medically coordinate Wisconsin prescribers to access the Prescriber Metrics Report of the prescribers they oversee. The Medical Coordinator role does not have access to the patient level detail in the prescriber's Prescriber Metrics Report, nor do they have access to view a prescriber's metrics until the prescriber accepts the coordinator's request in the WI ePDMP.

A Comprehensive Tool in the Fight Against Prescription Opioid Abuse

The information and tools available in the WI ePDMP are all part of an effort to promote safe, informed prescribing decisions of opioids and other controlled substances. Additional guidance for APNPs who prescribe controlled substances can be found in the Board of Nursing's Best Practices for Prescribing Controlled Substances Guidelines, available on the Board of Nursing's website.

The reported 32% decline in opioid prescriptions dispensed in Wisconsin since 2015 shows that progress is being made. By combining our efforts and using all available tools, we can continue to make strides toward fewer overdose deaths and ending the opioid epidemic.

December 20, 2018

«AddressBlock»

Dear Managing Pharmacist:

The Wisconsin Prescription Drug Monitoring Program (WI PDMP) is a valuable tool to address prescription drug abuse by helping healthcare professionals evaluate their patients' use of controlled substance prescription drugs to make more informed prescribing, treatment, and dispensing decisions. Under Wis. Stat. § 961.385, practitioners are required to review patient records in the WI PDMP prior to issuing a prescription order for a controlled substance. As such, accurate reporting of controlled substance prescription dispensing is paramount.

Section CSB 4.06 of the Wisconsin Administrative Code requires dispensers to submit data to the WI PDMP by 11:59 p.m. of the next business day after dispensing a monitored prescription drug, unless the dispenser has filed a written request for an exemption, as specified in Section CSB 4.08. In anticipation of a complete audit of dispenser compliance with the requirement to compile and submit dispensing data, the Wisconsin Department of Safety and Professional Services (DSPS) is verifying the information it has on file for all licensed pharmacies, based on the most recent pharmacy license renewal cycle.

Please verify the following information, which is based on DSPS credentialing records as of December 1, 2018:

Pharmacy Name: «NAME»
State License Number: «LICENSE»-«Registration»
DEA Number: «DEA_Number»
PDMP Exemption Status: «PDMP_STATUS»

If the information above is correct, no action is required. If the state license number or DEA number is incorrect, please contact WI PDMP staff via email at pdmp@wisconsin.gov with the correct information. If the exemption status is incorrect and your pharmacy does not dispense any monitored prescription drugs, please submit an Application to Change a Dispenser's Data Submission Status, available on the Forms page of the WI ePDMP website: <https://pdmp.wi.gov/forms>. Pharmacies that have not filed for an exemption are expected to submit dispensing data or zero reports to account for all business days and to correct dispensing data within five business days of discovering any errors, omissions, or inaccuracies.

Thank you for your attention to this matter. The information on file at DSPS will be used for PDMP dispenser compliance audit purposes. **To avoid possible disciplinary action against your pharmacy during the first audit of 2019, kindly respond to this notice with any corrections no later than January 18, 2019.**

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 18 December 2018 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Controlled Substance Board			
4) Meeting Date: 11 January 2019	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislative and Administrative Rule Matters <ol style="list-style-type: none"> 1. CSB 2.63 Relating to Scheduling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA 2. CSB 2.64 Relating to Scheduling N-Ethylpentylone 3. CSB 2.65 Relating to Scheduling FDA Approved Cannabidiol Drugs 4. Affirmative Action Relating to Excluding from Scheduling Industrial Hemp Cannabidiol 5. CSB 3 Relating to Special Use Authorization 6. CSB 5 Relating to Pharmacies and Physicians Dispensing Cannabidiol 7. CSB 4 Relating to Operation of Prescription Drug Monitoring Program 8. Updates on Legislation and Pending or Possible Rulemaking Projects 	
7) Place Item in: <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: 			
11) Authorization			
<i>Sharon Henes</i>		<i>mm/dd/yy</i>	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
Directions for including supporting documents: <ol style="list-style-type: none"> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting. 			

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.63 relating to scheduling of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

Statutory authority: ss. 961.11 (1) and (4), Stats.

Explanation of agency authority:

The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227. [s. 961.11 (1), Stats.]

If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30-day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2). [s. 961.11 (4), Stats.]

Related statute or rule: s. 961.14, Stats.

Summary of, and comparison with, existing or proposed federal regulation:

On July 10, 2018, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA as schedule I controlled substances under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on August 10, 2018 to similarly treat NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA under chapter 961 effective August 13, 2018 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.14 (4) (tb) 44., 45., 46., 47., and 48., Stats. which adds NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

Iowa: Iowa has not scheduled NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

Michigan: Michigan has not scheduled NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

Minnesota: Minnesota has not scheduled NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA.

Summary of factual data and analytical methodologies:

The methodology was to schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA to conform with the federal Controlled Substances Act.

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

This rule schedules a drug and does not have an effect on small business.

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 *, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; 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 Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by * to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.63 is created to read:

CSB 2.63 Addition of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA to schedule I. Section 961.14 (4) (tb) 44., 45., 46., 47., and 48., Stats., are created to read:

961.14(4)(tb) 44. Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate, commonly known as NM2201

45. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide, commonly known as 5F-AM-PINACA

46. 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide, commonly known as 4-CN-CUMYL-BUTINACA

47. Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate, commonly known as MMB-CHMICA

48. 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide, commonly known as 5F-CUMYL-P7AICA

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.64 relating to scheduling of N-Ethylpentylone.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

Statutory authority: ss. 961.11 (1) and (4), Stats.

Explanation of agency authority:

The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227. [s. 961.11 (1), Stats.]

If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30-day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2). [s. 961.11 (4), Stats.]

Related statute or rule: s. 961.14, Stats.

Summary of, and comparison with, existing or proposed federal regulation:

On August 31, 2018, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing N-Ethylpentylone into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating N-Ethylpentylone as a schedule I controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on October 3, 2018 to similarly treat N-Ethylpentylone under chapter 961 effective October 8, 2018 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.14 (7) (L) 34., Stats. which adds N-Ethylpentylone to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled N-Ethylpentylone.

Iowa: Iowa has not scheduled N-Ethylpentylone.

Michigan: Michigan has not scheduled N-Ethylpentylone.

Minnesota: Minnesota has not scheduled N-Ethylpentylone.

Summary of factual data and analytical methodologies:

The methodology was to schedule N-Ethylpentylone to conform with the federal Controlled Substances Act.

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

This rule schedules a drug and does not have an effect on small business.

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 *, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; 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 Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by * to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.64 is created to read:

CSB 2.64 Addition of N-Ethylpentylone to schedule I. Section 961.14 (7) (L) 34., Stats., is created to read:

961.14 (7) (L) 34. N-Ethylpentylone, commonly known as ephylone.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.65 relating to scheduling of approved cannabidiol drugs.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.22, Stats.

Statutory authority: ss. 961.11 (1) and (4), Stats.

Explanation of agency authority:

The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227. [s. 961.11 (1), Stats.]

If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30-day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2). [s. 961.11 (4), Stats.]

Related statute or rule: s. 961.14, Stats.

Summary of, and comparison with, existing or proposed federal regulation:

On September 28, 2018, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing Food and Drug Administration approved drug products that contain cannabidiol into Schedule V of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating Food and Drug Administration approved drug products that contain cannabidiol as a schedule V controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on October 9, 2018 to similarly treat Food and Drug Administration approved drug products that contain cannabidiol under chapter 961 effective October 15, 2018 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.22 (7), Stats. which adds Food and Drug Administration approved drug products that contain cannabidiol to schedule V.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled Food and Drug Administration approved drug products that contain cannabidiol.

Iowa: Iowa scheduled Food and Drug Administration approved drug products that contain cannabidiol as schedule V controlled substances.

Michigan: Michigan has not scheduled Food and Drug Administration approved drug products that contain cannabidiol.

Minnesota: Minnesota scheduled Food and Drug Administration approved drug products that contain cannabidiol as schedule V controlled substances.

Summary of factual data and analytical methodologies:

The methodology was to schedule scheduled Food and Drug Administration approved drug products that contain cannabidiol as schedule V controlled substances to conform with the federal Controlled Substances Act.

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

This rule schedules a drug and does not have an effect on small business.

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 *, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; 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 Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by * to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.65 is created to read:

CSB 2.65 Addition of approved cannabidiol drugs to schedule V. Section 961.22 (7), Stats., is created to read:

961.22 (7) APPROVED CANNABIDIOL DRUGS. A drug product in finished dosage formulation that has been approved by the United States food and drug administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING	:	AFFIRMATIVE ACTION
PROCEEDINGS BEFORE THE	:	ORDER OF THE
CONTROLLED SUBSTANCES BOARD	:	CONTROLLED SUBSTANCES BOARD

FINDINGS

1. On December 28, 2018, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 into schedule I of the federal Controlled Substances Act. The scheduling action is effective December 28, 2018.
2. The Controlled Substances Board did not receive an objection to similarly treating 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as a schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as controlled substances.
3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.13 and omitting the notice of proposed rule making, designating 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as a schedule I controlled substances.

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 under chapter 961, Stats. by creating the following:

CSB 2.67 Addition of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 to schedule I. Section 961.14 (4) (tb) 48., 49., 50., 51., and 52., Stats., is created to read:

- 961.14 (4) (tb) 48. thyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, commonly known as 5F-EDMB-PINACA.
49. methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate, commonly known as 5F-MDMB-PICA.
50. N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, commonly known as FUB-AKB48, FUB-APINACA or AKB48 N-(4-FLUOROBENZYL).
51. 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide, commonly known as 5F-CUMYL-PINACA or SGT-25.
52. (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, commonly known as FUB-144.

This order shall take effect on January 14, 2019 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated _____

Doug Englebert, Chair
Controlled Substances Board

Chapter CSB 3

SPECIAL USE AUTHORIZATION

CSB 3.01	Authority.
CSB 3.02	Definitions.
CSB 3.03	Permits generally.
CSB 3.04	SUA permit application.
CSB 3.045	Limited special use authorization.

CSB 3.05	Limitations on narcotic dog trainer drugs and drug quantities.
CSB 3.06	Amendment.
CSB 3.07	Record-keeping; records retention; disclosure.
CSB 3.08	Violations.

CSB 3.01 Authority. The provisions in this chapter are adopted under the authority in s. 961.335 (8), Stats.

History: CR 12-010; cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.02 Definitions. In this chapter:

- (1) “Board” means the controlled substances board.
- (2) “Controlled substance” has the meaning given in s. 961.01 (4), Stats.
- (3) “Humane shelter” means a facility that is intended to provide for and promote the welfare, protection, shelter, and humane treatment of animals, and that is operated by a humane society, animal welfare society, animal rescue group or other non-profit group. “Humane shelter” includes a shelter that provides foster care to animals.
- (4) “Special use” means to manufacture, obtain, possess, use, administer, or dispense a controlled substance for purposes that include, but are not limited to, scientific research, instructional activities, chemical analysis, drug-detecting animal training, and euthanasia in humane shelters.
- (5) “Special use authorization” or “SUA” means permission from the board to manufacture, obtain, possess, use, administer, or dispense a controlled substance for a special use.
- (6) “SUA permit” means a special use authorization permit granted to an individual by the board.

History: CR 12-010; cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.03 Permits generally. (1) No individual may manufacture, obtain, possess, use, administer, or dispense a controlled substance for a special use without a valid SUA permit for such purpose.

(2) An SUA permit may be issued to an individual only. Entities are not eligible to receive an SUA permit, except that an individual may be designated and authorized to receive the permit for a college or university department, research unit, or similar administrative organization unit. Students, laboratory technicians, research specialists, or chemical analysts under the designee’s supervision may possess and use the substances named in the designee’s permit for the authorized purposes without obtaining an individual permit.

(3) An SUA permit authorizes the holder to manufacture, obtain, possess, use, administer, or dispense the controlled substances specified in the permit and in the amounts specified in the permit. A permit holder shall use the authorized controlled substances only in the manner delineated in the SUA permit application, and as approved by the board. Any deviation from the permit’s specifications and subsequent amendments shall constitute a violation of the permit, and may result in revocation or suspension of the permit as set forth in s. CSB 3.08 (2).

(4) An SUA permit is valid for one year from the date of issuance. An SUA permit shall not be extended or renewed. A new application shall be completed and a new permit shall be granted to continue authorization beyond an existing permit’s expiration date.

History: CR 12-010; cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.04 SUA permit application. (1) Every applicant for an SUA permit shall:

(a) Submit a completed application and any required checklists using forms provided by the board. A complete application shall include a detailed description of the anticipated uses for each identified controlled substance in Schedules I to V of ch. 961, Stats., including each identified controlled substance by name and schedule and the protocols for such uses.

Note: Application forms and checklists are available upon request to the board office at 1400 E. Washington Ave., P.O. Box 8935, Madison, Wisconsin 53708, or online at <http://dsps.wi.gov>, under “Professions,” then “Controlled Substance Special Use Authorization.”

(b) Pay the applicable permit fee of \$25 as set forth in s. 961.335, Stats. No fee for an SUA permit may be charged to an employee of a state agency or institution if the permit is necessary to perform employment functions.

(c) Provide proof that the applicant has submitted an application for registration with the federal drug enforcement administration.

(d) Provide proof of the applicant’s compliance with the board’s requirements for maintaining the physical security of the controlled substances identified in the application.

(e) Provide the calculations that led to the amounts requested in the application.

(f) Any individual applying for an SUA permit shall provide any other information or documentation requested by the board.

(2) In addition to sub. (1), researchers shall also provide the following:

(a) A detailed one-page description of each research protocol that involves the use of controlled substances.

(b) For research involving animals, verification of Institutional Animal Care and Use Committee approval.

(c) For research involving human subjects, verification of Institutional Review Board approval.

(3) In addition to sub. (1), humane shelters shall also provide all of the following:

(a) Estimates as to the number of animals and dosage per animal.

(b) Documentation of completion of a board-approved euthanasia by injection course by each staff member performing euthanasia.

(4) In addition to sub. (1), narcotic dog trainers shall also provide the following:

(a) Unless other documentation is required by the board, a letter from the sheriff or chief of police, in the jurisdiction where the controlled substances are stored, that includes all of the following for dog training purposes:

1. Authorizing possession of controlled substances.
2. Accepting responsibility for the narcotic dog trainer.
3. Agreeing to supervise the narcotic dog trainer’s storage and use of controlled substances.

(b) Verification of membership in a board-approved national or Wisconsin police dog association for each narcotic dog trainer.

(c) For private narcotic dog trainers, an appearance before the board shall be required.

(5) In addition to sub. (1), municipal law enforcement animal control shall also provide all of the following:

(a) Unless other documentation is required by the board, a letter from the sheriff or chief of police, in the jurisdiction where the controlled substances are stored, that includes all of the following for euthanasia purposes:

1. Authorizing possession of controlled substances.
2. Accepting responsibility for the animal control officer.
3. Agreeing to supervise the animal control officer's storage and use of controlled substances.

(b) Documentation of completion of a board-approved euthanasia course by the officer performing euthanasia.

(6) In addition to sub. (1), analytical labs shall also provide all of the following:

(a) An inventory listing the total weight in grams if solid, or volume and concentration if liquid, of each controlled substance in the lab or intended for purchase for the lab.

(b) Whenever the lab purchases or otherwise adds to its inventory a new controlled substance or an additional amount of a controlled substance that was not previously authorized in a permit, an amended SUA application that includes the total weight in grams if solid, or volume and concentration if liquid, for each such new or additional substance.

(c) A detailed description of standard operating procedures relating to the use of controlled substances that includes the receipt, use, and disposition of controlled substances.

(7) The board may request an appearance before the board if additional information is required.

History: CR 12-010: cr. Register October 2012 No. 682, eff. 11-1-12; CR 15-083: am. (6) (a), (b) Register August 2016 No. 728, eff. 9-1-16.

CSB 3.045 Limited special use authorization. The board may grant a limited SUA or deny a SUA based upon consideration of public health and safety including any of the following reasons:

(1) An act constituting a violation under s. CSB 3.08 (1).

(2) Making any materially false statement or giving any materially false information in connection with an application for a SUA.

(3) Violating any federal or state statute or rule which substantially relates to the ability to manufacture, obtain, possess, use, administer, or dispense a controlled substance for a special use.

(4) An act which shows the person to be unable to safely use the SUA permit due to alcohol or other substance use.

History: CR 14-009: cr. Register July 2014 No. 703, eff. 8-1-14; correction in (title) made under s. 13.92 (4) (b) 2., Stats., Register July 2014 No. 703.

CSB 3.05 Limitations on narcotic dog trainer drugs and drug quantities. (1) Narcotic dog trainers shall be limited to having possession of the following drugs and quantities at any given time during the permit period:

(a) Up to 2 kilograms of marijuana. Marijuana may require periodic replacement during the permit period. Total use per year, taking into account replacement, shall be requested.

(b) Up to 30 grams of cocaine.

(c) Up to 30 grams of cocaine base, commonly known as crack cocaine.

(d) Up to 30 grams of heroin.

(e) Up to 30 grams of methamphetamine.

(2) A trainer may request, and the board may approve, with appropriate justification by the trainer, other controlled substances or different quantities of controlled substances.

History: CR 12-010: cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.06 Amendment. (1) A permit shall be effective only for the individual, substances, and project specified on its face and for additional projects which derive directly from the stated project. An individual holding a valid SUA permit may apply for an amendment to the permit by filing a written request with the board indicating the justification for the amendment and by paying a \$5 fee. The board may approve a request to amend a permit for any of the following reasons:

(a) A change to the original permit holder.

(b) The addition of new individuals to the permit who are participating in the functions for which the authorization was approved.

(c) An increase in the amount of a previously authorized controlled substance.

(d) The addition of specific controlled substances or schedules not previously authorized.

(e) The addition of further activity in accordance with s. 961.335 (5), Stats.

(2) An application for an amendment shall be submitted to the department and approved by the board prior to a permit holder operating under the terms of the amendment.

(3) Individuals applying for an amendment shall provide any other information or documentation requested by the board including information and documentation related to previous special use authorization permits.

History: CR 12-010: cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.07 Record-keeping; records retention; disclosure. (1) A permit holder shall maintain updated and accurate records of all of the following:

(a) The purchase of controlled substances pursuant to the permit, including receipts.

(b) The disbursement, use, and disposition of all controlled substances authorized by the permit.

(c) The total weight in grams if solid, or volume and concentration if liquid, of each controlled substance on hand.

(d) Documentation related to any discrepancies in a controlled substance inventory and usage, and all documentation related to investigation of such discrepancies.

(2) A permit holder shall retain the records described in sub. (1) for 4 years after the expiration of the special use authorization permit.

(3) A permit holder shall provide copies of the original records upon request of the board or the department of safety and professional services, except for those that are protected from disclosure by s. 961.335 (7), Stats.

History: CR 12-010: cr. Register October 2012 No. 682, eff. 11-1-12; CR 15-083: am. (1) (c) Register August 2016 No. 728, eff. 9-1-16.

CSB 3.08 Violations. (1) The following acts shall constitute a violation of an SUA permit:

(a) Any deviation from the permit's specifications related to controlled substances, schedules of drugs, or amounts authorized.

(b) Failure to comply with this chapter or s. 961.335, Stats.

(c) Failure to maintain physical security requirements for controlled substances as required by state and federal law.

(d) Failure to comply with board-approved euthanasia standards.

Note: The board considers the most current version of the euthanasia standards as stated in the American Veterinary Medical Association (AVMA) panel on euthanasia available at <http://www.avma.org>.

(e) Failure to notify the board of the revocation or limitation of a drug enforcement administration registration, within 3 business days of the revocation or limitation.

(2) Any violation of a special use authorization permit may, in the board's discretion, result in the suspension or revocation of the special use authorization permit.

History: CR 12-010: cr. Register October 2012 No. 682, eff. 11-1-12.

Chapter CSB 4

PRESCRIPTION DRUG MONITORING PROGRAM

<p>CSB 4.01 Authority and scope. CSB 4.02 Definitions. CSB 4.03 Drugs that have a substantial potential for abuse. CSB 4.04 Compilation of dispensing data. CSB 4.05 Electronic submission of dispensing data. CSB 4.06 Frequency of submissions. CSB 4.07 Correction of dispensing data. CSB 4.08 Exemptions from compiling and submitting dispensing data. CSB 4.09 Access to monitored prescription drug history reports and PDMP data about a patient. CSB 4.093 Monitored prescription drug history reports and audit trails about</p>	<p>healthcare professionals. CSB 4.097 Deny, suspend, revoke or otherwise restrict or limit access. CSB 4.10 Requests for review. CSB 4.105 Practitioners' requirement to review monitored prescription drug history reports. CSB 4.11 Methods of obtaining monitored prescription drug history reports. CSB 4.12 Use of PDMP data by the board and department. CSB 4.13 Confidentiality of PDMP records. CSB 4.14 Exchange of PDMP data. CSB 4.15 Disclosure of suspicious or critically dangerous conduct or practices.</p>
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Note: Chapter Phar 18 was renumbered chapter CSB 4 under s. 13.92 (4) (b) 1., Stats., Register September 2015 No. 717.

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 disclose information relating to the prescribing and dispensing of monitored prescription drugs.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. am., eff. 4-1-17; CR 17-028: am. Register December 2017 No. 744, eff. 1-1-18.

CSB 4.02 Definitions. As used in this chapter:

(1) "Access" means to have the ability to view 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. 961.385 (1) (a), Stats.

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

(3) "Animal" has the meaning given in s. 89.02 (1m), Stats.

(3m) "ASAP" means the American Society for Automation in Pharmacy.

Note: Contact: American Society for Automation in Pharmacy, 492 Norristown Road, Suite 160; Blue Bell, PA 19422; phone: (610) 825-7783; fax: (610) 825-7641; webpage: <http://asapnet.org/index.html>.

(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.

(4) "Board" means the Controlled Substances Board.

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

(5) "Controlled substance" means a drug, substance, analog, or precursor described in any of the following:

(a) Schedule I, II, III, IV, or V in the federal controlled substances act, 21 USC 812 (b) (1) to (b) (5) and (c), as changed and updated by 21 CFR 1308.

(b) Schedule I, II, III, IV, or V in subch. II of ch. 961, Stats., as amended by ch. CSB 2.

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

(6) "Department" means the department of safety and professional services.

(7) "Dispense" has the meaning given in s. 961.385 (1) (af), Stats.

(8) "Dispenser" means all of the following:

(a) A pharmacy.

Note: A site of remote dispensing authorized under s. 450.062, Stats., and s. Phar 7.095 is under the supervision of a pharmacy.

(b) A practitioner who dispenses a monitored prescription drug.

(9) "Dispenser delegate" means any of the following:

(a) A managing pharmacist of a pharmacy.

(b) An agent or employee of a practitioner who has been delegated the task of satisfying the data compilation and submission requirements of ss. CSB 4.04 and 4.05.

(10) "Dispensing data" means data compiled pursuant to s. CSB 4.04.

(11) "Drug" has the meaning given in s. 450.01 (10), Stats.

(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.

(11g) "Hospital" has the meaning given in s. 50.33 (2), Stats.

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

(11r) "Managing pharmacist" means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

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

(12) (a) "Monitored prescription drug" means all of the following:

1. A controlled substance included in s. 961.385 (1) (ag), Stats.

2. A drug identified by the board as having a substantial potential for abuse in s. CSB 4.03.

(b) "Monitored prescription drug" does not mean a controlled substance that by law may be dispensed without a prescription order.

(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.

(13) "Patient" has the meaning given in s. 961.385 (1) (aj), Stats.

(14e) "PDMP" means the Wisconsin prescription drug monitoring program.

(15) "PDMP data" means the information compiled and analyzed by the PDMP system from dispensing data submitted to it by dispensers

(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.

(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 monitored prescription drug history reports.

(16) “Pharmacy” has the 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 of a practitioner to whom the practitioner has delegated the task of accessing monitored prescription drug history reports.

(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.

(19) “Prescription” has the meaning given in s. 450.01 (19), Stats.

(20) “Prescription order” has the meaning given in s. 961.385 (1) (b), Stats.

(21) “Program” means the prescription drug monitoring program established under this chapter.

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

(23) “Zero report” means a report that indicates that a dispenser has not dispensed a monitored prescription drug since the previous submission of dispensing data or a zero report.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (5) (b) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13-065: cr. (3m), (13e), am. (16), (17), r. (22) Register February 2014 No. 698, eff. 3-1-14; (13e) renum. to (14e) under s. 13.92 (4) (b) 1., Stats., Register February 2014 No. 698; correction in (17) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14-003: am. (8) (a), renum. (9) to (9) (intro.) and am., cr. (9) (a), (b), (11g), (11r), am. (15) (intro.), cr. (15g), (15r), am. (17) Register August 2014 No. 704, eff. 9-1-14; correction in (3), (9) (b), (10), (12) (a) 1., 2., (15) (b), (15g), (17), (20) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15-101: am. (4) Register June 2016 No. 726, eff. 7-1-16; EmR1706: emerg. am. (1), (2), cr. (2m), (3s), (4m), (5m), am. (7), cr. (11c), (11n), am. (11r), cr. (11w), am. (12) (a) 1., cr. (12m), am. (13), r. (14), cons. and renum. (15) (intro.) and (a) to (15) and am., r. (15) (b), cr. (15b), (15e), am. (15g), (15r), (16), (17), (18), cr. (18m), (21m), eff. 4-1-17; CR 17-028: am. (1), (2), cr. (2m), (3s), (4m), (5m), am. (7), cr. (11c), (11n), am. (11r), cr. (11w), am. (12) (a) 1., cr. (12m), am. (13), r. (14), cons. and renum. (15) (intro.) and (a) to (15) and am., r. (15) (b), cr. (15b), (15e), am. (15g), (15r), (16), (17), (18), cr. (18m), (21m) Register December 2017 No. 744, eff. 1-1-18.

CSB 4.03 Drugs that have a substantial potential for abuse. Pursuant to s. 961.385 (1) (ag), Stats., the board has identified all of the following drugs as having a substantial potential for abuse:

(1) A controlled substance identified in schedule II, III, IV or V in the federal controlled substances act, 21 USC 812 (b) (2) to (b) (5) and (c), as changed and updated by 21 CFR 1308.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13-065: am. (intro.) Register February 2014 No. 698, eff. 3-1-14; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15-101: r. (3) Register June 2016 No. 726, eff. 7-1-16; EmR1706: emerg. r. (2), eff. 4-1-17; CR 17-028: r. (2) Register December 2017 No. 744, eff. 1-1-18.

CSB 4.04 Compilation of dispensing data. (1) As used in this section:

(a) “DEA registration number” means the registration number issued to a dispenser or practitioner by the federal department of justice, drug enforcement administration.

(c) “NDC number” means national drug code number, the universal product identifier used in the U.S. to identify a specific drug product.

(2) Subject to s. CSB 4.08, a dispenser shall compile dispensing data that contains all of the following information each time the dispenser dispenses a monitored prescription drug:

(a) The dispenser’s full name.

(b) The dispenser’s DEA registration number.

(c) The date dispensed.

(d) The prescription number.

(e) The NDC number of the monitored prescription drug.

(f) The quantity dispensed.

(g) The estimated number of days of drug therapy.

(ge) The classification code for payment type.

(gm) The number of refills authorized by the prescriber.

(gs) The refill number of the prescription.

(h) The practitioner’s full name.

(i) The practitioner’s DEA registration number.

(j) The date prescribed.

(L) The patient’s full name or if the patient is an animal, the animal’s name and the owner’s last name.

(m) The patient’s address, or if the patient is an animal, patient’s owner’s address, including street address, city, state, and ZIP code.

(n) The patient’s date of birth, or if the patient is an animal, patient’s owner’s date of birth.

(o) The patient’s gender.

(p) The name recorded under s. 450.11 (1b) (bm), Stats.

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

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (1) (b), (e), (3) (b), (d), (i), (k) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (title), renum. (2) to (2) (intro.) and am., cr. (2) (ge), (gm), (gs), renum. (3) (a) to (g) and (h) to (j) to (2) (a) to (g) and (h) to (j), r. (3) (k), renum. (3) (L) to (o) to (2) (L) to (o) and am. (L) to (n), am. (4) Register August 2014 No. 704, eff. 9-1-14; correction in (2) (intro.) made under s. 35.17, Stats., and in (4) made under s. 13.92 (4) (b) 7., Stats., Register August 2014 No. 704; correction in (2) (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15-070: cr. (2) (p) Register April 2016 No. 724, eff. 4-9-17; numbering correction in (2) (p) under s. 13.92 (4) (b) 1. Register April 2016 No. 724; republished to correct CR 15-070: cr. (2) (p) effective date Register May 2016 No. 725; EmR1706: emerg. r. (1) (b), (d), (e), am. (2) (b), (e), (i), (4), eff. 4-1-17; CR 17-028: r. (1) (b), (d), (e), am. (2) (b), (e), (i), (4) Register December 2017 No. 744, eff. 1-1-18.

CSB 4.05 Electronic submission of dispensing data. (1) Unless exempt under s. CSB 4.08, a dispenser shall electronically submit dispensing data to the PDMP in any of the following ways:

(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.

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.

(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.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (2) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (1), (4) Register August 2014 No. 704, eff. 9-1-14; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. renum. (1) to (1) (intro.), cr. (1) (a), (b), (3), r. and recr. (4), eff. 4-1-17; CR 17-028: renum. (1) to (1) (intro.), cr. (1) (a), (b), r. (2), (3), r. and recr. (4) Register December 2017 No. 744, eff. 1-1-18.

CSB 4.06 Frequency of submissions. (1) A dispenser shall submit dispensing data to the PDMP no later than 11:59 p.m. of the next business day after the monitored prescription drug is dispensed.

(2) If a dispenser does not dispense a monitored prescription drug 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 PDMP that accounts for each business day on which the dispenser did not dispense a monitored prescription drug.

(3) If a dispenser is not able to submit dispensing data zero report before 11:59 p.m. of the next business day as required by 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.

Note: The application for an emergency waiver may be obtained online at www.dsp.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.

(4) Unless otherwise specified by the board, an emergency waiver granted under sub. (3) shall only be effective for 7 days.

(5) The board may refer a dispenser and dispenser delegate 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 that submit false information to the PDMP to the appropriate licensing or regulatory board for discipline.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (1), (2), (3) (intro.), r. (4) to (6), (9), renum. (7) to (4) and am., renum. (8) to (5) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (2), (5) Register August 2014 No. 704, eff. 9-1-14; EmR1706: emerg. am. (1), (2), (3), (5), eff. 4-1-17; CR 17-028: am. (1), (2), (3), (5) Register December 2017 No. 744, eff. 1-1-18.

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.

Note: The written notice to the board may be submitted through an account with the board, sent by electronic mail or sent by U.S. mail to the Department of Safety and Professional Services 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. Register August 2014 No. 704, eff. 9-1-14; EmR1706: emerg. r. and recr. eff. 4-1-17; CR 17-028: r. and recr. Register December 2017 No. 744, eff. 1-1-18.

CSB 4.08 Exemptions from compiling and submitting dispensing data. (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 its license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

(a) The dispenser provides evidence sufficient to the board that the dispenser does not dispense monitored prescription drugs.

(b) The dispenser files with the board a written request for exemption on a form provided by the board.

Note: The application for an exemption may be obtained online at www.dsp.wi.gov or at no charge from the Department of Safety and Professional Services 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

(2) A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is administered directly to a patient.

(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.

(3) A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is a substance listed in the schedule in s. 961.22, Stats., and is not a narcotic drug, as defined in s. 961.01 (15), Stats., and is dispensed pursuant to a prescription order for a number of doses that is intended to last the patient 7 days or less.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (1) (a), cr. (3) Register August 2014 No. 704, eff. 9-1-14; CR 15-101: am. (1) Register June 2016 No. 726, eff. 7-1-16; EmR1706: emerg. cr. (2m), eff. 4-1-17; CR 17-028: cr. (2m) Register December 2017 No. 744, eff. 1-1-18.

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 sub. (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 subs. (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.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (1), renum. (2) to (2) (intro.) and am., cr. (2) (a) to (d), am. (3) Register August 2014 No. 704, eff. 9-1-14; corrections in (1), (2) (b), (3) (a) Register September 2015 No. 717; EmR1706: emerg. r. and recr., eff. 4-1-17; CR 17-028: r. and recr. Register December 2017 No. 744, eff. 4-1-17; s. 35.17 corrections in (3) (intro.), (4) (intro.), Register December 2017 No. 744.

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 themselves.

(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 subs. (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.

History: EmR1706: emerg. cr. eff. 4-1-17; CR 17-028: cr. Register December 2017 No. 744, eff. 4-1-17; s. 35.17 correction in (4), Register December 2017 No. 744.

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 trails 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).

History: EmR1706: emerg. cr., eff. 4-1-17; CR 17-028: cr. Register December 2017 No. 744, eff. 1-1-18.

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

(b) The denial of an emergency waiver requested pursuant to s. CSB 4.06 (3).

(c) The denial, suspension, revocation or other restriction or limitation imposed on the healthcare professional's, pharmacist delegate's, practitioner delegate's, or medical coordinator's account pursuant to s. CSB 4.097.

(2) To request a review, the dispenser, health care professional, pharmacist delegate, 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 dispenser's, healthcare professional's, pharmacist delegate's, practitioner delegate's, or medical coordinator's name and address, including street address, city, state and ZIP code.

(b) The citation to the specific statute or rule on which the request is based.

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

(4) No discovery is permitted.

(5) The board shall preside over the review. The review shall be recorded by audio tape unless otherwise specified by the board.

(6) The board shall provide the dispenser, healthcare professional, pharmacist delegate, 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 dispenser, healthcare professional, pharmacist delegate, 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.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (1) (b) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14-003: am. (1) (intro.), (2) (intro.), (b), (3), (6), (7) Register August 2014 No. 704, eff. 9-1-14; correction in (1) (a) to (c) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15-101: am. (1) (c), (2) (a) Register June 2016 No. 726, eff. 7-1-16; s. 35.17 correction in (1) (c), Register June 2016 No. 726; EmR1706: emerg. am. (1) (intro.), r. (1) (a), am. (1) (c), (2) (intro.), (a), (3), (6), (7), eff. 4-1-17; CR 17-028: am. (1) (intro.), r. (1) (a), am. (1) (c), (2) (intro.), (a), (3), (6), (7) Register December 2017 No. 744, eff. 1-1-18; correction in (1) (c) made under s. 13.92 (4) (b) 7., Stats., December 2017 No. 744.

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.

History: EmR1706: emerg. cr., eff. 4-1-17; CR 17-028: cr. Register December 2017 No. 744, eff. 1-1-18.

CSB 4.11 Methods of obtaining monitored prescription drug history reports. (1) The board shall disclose 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 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 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:

- (a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government-issued photographic identification.
- (b) Provides proof sufficient to the board of the authorization or delegation from the patient.
- (c) Makes a request for the monitored prescription drug history report on a form provided by the board.

(5) The board shall disclose the minimum necessary amount of information 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 PDMP system.
- (b) Provides proof sufficient to the board that the federal or state governmental agency is entitled to the information under s. 146.82 (2) (a) 5., Stats.
- (c) Makes a request for the monitored prescription drug history report through its PDMP system account.
- (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.

(6) The board shall disclose the minimum necessary amount of PDMP data or information 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 PDMP system.
- (b) Provides proof sufficient to the board that the department is entitled to the information under s. 146.82 (2) (a) 5., Stats.
- (c) Makes a request for the monitored prescription drug history report through its PDMP system account.

(7) The board shall disclose the minimum necessary amount of 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 PDMP system.
- (b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 21., Stats.
- (c) Makes a request for the monitored prescription drug history report through its PDMP system account.

(8) The board shall disclose the minimum necessary amount of 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 PDMP system.
 - (b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 18., Stats.
 - (c) Makes a request for the monitored prescription drug history report through its PDMP system account with the board.
- (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 research purposes.
- (10) The board shall disclose the minimum necessary amount of information in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of a law enforcement agency or prosecutorial unit if the designated staff does all of the following:

- (a) Creates an account with the PDMP system.
- (b) Provides documentation demonstrating the law enforcement agency or prosecutorial unit is 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 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 the monitored prescription drug history report through its account with the PDMP system.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: r. (3), (4), am. (6) (intro.), renum. (9) (intro.) to (9) and am., r. (9) (a) to (c) Register August 2014 No. 704, eff. 9-1-14; correction in (5) (intro.), (6) (intro.), (7) (intro.), (8) (intro.), (10) (intro.) Register September 2015 No. 717; CR 15-101: am. (1) (intro.), (b), (2) (intro.), (c), (7) (intro.), (c), (8) (intro.), (c) Register June 2016 No. 726, eff. 7-1-16; EmR1706: emerg. am. (Title), (1), (2) (intro.), (c), (5) (intro.), (a), (c), cr. (d), am. (6) (intro.), (a), (c), (7) (intro.), (a), (c), (8) (intro.), (a), (c), (9), (10) eff. 4-1-17; CR 17-028: (Title), (1), (2) (intro.), (c), (5) (intro.), (a), (c), cr. (d), am. (6) (intro.), (a), (c), (7) (intro.), (a), (c), (8) (intro.), (a), (c), (9), (10) Register December 2017 No. 744, eff. 1-1-18.

CSB 4.12 Use of PDMP data by the board and department. (1) The board shall develop and maintain a PDMP database to store dispensing data and PDMP data in a secure environment and an encrypted format.

(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.

(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 ss. CSB 4.09 or 4.093 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.

(6) 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 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.

(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.

(b) The collection of dispensing data as part of the assigned duties and responsibilities under s. 961.385, Stats., and this chapter.

(c) Evaluating and responding to legitimate requests for monitored prescription drug history reports, audit trails, and PDMP data.

(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.

(d) Other legally authorized purposes.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (4), cr. (4g), (4r) Register August 2014 No. 704, eff. 9-1-14; correction in (6) (b) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. am. (title), (1), r. (2), cr. (2m), r. and recr. (3), r. (4), (4g), (4r), (5), am. (6) (intro.), (a), cr. (6) (am), am. (6) (c), cr. (6) (cg), (cr), eff. 4-1-17; CR 17-028: am. (title), (1), r. (2), cr. (2m), r. and recr. (3), r. (4), (4g), (4r), (5), am. (6) (intro.), (a), cr. (6) (am), am. (6) (c), cr. (6) (cg), (cr), Register December 2017 No. 744, eff. 1-1-18; ; correction in (3) (b) made under s. 13.92 (4) (b) 7., Stats., December 2017 No. 744..

CSB 4.13 Confidentiality of PDMP records. (1) The dispensing data, PDMP data, audit trails, monitored prescription drug history reports, and prescribing metrics reports maintained, created, or stored as a part of the program 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 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 referred to the appropriate licensing or regulatory board for discipline, or the appropriate law enforcement agency for investigation and possible prosecution if the board determines that a criminal violation may have occurred.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. am., eff. 4-1-17; CR 17-028: am. Register December 2017 No. 744, eff. 1-1-18.

CSB 4.14 Exchange of PDMP data. (1) The board may exchange monitored prescription drug history reports and PDMP

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:

(a) The prescription monitoring program is compatible with the program.

(b) The relevant agency operating the prescription monitoring program agrees to exchange similar information with the program.

(2) In determining the compatibility of a prescription monitoring program to the program, the board may consider any of the following:

(a) The safeguards for privacy of patient records and the prescription monitoring program's success in protecting patient privacy.

(b) The persons authorized to access the information stored by the prescription monitoring program.

(c) The schedules of controlled substances monitored by the prescription monitoring program.

(d) The information required by the agency to be submitted regarding the dispensing of a prescription drug.

(e) The costs and benefits to the board of sharing information.

(3) The board may assess a prescription monitoring program's continued compatibility with the program at any time.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (1) (intro.) Register August 2014 No. 704, eff. 9-1-14; EmR1706: emerg. am. (title), (1) (intro.), eff. 4-1-17; CR 17-028: am. (title), (1) (intro.) Register December 2017 No. 744, eff. 1-1-18.

CSB 4.15 Disclosure of suspicious or critically dangerous conduct or practices. (1) The board may review dispensing data, monitored prescription drug history reports, PDMP 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.

(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 monitored prescription drug history reports, audit trails, and PDMP data 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.

(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.

History: CR 15-101: cr. Register June 2016 No. 726, eff. 7-1-16; CR 17-028: am. (1), (5) (intro.), cr. (6) Register December 2017 No. 744, eff. 1-1-18.