



CONTROLLED SUBSTANCES BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison
Contact: Christian Albouras (608) 266-2112
May 10, 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 (1-3)

B. Approval of Minutes of March 15, 2019 (4-5)

C. Administrative Matters - Discussion and Consideration

1. Department, Staff and Board Updates
2. Introductions, Announcements, and Recognition
3. 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. John Weitekamp – Pharmacy Examining Board Designee
 - e. Subhadeep Barman – Psychiatrist
 - f. Peter Kallio – Board of Nursing Designee
 - g. Leonardo Huck – Dentistry Examining Board Designee
 - h. Sandy Koresch – Attorney General Designee
 - i. Timothy Westlake – Medical Examining Board Designee

D. Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration (6)

1. WI ePDMP Operations Update
 - a. Statistics
 - b. Recent and Upcoming Releases (7)
 - c. Interstate Data Sharing
 - d. Status of Grants
 - e. Electronic Health Record (EHR) Integration Status
2. Quarterly Report Q1 2019 (8-23)
3. Dispenser Compliance Audit Update
4. Outreach Calendar (24-25)
5. Referral Workgroup Discussion

- E. Legislative and Administrative Rule Matters – Discussion and Consideration (26-53)**
 - 1. Adopt CR 18-055 Relating to Scheduling of Oral Solutions Containing Dronabinol (27-29)
 - 2. Adopt CR 18-024 Relating to Excluding from Scheduling Naldemine (30-32)
 - 3. Adopt CR 18-023 Relating to Scheduling of Ortho-Fluorofentanyl (33-35)
 - 4. Adopt CR 18-022 Relating to Scheduling of FUB-AMB (36-38)
 - 5. Adopt CR 18-069 Relating to Scheduling of MT-45 (39-41)
 - 6. Adopt CR 18-070 Relating to Scheduling of Para-chloroisobutyryl Fentanyl (42-44)
 - 7. Scope CSB 2.66, Relating to Synthetic Cannabinoids (45-46)
 - 8. CSB 4, Relating to Operation of the PDMP (47-53)
 - 9. Industrial Hemp
 - 10. Budget Items Proposed for the PDMP
 - 11. Legislation and Pending or Possible Rulemaking Projects

- F. Informational Items (54-73)**
 - 1. Update on Center for Disease Control (CDC) Prescribing Guidelines (55-56)
 - 2. Article – ‘Down to My Lowest Point.’ As Opioid Prescriptions Fall, Investigation Shows New Drug Spikes (57-73)

- G. Controlled Substances Board Annual Report – Discussion and Consideration**

- H. Board Member Reports**
 - 1. Medical Examining Board – Timothy Westlake
 - 2. Dentistry Examining Board – Leonardo Huck
 - 3. Board of Nursing – Peter Kallio
 - 4. Pharmacy Examining Board – John Weitekamp

- I. Liaison Reports**
 - 1. SCAODA Liaison – Subhadeep Barman
 - 2. Special Use Authorizations 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. Special Use Authorizations – Discussion and Consideration

N. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: JULY 12, 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
MARCH 15, 2019**

PRESENT: Yvonne Bellay, Doug Englebert, Leonardo Huck, Peter Kallio, Sandy Koresch, John Weitekamp

EXCUSED: Subhadeep Barman, Alan Bloom, Timothy Westlake

STAFF: Yolanda Y. McGowan, DPD Division Administrator; Sharon Henes, Administrative Rules Coordinator; Kimberly Wood, Program Assistant Supervisor-Adv.; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 10:10 a.m. A quorum of six (6) members was confirmed.

ADOPTION OF AGENDA

Amendments to the Agenda:

- Open Session:
 - Under item “C. Administrative Matters – Discussion and Consideration, 3. Board Members”
 - **CHANGE** “Elizabeth Smith Houskamp” to “Peter Kallio” as follows:
 - Peter Kallio – Board of Nursing Designee
 - **CHANGE** “Vacant” to “Sandy Koresch” as follows:
 - Sandy Koresch – Attorney General Designee
 - Under item “E. Legislative and Administrative Rule Matters – Discussion and Consideration”
 - **CHANGE** “CSGB 2.64” to “CSB 2.64” as follows:
 - Clearinghouse Report for CSB 2.64, Relating to Scheduling N-Ethylpentylone
 - **REMOVE:** Sub-item 4 “CSB 3, Relating to Special Use Authorization”

MOTION: Peter Kallio moved, seconded by Leonardo Huck, to adopt the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF JANUARY 11, 2019

MOTION: Peter Kallio moved, seconded by Leonardo Huck, to approve the minutes of January 11, 2019 as published. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Introductions, Announcements, and Recognition

MOTION: Peter Kallio moved, seconded by Leonardo Huck, to recognize and thank Philip Trapskin and Tina Virgil for their service to the Controlled Substances Board. Motion carried unanimously.

PDMP UPDATE

WI ePDMP Operations Update

MOTION: Peter Kallio moved, seconded by John Weitekamp, to approve the workflow as outlined on page 8 of the PDMP Workgroup Monitoring Report. Motion carried unanimously.

LEGISLATIVE AND ADMINISTRATIVE RULE MATTERS

Clearinghouse Report for CSB 2.63, Relating to Scheduling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA

MOTION: Leonardo Huck moved, seconded by Yvonne Bellay, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule CSB 2.63, relating to scheduling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA, for submission to the Governor's Office and Legislature. Motion carried unanimously.

CONTROLLED SUBSTANCES BOARD ANNUAL REPORT

MOTION: Peter Kallio moved, seconded by Leonardo Huck, to approve the 2019 Controlled Substances Board Annual Report for submission to the Legislature. Motion carried unanimously.

ADJOURNMENT

MOTION: Peter Kallio moved, seconded by Leonardo Huck, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:25 a.m.

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Andrea Magermans and Sarah Bradley		2) Date When Request Submitted: 4/30/2019 <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: 5/10/2019	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 <ol style="list-style-type: none"> a. Statistics b. Recent and Upcoming Releases c. Interstate data sharing d. Status of Grants e. EHR Integration Status 2. Quarterly Report Q1 2019 3. Dispenser Compliance Audit 4. Outreach Calendar 5. Referral Workgroup Discussion 																					
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 35%;">11) Signature of person making this request</td> <td style="width: 30%; text-align: center;">Authorization</td> <td style="width: 35%; text-align: right;">Date</td> </tr> <tr> <td>Andrea Magermans 4/30/19</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="2">Executive Director signature (indicates approval to add post agenda deadline item to agenda)</td> <td style="text-align: right;">Date</td> </tr> <tr> <td colspan="2"></td> <td></td> </tr> </table>				11) Signature of person making this request	Authorization	Date	Andrea Magermans 4/30/19			Supervisor (if required)		Date				Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date			
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Andrea Magermans 4/30/19																					
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. 																					

Wisconsin ePDMP

2019 Development and Release Summary

updated 4.30.2019

	Description
<p>R14 April 2019</p>	<p>RxCheck</p> <ul style="list-style-type: none"> • Technical tasks to establish connection to RxCheck interstate data sharing hub
<p>R12 and R13 March 2019</p>	<p>Data Quality Software Stability Work</p> <ul style="list-style-type: none"> • Technical tasks to simplify workflows and improve identification/resolution of workflow issues
<p>R11 February 2019</p>	<p>DHS Extract</p> <ul style="list-style-type: none"> • Addition of patient geocode latitude and longitude <p>Quality Assurance and Support Items</p>
<p>Proposed 2019 Development</p> <p><i>tentative release dates:</i> <i>June</i> <i>September</i> <i>November</i></p>	<p>All Users</p> <ul style="list-style-type: none"> • Updated layout and design of Patient Report including alerts and dispensing details, based on user feedback • Annual acceptance of Term and Conditions of the WI ePDMP <p>Healthcare Prescriber User</p> <ul style="list-style-type: none"> • Additional data elements for Patients Panel • MME calculator • Renewal process for Medical Coordinator access to metrics • Periodic review of linked delegates <p>Delegate Users</p> <ul style="list-style-type: none"> • Better access to history of recent Patient Reports <p>Pharmacy Users</p> <ul style="list-style-type: none"> • Improvements to workflow for error corrections/void • Display of Date Sold, if provided in the submission <p>Law Enforcement Users</p> <ul style="list-style-type: none"> • Additional data element on overdose alerts to capture administration of Naloxone



Controlled Substances Board



WISCONSIN | ePDMP

Report 8

Quarter 1

January 1 – March 31, 2019

Contact Information

Wisconsin Controlled Substances Board

Chairperson: Doug Englebert

Members:

Englebert, Doug, Chairperson	Department of Health Services Designated Member
Bloom, Alan, Vice Chairperson	Pharmacologist
Bellay, Yvonne M., Secretary	Department of Agriculture, Trade and Consumer Protection Designated Member
Barman, Subhadeep	Psychiatrist
Huck, Leonardo	Dentistry Board Representative
Kallio, Peter J.	Board of Nursing Representative
Weitekamp, John	Pharmacy Board Representative
Koresch, Sandy	Attorney General Designee
Westlake, Timothy W.	Medical Board Representative

Wisconsin Department of Safety and Professional Services

4822 Madison Yards Way

Madison, WI 53705

608-266-2112

DSPS@wisconsin.gov

Website: <https://dsps.wi.gov>

Wisconsin Prescription Drug Monitoring Program

PDMP@wisconsin.gov

Website: <https://pdmp.wi.gov/>

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Introduction

This report is being provided pursuant to ss. 961.385 (5) – (6), Wis. Stats., which requires the Controlled Substances Board (CSB) to submit a quarterly report to the Wisconsin Department of Safety and Professional Services (DSPS) about the Wisconsin Prescription Drug Monitoring Program (WI PDMP). This report is intended to satisfy that requirement for the first quarter of 2019 and will primarily focus on analysis of PDMP data from Q1 2019 and the preceding 12 months. For annual analysis of the WI PDMP from 2015 through 2018, see the Q4 2018 report found at:

<https://dsps.wi.gov/Pages/BoardsCouncils/CSB/Reports.aspx>

The WI PDMP was first deployed in June 2013. It is administered by DSPS pursuant to the regulations and policies established by the CSB. An enhanced system, the WI ePDMP, was launched on January 17, 2017, allowing the WI PDMP to become a multi-faceted tool in Wisconsin's efforts to address prescription drug abuse, misuse, and diversion through clinical decision support, prescribing practice assessment, communication among disciplines, and public health surveillance. Effective April 1, 2017, prescribers are required to check the WI ePDMP prior to issuing a prescription order for a monitored prescription drug, defined as controlled substance prescription drugs in Schedules II-V.

The WI ePDMP Public Statistics Dashboard (<https://pdmp.wi.gov/statistics>) provides interactive data visualizations for much of the data contained in this report, including county-level data for many of the charts.

User Satisfaction

A WI ePDMP user satisfaction survey was conducted in April 2018, and detailed results of the survey were provided in the Q2 2018 report. In brief, the survey was sent to approximately 30,000 registered healthcare professionals and had responses from over 6,000 users, a response rate of 20%. The survey indicated that most users are satisfied with the WI ePDMP, with 77% percent of respondents providing responses of either "Satisfied" or "Very Satisfied."

User-led enhancements identified through the survey and other input mechanisms are currently being refined and prioritized for the 2019 and 2020 development timeline. These enhancements include:

- Streamlining the Patient Report to expand the use of visualization, reduce the need to scroll through the page, and add detail available in the dispensing detail;
- Improving the error correction/record voiding process used by dispensers to correct or void a previously reported dispensing record.

User-group feedback will continue to be utilized throughout the development process to ensure enhancements meet the needs of the WI ePDMP users.

Impact on Referrals for Investigation

Pursuant to s. 961.385 (2) (f) and (3) (c), Wis. Stats., the CSB may disclose PDMP data to a licensing or regulatory board and refer for discipline a pharmacist, pharmacy, or practitioner who fails to comply with the rules of the Prescription Drug Monitoring Program or if circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner, or patient. In 2018, the CSB Referral Criteria Workgroup was formed to develop recommendations for how the CSB could define suspicious or critically dangerous conduct or practices.

Based on the initial recommendations, the Wisconsin Medical Examining Board (MEB), Dentistry Examining Board (DEB), and Board of Nursing (BON) received summaries of the PDMP dispensing data specific to their professions at their meetings in the fall of 2018. The data focused on opioid dispensing volume for the six-month time period of December 1, 2017 through May 31, 2018. Based on the data presented, the following actions occurred:

- The top seven physician (MD/DO) prescribers and the top seven physician assistant (PA) prescribers, based on opioid dispensing volume for the six-month period, were referred to the MEB.
- The top four dentistry prescribers, based on opioid dispensing volume for the six-month period, were referred to the DEB. An additional 12 dentistry prescribers were referred from the highest 1% of opioid prescribers for the profession for having written prescriptions for over three days without any indication of use of the WI ePDMP.
- The top four Advanced Practice Nurse Prescribers (APNP), based on opioid dispensing volume for the six-month time period, were referred to the BON. The BON requested additional targeted outreach to over 800 APNPs who had an estimated WI ePDMP usage of less than 50% in an effort to educate these prescribers about the requirement to use the PDMP, as well as the tools available in the PDMP that can help promote safe prescribing practices.

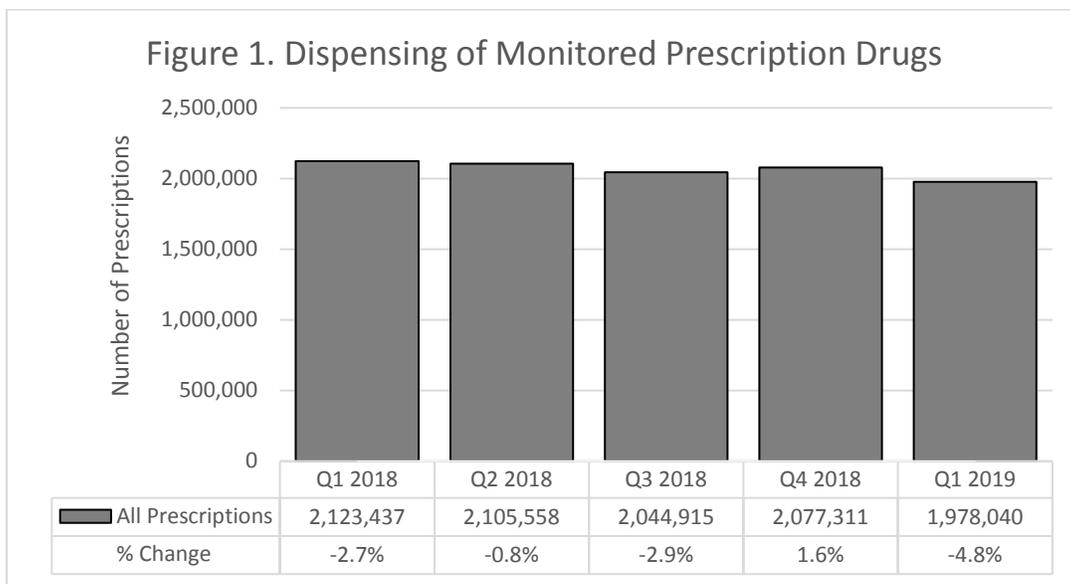
The investigation of the referred prescribers is ongoing, with letters issued to the identified medical, dentistry, and nursing licensees in Q4 2018 and Q1 2019. The DSPS Division of Legal Services and Compliance has received responses from the referred licensees and is proceeding with the investigations.

The CSB Referral Criteria Workgroup continues to meet in 2019 to refine the process for using PDMP data to proactively monitor licensees and their prescribing practices for suspicious or critically dangerous conduct or practices and to determine when such activity should result in a referral to the appropriate licensing board. Results of the current investigations will also be used by the CSB Referral Criteria Workgroup to guide the process of proactive monitoring and referrals.

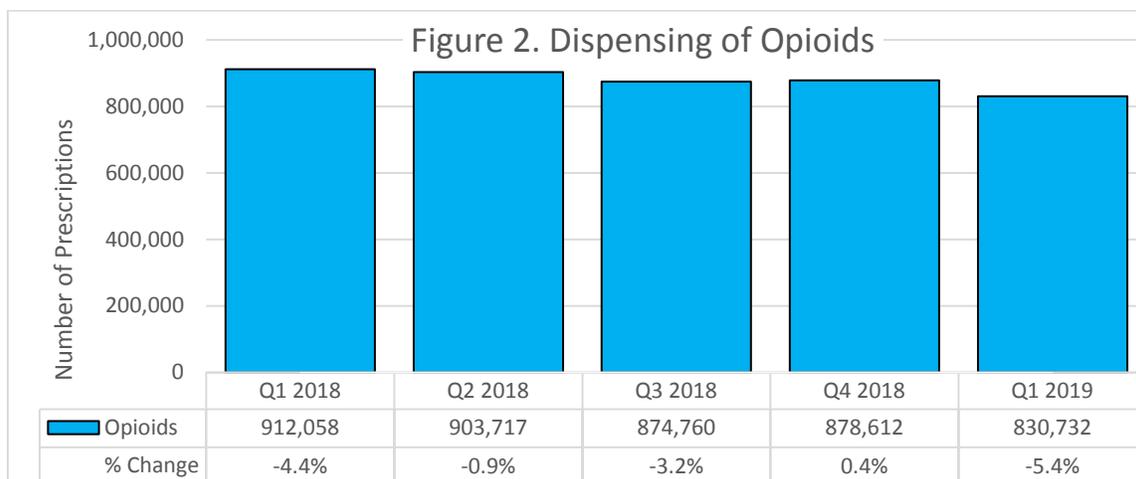
Monitored Prescription Drug Dispensing Trend

Overall, the trend of decreased dispensing of monitored prescription drugs continues in Wisconsin. Beginning in Q1 2016, the dispensing of both opioids and benzodiazepines has decreased each quarter. Dispensing of stimulants has been variable by quarter between increased and decreased dispensing with no overall change in dispensing volume.

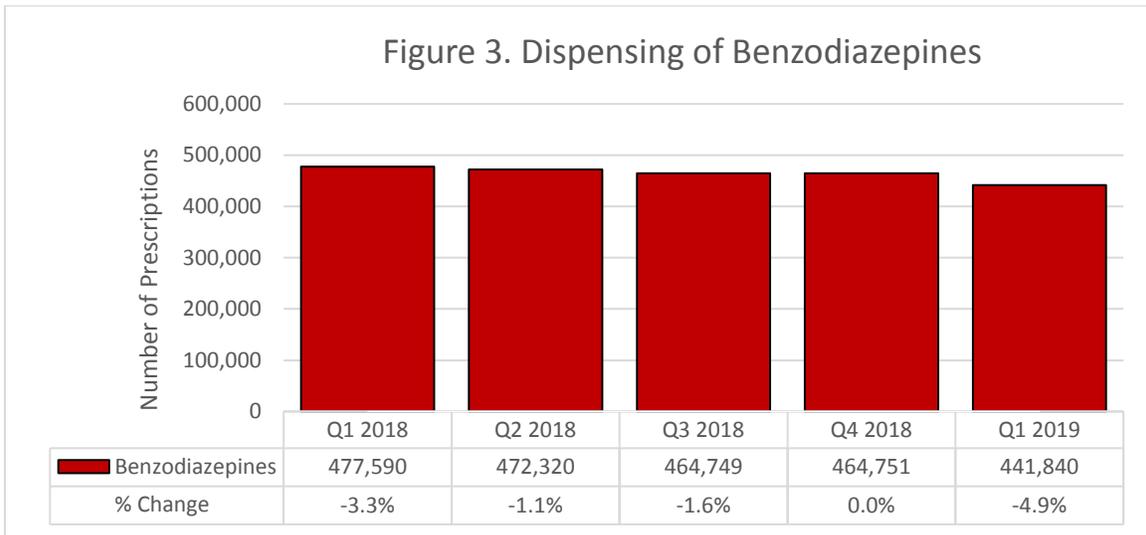
From Q4 2018 to Q1 2019 specifically, there was a 5% reduction in the number of monitored prescription drugs dispensed, the highest reduction per quarter since Q2 2017. This equates to an overall 7% reduction from the dispensing levels of Q1 2018.



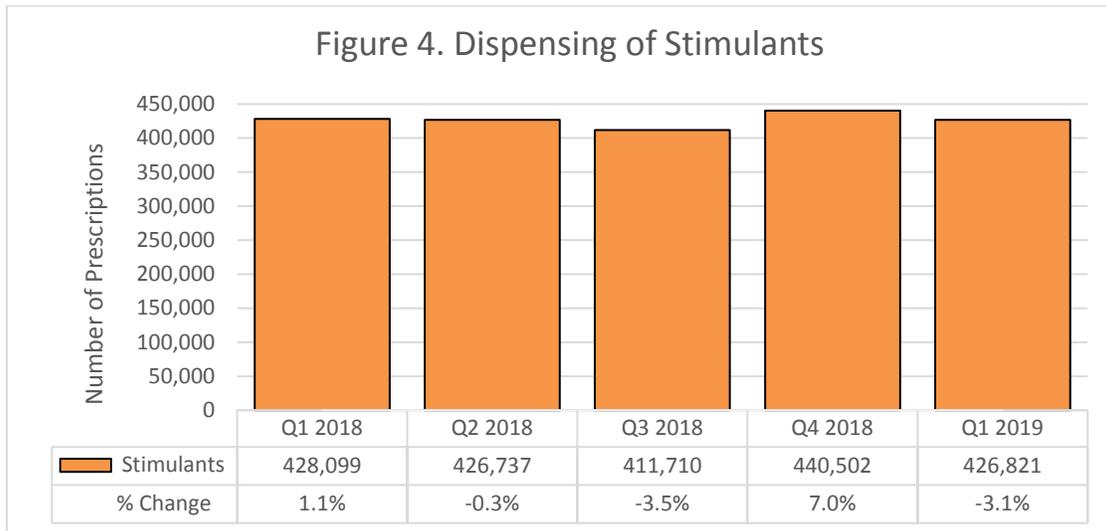
Opioid dispensing from Q4 2018 to Q1 2019 decreased by 5%, the highest reduction from a previous quarter since Q2 2017. This equates to a 9% reduction from the dispensing levels of Q1 2018.



Benzodiazepine dispensing from Q4 2018 to Q1 2019 also decreased by 5%, the highest reduction from a previous quarter since Q2 2017. This equates to an overall 7% reduction from the dispensing levels of Q1 2018.



Dispensing of stimulants continues to fluctuate quarterly between increased and decreased dispensing. Dispensing for Q1 2019 decreased by 3% from Q4 2018. Overall, dispensing of stimulants remains unchanged from the dispensing levels of Q1 2018.



Top 15 Dispensed Monitored Prescription Drugs

Table 1 shows the top 15 most dispensed monitored prescription drugs in Q1 2019 compared to Q4 2018, ranked in order of the number of prescriptions dispensed in Q1 2019. The top 15 monitored prescription drugs dispensed make up almost 88% of the dispensing for any given quarter.

The rate of pharmacy-dispensed Buprenorphine HCl-Naloxone HCl Dihydrate, one of the medications commonly used as part of Medication-Assisted Treatment (MAT) for opioid use disorder, continues to rise. Buprenorphine HCl-Naloxone HCl Dihydrate moved into the 15th spot of the most dispensed monitored prescription drugs in Q3 2018 and is the 14th most dispensed monitored prescription drug in Q1 2019.

	Drug Name	Drug Class	Q1 2019 Dispensing	Q4 2018 Dispensing	Percent Change
1	Hydrocodone-Acetaminophen	Opioid	273,433	291,570	-6.2%
2	Amphetamine-Dextroamphetamine	Stimulant	196,595	203,054	-3.2%
3	Tramadol HCl	Opioid	166,730	173,385	-3.8%
4	Lorazepam	Benzodiazepine	138,998	145,444	-4.4%
5	Alprazolam	Benzodiazepine	134,266	141,635	-5.2%
6	Oxycodone HCl	Opioid	130,541	139,873	-6.7%
7	Clonazepam	Benzodiazepine	115,643	121,287	-4.7%
8	Zolpidem Tartrate	Other	109,582	116,571	-6.0%
9	Methylphenidate HCl	Stimulant	96,697	100,589	-3.9%
10	Lisdexamfetamine Dimesylate	Stimulant	95,789	98,069	-2.3%
11	Oxycodone w/ Acetaminophen	Opioid	86,402	94,529	-8.6%
12	Pregabalin	Other	57,650	61,558	-6.3%
13	Diazepam	Benzodiazepine	46,636	49,857	-6.5%
14	Buprenorphine HCl-Naloxone HCl Dihydrate	Opioid	44,561	43,122	3.3%
15	Morphine Sulfate	Opioid	41,542	45,087	-7.9%

The rate of pharmacy-dispensed Buprenorphine HCl-Naloxone HCl Dihydrate increased by 3% in Q1 2019, which equates to an increase of 21% in the past 12 months. Note that this does not include dispensings that occur at an opioid treatment program due to federal regulation 42 CFR Part 2, which prohibits federally funded opioid treatment programs from submitting dispensing data to state PDMPs.

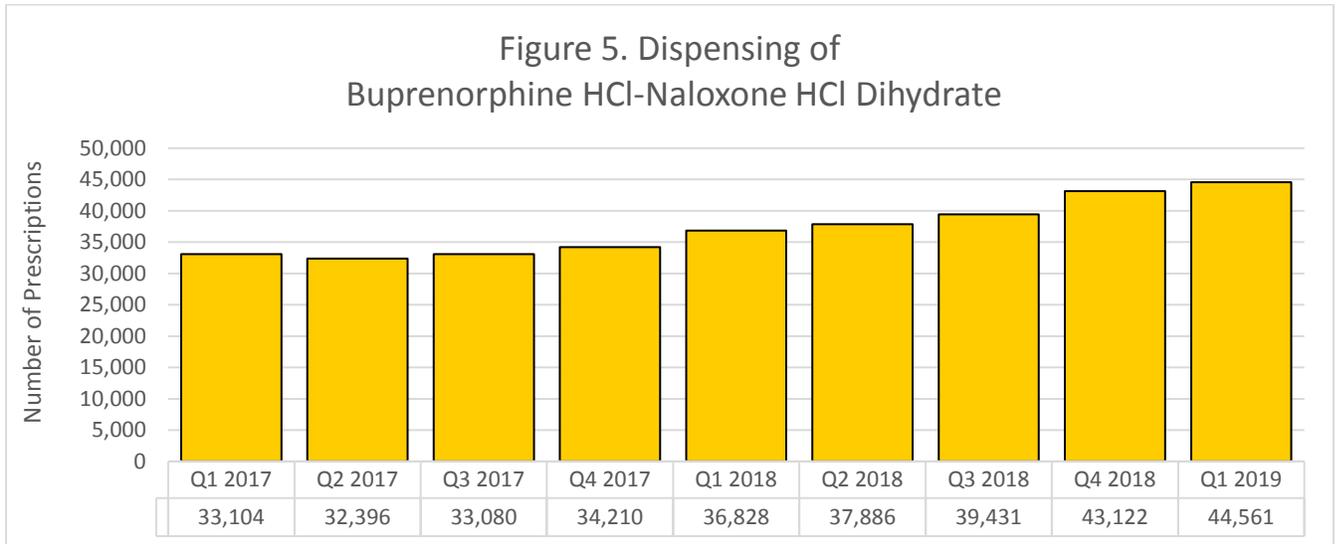


Table 2 below shows the top 15 most dispensed monitored prescription drugs in Q1 2019 compared to Q4 2018, ranked in order of total quantity of pills, or doses, dispensed in Q1 2019, rather than number of prescription orders filled.

Table 2. Top 15 Dispensed Monitored Prescription Drug by Pill (Dose) Volume					
	Drug Name	Drug Class	Q1 2019 Pill (Dose)	Q4 2018 Pill (Dose)	Percent Change
1	Hydrocodone-Acetaminophen	Opioid	13,790,909	14,965,935	-7.9%
2	Tramadol HCl	Opioid	10,514,082	11,682,290	-10.0%
3	Amphetamine-Dextroamphetamine	Stimulant	9,318,821	9,614,784	-3.1%
4	Oxycodone HCl	Opioid	8,898,163	9,827,267	-9.5%
5	Alprazolam	Benzodiazepine	7,255,412	7,833,691	-7.4%
6	Clonazepam	Benzodiazepine	6,448,139	6,897,058	-6.5%
7	Lorazepam	Benzodiazepine	6,165,062	6,584,221	-6.4%
8	Oxycodone w/ Acetaminophen	Opioid	5,633,679	6,165,772	-8.6%
9	Methylphenidate HCl	Stimulant	4,347,892	4,543,997	-4.3%
10	Pregabalin	Other	4,212,727	4,563,222	-7.7%
11	Zolpidem Tartrate	Other	3,639,948	3,900,323	-6.7%
12	Lisdexamfetamine Dimesylate	Stimulant	2,989,651	3,061,118	-2.3%
13	Morphine Sulfate	Opioid	2,357,519	2,556,091	-7.8%
14	Diazepam	Benzodiazepine	1,794,964	1,953,973	-8.1%
15	Buprenorphine HCl-Naloxone HCl Dihydrate	Opioid	1,375,269	1,365,001	0.8%

Data-Driven Alerts

The WI ePDMP application uses sophisticated data analytics to assess a patient's monitored prescription drug history. Analytics are performed on the patient's prescription history to identify and alert WI ePDMP users to potential indications of abuse, diversion, or overdose risk, such as high morphine milligram equivalent doses, overlapping benzodiazepine and opioid prescriptions, and multiple prescribers or dispensers. Data-driven alerts are presented on the patient report as way to call attention to specific detail from the dispensing data.

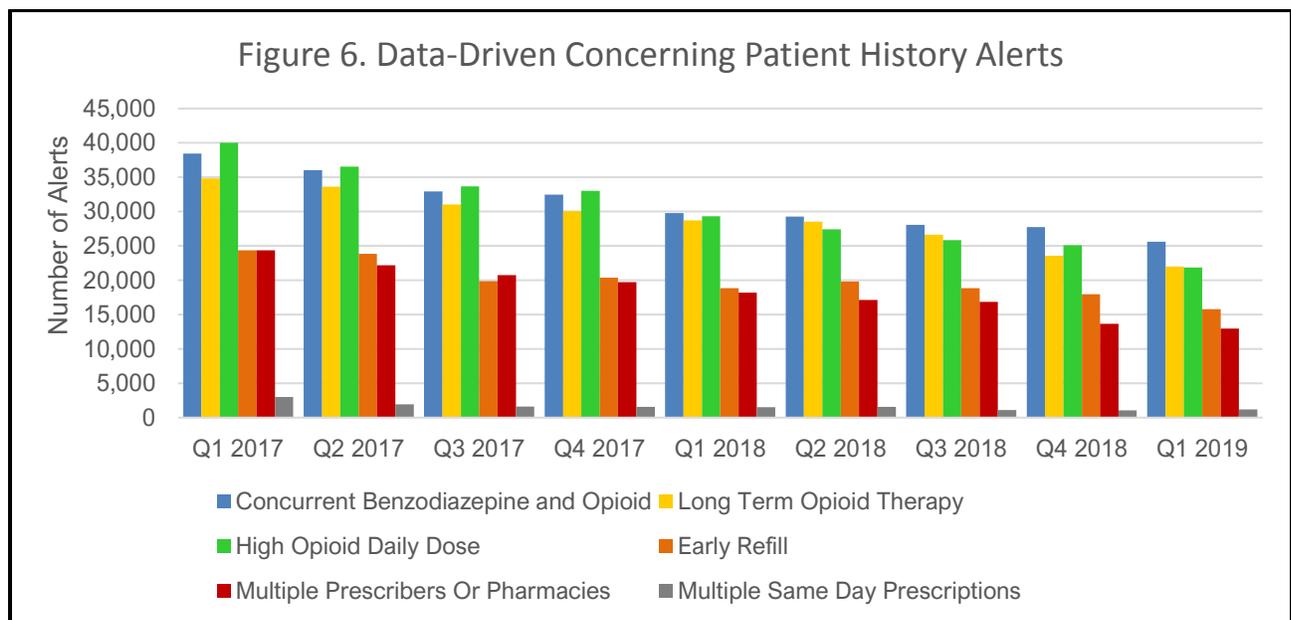
The 6 types of data-driven concerning patient history alerts are:

1. **Concurrent Benzodiazepine and Opioid Prescription Alert**, which indicates when a patient's active current prescriptions include both an opioid and a benzodiazepine, a combination that significantly increases the patient's risk of overdose.
2. **High Current Daily Dose of Opioids Alert**, which indicates when a patient's active current prescriptions are estimated to provide a daily dose of opioids that exceeds 90 morphine milligram equivalent (MME), thereby increasing the patient's risk of overdose.
3. **Long-Term Opioid Therapy with Multiple Prescribers Alert**, which indicates when a patient has been prescribed at least one opioid prescription from two or more prescribers for 90 or more days.
4. **Early Refill Alert**, which indicates when a patient has refilled a controlled substance prescription two or more days earlier than the expected refill date based on the estimated duration of the prescription calculated and reported by the pharmacy.
5. **Multiple Prescribers or Pharmacies Alert**, which indicates that the patient has obtained prescriptions from at least five prescribers or five pharmacies within the previous 90 days. The five prescribers or dispensers may be associated with the same clinic, practice or location, but the WI ePDMP still views them as separate prescribers/dispensers. This alert is not a direct indication of doctor shopping; it is simply a flag for further inspection of the dispensing history.
6. **Multiple Same Day Prescriptions Alert**, which indicates when a patient has received the same controlled substance drug from multiple prescribers or pharmacies on the same day.

Overall, there was a 9% reduction in the number of concerning patient history alerts generated by analytics of the dispensing data from Q4 2018 to Q1 2019. Specifically, the alerts for Multiple Prescribers or Pharmacies, an alert that may be an indication of "doctor shopping," decreased in occurrence by 5%. The occurrence of High Opioid Daily Dose alerts decreased by 13%, and Concurrent Benzodiazepine and Opioid alerts decreased by 8%. There was an increase in frequency of occurrence for Multiple Same Day Prescriptions in Q1 2019; however, when compared to Q1 2018, the occurrence rate for that alert type has decreased by over 20%. This is also the least frequent of alert types, making up only approximately 1% of all data-driven alerts.

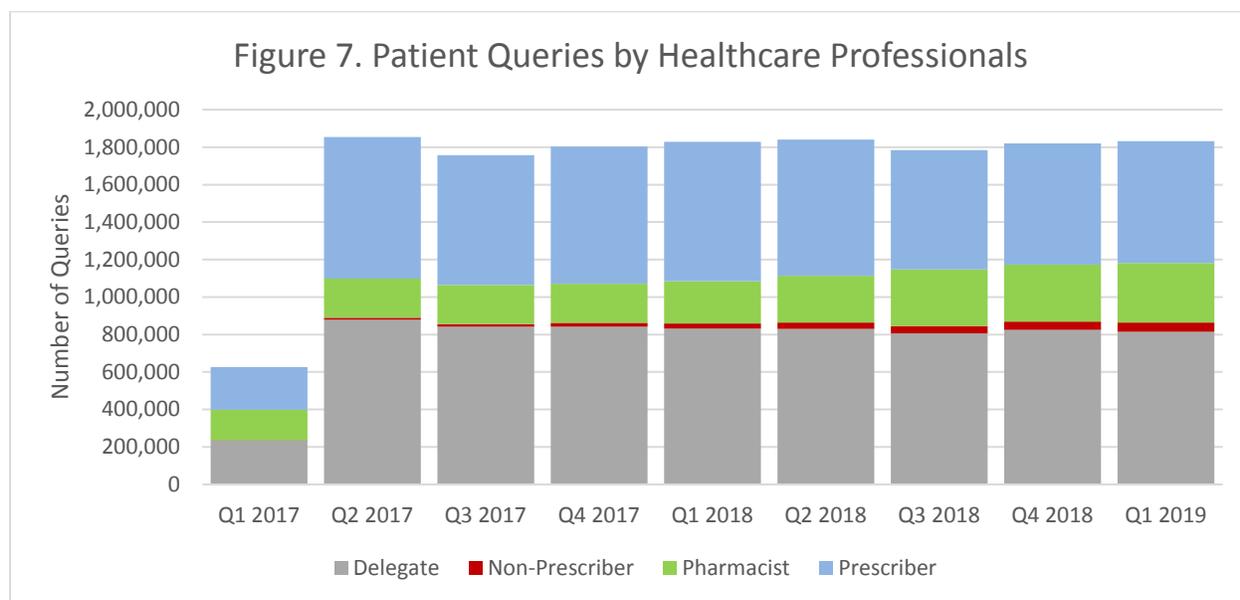
See Table 3 and Figure 6 for detail on the overall volume of alerts by alert type as well as the percent change that occurred from Q4 2018 to Q1 2019.

Table 3. Concerning Patient History Alerts Listed by Volume of Alerts Generated in Q1 2019				
	Alert Type	Q1 2019	Q4 2018	Percent Change
1	Concurrent Benzodiazepine and Opioid	25,590	27,742	-7.8%
2	Long Term Opioid Therapy	21,991	23,588	-6.8%
3	High Opioid Daily Dose	21,838	25,094	-13.0%
4	Early Refill	15,799	17,988	-12.2
5	Multiple Prescribers or Pharmacies	12,964	13,645	-5.0%
6	Multiple Same Day Prescriptions	1,185	1,038	14.2%
	All Alert Types	99,367	109,095	-8.9%



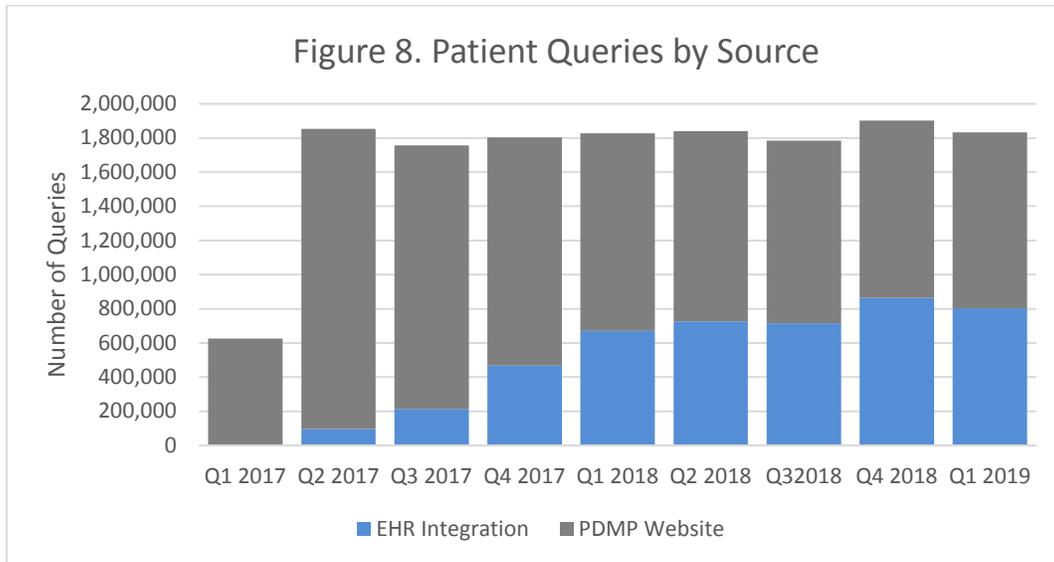
Disclosure of WI PDMP Data

Between January 1 and March 30, 2019, healthcare users made a total of 1,832,655 patient queries. Breaking down the queries by user type shows that 44% of the queries were performed by delegates of prescribers or pharmacists, 36% were performed by prescribers, 17% by pharmacists, and 3% by other non-prescribing healthcare professionals. The number of queries per month is remaining consistent even with the overall decreases seen in the dispensing of monitored prescription drugs.

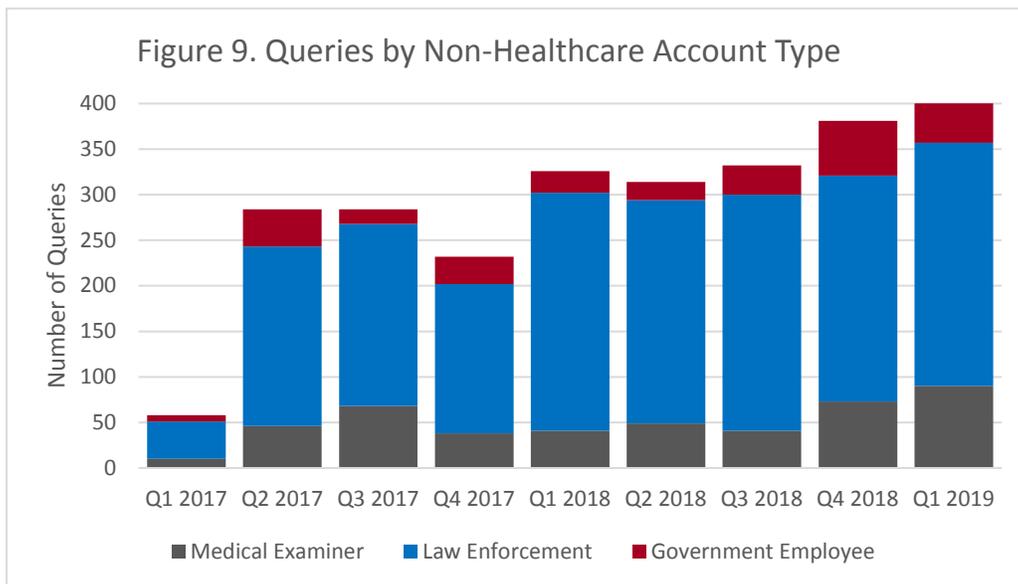


The WI ePDMP is currently connected to 18 other state PDMPs via the National Association of Boards of Pharmacy's PMP InterConnect (PMPi). This allows healthcare users to expand the WI ePDMP patient query to return results from PDMPs in other states, including border states such as Minnesota, Michigan, Illinois, Iowa and Indiana. The most recent state to be added to the list of states with which the WI ePDMP is connected via the PMPi is Florida.

As of March 30, 2019, healthcare professionals from 14 health systems in Wisconsin have one-click access to the PDMP from within their electronic health record (EHR) platform. In Q1 2019, 44% of patient queries were through the direct EHR integration, which is consistent with the Q4 2018 query volume by source. Additional health systems have expressed interest in initiating the single-sign-on option from within their EHR.



Authorized individuals from non-healthcare groups made a total of 420 requests for PDMP data in Q1 2019, which is a 10% increase over the previous quarter.

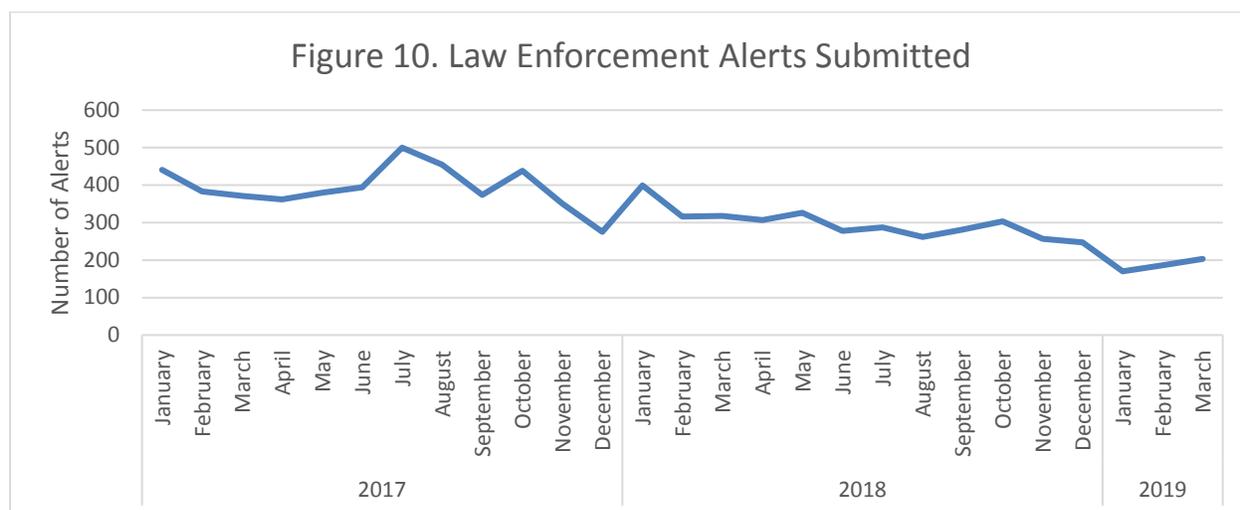


Law Enforcement Reports

In Q1 2019 there were 559 events reported to the WI ePDMP by Wisconsin law enforcement agencies as required by s. 961.37 (3) (a), Wis. Stat. The law requires the agencies to submit a report in each of the following situations:

1. When a law enforcement officer receives a report of a stolen controlled substance prescription.
2. When a law enforcement officer reasonably suspects that a violation of the Controlled Substances Act involving a prescribed drug is occurring or has occurred.
3. When a law enforcement officer believes someone is undergoing or has immediately prior experienced an opioid-related drug overdose.
4. When a law enforcement officer believes someone died as a result of using a narcotic drug.

Prescribers of patients associated with these events receive a proactive email notice from the WI ePDMP, in addition to the event being captured as an alert on the patient report in the WI ePDMP. Figure 10 shows the number of law enforcement reports submitted to the WI ePDMP by month since the WI ePDMP was launched. There is no statutory requirement for law enforcement agencies to submit their reports within a certain timeframe after the date of the event, and outreach efforts continue to emphasize the value that law enforcement reporting brings for healthcare clinical decision making.



The distribution of submission by report type for Q1 2019 remains fairly consistent with the previous reporting:

- 43% of the reports submitted were reports of stolen controlled substance prescriptions
- 25% of the reports submitted were suspected violations of the Controlled Substances Act
- 25% of the reports submitted were suspected non-fatal opioid-related overdose events, and
- 6% of the reports submitted were suspected narcotic-related deaths.

Summary

The first quarter of 2019 shows the most significant quarterly decline in the number of opioids and benzodiazepine dispensed in Wisconsin since early 2017. The number of patient queries conducted per month remains consistent even though the overall quantity of monitored prescription drugs being dispensed is decreasing.

Data show decreased dispensing for Q1 2019 compared to Q1 2018:

- There was a 5% decrease in the total number of monitored prescription drugs dispensed in Q1 2019 from the previous quarter for a total decrease of nearly 7% when compared to the previous year.
 - 9% decrease in the number of opioid prescriptions dispensed, or 81,000 fewer prescriptions compared to the previous year
 - 7% decrease in the number of benzodiazepine prescriptions dispensed, or nearly 36,000 fewer prescriptions compared to the previous year
 - Minimal change in the total dispensing of stimulants prescriptions dispensed compared to the previous year

Dispensing rates of opioids and benzodiazepines have steadily declined since Q4 2015. The dispensing rates of these monitored prescription drugs in Q1 2019 show the following declines when compared to the dispensing rates of Q4 2015:

- 26% decrease in the total number of monitored prescription drugs dispensed, nearly 700,000 fewer prescriptions
 - 35% decrease in the number of opioid prescriptions dispensed, over 450,000 fewer prescriptions
 - 26% decrease in the number of benzodiazepine prescriptions dispensed, nearly 160,000 fewer prescriptions

Encouraging trends found in the WI PDMP continued in Q1 2019:

- Dispensing of Buprenorphine HCl-Naloxone HCl Dihydrate (Suboxone®), one of the medications commonly used as part of Medication-Assisted Treatment (MAT) for opioid use disorder, increased by 3% in Q1 2019, which equates to an increase of 21% in the past 12 months.
- The occurrence of data-driven concerning patient history alerts, including measures that indicate drug seeking behaviors and increased risk for overdose, declined by 9% from the previous quarter and 21% compared to Q1 2018.

Additional detail about the WI ePDMP data, including county-level detail for many of the charts, can be found on the WI ePDMP Public Statistics Dashboard (<https://pdmp.wi.gov/statistics>), under the corresponding tabs of Controlled Substance Dispensing, PDMP Utilization, and Law Enforcement Alerts. For annual analysis of the WI PDMP from 2015 through 2018, see the Q4 2018 report found at: <https://dsps.wi.gov/Pages/BoardsCouncils/CSB/Reports.aspx>

2019 - WI ePDMP Outreach Calendar

JANUARY		FEBRUARY		MARCH	
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10		10	
11		11		11	
12		12		12	
13		13		13	1. PSW Legislative Day 2. WHA Physician Leaders Council
14	Platteville Roundtable	14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	DHS OTP Business Meeting
19		19		19	1. DHS Opioid Forum 2. DOJ DCI Narcotics Investigators School
20		20		20	DHS Opioid Forum
21		21		21	
22		22		22	
23		23		23	
24		24		24	
25		25		25	
26		26		26	
27		27		27	
28		28		28	
29				29	
30				30	
31				31	

2019 – WI ePDMP Outreach Calendar

APRIL		MAY		JUNE	
1		1		1	
2		2	RxCheck Meeting-Washington, DC	2	
3		3	RxCheck Meeting-Washington, DC	3	
4	Law Enforcement Training-M Marshfield	4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
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16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	
21		21	Waukesha County Heroin Task Force presentation	21	
22	Rx Abuse Summit - Atlanta	22		22	
23	Rx Abuse Summit - Atlanta	23		23	
24	Rx Abuse Summit - Atlanta	24		24	
25	Rx Abuse Summit - Atlanta	25		25	Harold Rogers National PDMP Meeting-Washington, DC
26		26		26	Harold Rogers National PDMP Meeting-Washington, DC
27		27		27	
28		28		28	
29		29		29	
		30		30	
		31			

**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: 1 May 2019 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: 10 May 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. Adopt CR 18-055 Relating to Scheduling of Oral Solutions Containing Dronabinol. 2. Adopt CR 18-024 Relating to Excluding From Scheduling Naldemine 3. Adopt CR 18-023 Relating to Scheduling of Ortho-Fluorofentanyl 4. Adopt CR 18-022 Relating to Scheduling of FUB-AMB 5. Adopt CR 18-069 Relating to Scheduling of MT-45 6. Adopt CR 18-070 Relating to Scheduling of Para-chloroisobutryl Fentanyl 7. Scope CSB 2.66 Relating to Synthetic Cannabinoids 8. CSB 4 Relating to Operation of the Prescription Drug Monitoring Program 9. Industrial Hemp 10. 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>			
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 : ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 18-055)

ORDER

An order of the Controlled Substances Board to create CSB 2.54 relating to scheduling of oral solutions containing dronabinol.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, 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 March 23, 2017, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing Food and Drug Administration approved products of oral solutions containing dronabinol into Schedule II 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 products of oral solutions containing dronabinol as a schedule II controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on May 12, 2017 to similarly treat Food and Drug Administration approved products of oral solutions containing dronabinol under chapter 961 effective May 15, 2017 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.16 (10) (a), Stats. which adds Food and Drug Administration approved products of oral solutions containing dronabinol to schedule II.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled Food and Drug Administration approved products of oral solutions containing dronabinol.

Iowa: Iowa has not scheduled Food and Drug Administration approved products of oral solutions containing dronabinol.

Michigan: Michigan has not scheduled Food and Drug Administration approved products of oral solutions containing dronabinol.

Minnesota: Minnesota has not scheduled Food and Drug Administration approved products of oral solutions containing dronabinol.

Summary of factual data and analytical methodologies:

The methodology was to schedule Food and Drug Administration approved products of oral solutions containing dronabinol 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.54 is created to read:

CSB 2.54 Addition of oral solutions containing dronabinol to schedule II. Section 961.16 (10) (a), Stats., is created to read:

961.16 (10) (a) Dronabinol [(-)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)] in an oral solution in a drug product approved by the U.S. food and drug administration.

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)

Dated _____

Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 18-024)

ORDER

An order of the Controlled Substances Board to create CSB 2.58 relating to excluding from scheduling naldemedine.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, 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. 961.16, Stats.

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

On September 29, 2017, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing naldemedine from the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to excluding naldemedine as a controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on November 10, 2017 to similarly treat naldemedine under chapter 961 effective November 20, 2017 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule amends s. 961.16 (2) (a) (intro.), Stats. which excludes naldemedine from the controlled substance schedules.

Comparison with rules in adjacent states:

Illinois: Illinois has not excluded naldemedine from scheduling.

Iowa: Iowa has not excluded naldemedine from scheduling.

Michigan: Michigan has not excluded naldemedine from scheduling.

Minnesota: Minnesota has not excluded naldemedine from scheduling.

Summary of factual data and analytical methodologies:

The methodology was to exclude naldemedine from scheduling 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.58 is created to read:

CSB 2.58 Exclusion of naldemedine. Section 961.16 (2) (a) (intro), Stats., is amended to read: *961.16 (2) (a) (intro) Opium and substances derived from opium, and any salt, compound, derivative or preparation of opium or substances derived from opium. Apomorphine, dextrorphan, nalbuphine, butorphanol, naldemedine, nalmefene, naloxegol, naloxone and naltrexone and their respective salts and the isoquinoline alkaloids of opium and their respective salts are excluded from this paragraph. The following substances, and any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:*

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)

Dated _____

Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
 : (CLEARINGHOUSE RULE 18-023)

ORDER

An order of the Controlled Substances Board to create CSB 2.59 relating to scheduling of ortho-fluorofentanyl.

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 October 26, 2017, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing ortho-fluorofentanyl into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating ortho-fluorofentanyl as a schedule I controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on November 30, 2017 to similarly treat ortho-fluorofentanyl under chapter 961 effective December 4, 2017 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 (2) (nd) 16m., Stats. which adds ortho-fluorofentanyl to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled ortho-fluorofentanyl.

Iowa: Iowa has not scheduled ortho-fluorofentanyl.

Michigan: Michigan has not scheduled ortho-fluorofentanyl.

Minnesota: Minnesota has not scheduled ortho-fluorofentanyl.

Summary of factual data and analytical methodologies:

The methodology was to schedule ortho-fluorofentanyl 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.59 is created to read:

CSB 2.59 Addition of ortho-fluorofentanyl to schedule I. Section 961.14 (2) (nd)16m., Stats., is created to read:

961.14 (2) (nd) 16m. Ortho-fluorofentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide)

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)

Dated _____

Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 18-022)

ORDER

An order of the Controlled Substances Board to create CSB 2.60 relating to scheduling of FUB-AMB.

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 November 3, 2017, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing FUB-AMB into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating FUB-AMB as a schedule I controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on December 6, 2017 to similarly treat FUB-AMB under chapter 961 effective December 11, 2017 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) 43., Stats. which adds FUB-AMB to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled FUB-AMB.

Iowa: Iowa has not scheduled FUB-AMB.

Michigan: Michigan has not scheduled FUB-AMB.

Minnesota: Minnesota has scheduled FUB-AMB as a schedule I controlled substance.

Summary of factual data and analytical methodologies:

The methodology was to schedule FUB-AMB 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.60 is created to read:

CSB 2.60 Addition of FUB-AMB to schedule I. Section 961.14 (4) (tb) 43., Stats., is created to read:

961.14 (4) (tb) 43. methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, commonly known as FUB-AMB, MMB-FUBINACA or AMB-FUBINACA.

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)

Dated _____

Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 18-069)

ORDER

An order of the Controlled Substances Board to create CSB 2.61 relating to scheduling of MT-45.

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 December 13, 2017, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing MT-45 into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating MT-45 as a schedule I controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on January 16, 2018 to similarly treat MT-45 under chapter 961 effective January 22, 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 (2) (rk), Stats. which adds MT-45 to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled MT-45.

Iowa: Iowa has not scheduled MT-45.

Michigan: Michigan has not scheduled MT-45.

Minnesota: Minnesota has not scheduled MT-45.

Summary of factual data and analytical methodologies:

The methodology was to schedule MT-45 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.61 is created to read:

CSB 2.61 Addition of MT-45 to schedule I. Section 961.14 (2) (rk) Stats., is created to read:

961.14 (2) (rk) MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine)

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)

Dated _____

Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 18-070)

ORDER

An order of the Controlled Substances Board to create CSB 2.62 relating to scheduling of par-chloroisobutyryl fentanyl.

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 February 1, 2018, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing para-chloroisobutyryl fentanyl into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating para-chloroisobutyryl fentanyl as a schedule I controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on March 5, 2018 to similarly treat para-chloroisobutyryl fentanyl under chapter 961 effective March 12, 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 (2) (nd)16s., Stats. which adds para-chloroisobutyryl fentanyl to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled para-chloroisobutyryl fentanyl.

Iowa: Iowa has scheduled para-chloroisobutyryl fentanyl as a Schedule I controlled substance.

Michigan: Michigan has not scheduled para-chloroisobutyryl fentanyl.

Minnesota: Minnesota has not scheduled para-chloroisobutyryl fentanyl.

Summary of factual data and analytical methodologies:

The methodology was to schedule para-chloroisobutyryl fentanyl 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.62 is created to read:

CSB 2.62 Addition of para-chloroisobutyryl fentanyl to schedule I. Section 961.14 (2) (nd) 16s., Stats., is created to read:

961.14 (2) (nd) 16s. Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

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)

Dated _____

Chair
Controlled Substances Board

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.66

Relating to: Scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The objective of the rule is to schedule 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as Schedule I controlled substance. The Controlled Substances Board has determined the scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as Schedule I controlled substance is in the best interest of the citizens of Wisconsin.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

On December 28, 2018, the United States Department of Justice, Drug Enforcement Administration published its order of temporary scheduling 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 was effective December 28, 2018. The Controlled Substances Board did not receive an objection to similarly treat 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as Schedule I controlled substances under ch. 961, Stats., within 30 days of the date of publication in the Federal Register of the temporary order designating 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as controlled substances.

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

- 961.14 (4) (tb) 49. ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate, commonly known as 5F-EDMB-PINACA.
50. methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate, commonly known as 5F-MDMB-PICA.
51. *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide, commonly known as FUB-AKB48, FUB-APINACA or AKB48 *N*-(4-FLUOROBENZYL).
52. 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide, commonly known as 5F-CUMYL-PINACA or SGT-25.
53. (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, commonly known as FUB-144.

The Affirmative Action order, dated February 4, 2019, took effect on March 11, 2019 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

961.11 (1) 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.

961.11(4) 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).

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

25 hours

6. List with description of all entities that may be affected by the proposed rule:

Law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

On December 28, 2018, the United States Department of Justice, Drug Enforcement Administration published its order of temporary scheduling 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 was effective on December 28, 2018.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

Authorized Signature

Date Submitted

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 himself.

(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.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Kimberly Wood, Program Assistant Supervisor-Adv. On behalf of Doug Englebert, Chairperson		2) Date When Request Submitted: 4/30/2019 <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: 5/10/2019	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Informational Items: 1. Update on Center for Disease Control (CDC) Prescribing Guidelines 2. Article – ‘Down to My Lowest Point:’ As Opioid Prescriptions Fall, Investigation Shows New Drug Spikes	
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: Please review the articles herein. These articles can also be found using the links below. Update on Center for Disease Control (CDC) Prescribing Guidelines: https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-CDC-Opioid-Guideline-Clarification-Letter-to-ASCO-ASH-NCCN.pdf Article – ‘Down to My Lowest Point:’ As Opioid Prescriptions Fall, Investigation Shows New Drug Spikes: https://fox6now.com/2019/04/28/1144333/			
11) Authorization			
<i>Kimberly Wood</i>		4/30/2019	
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.			



February 28, 2019

Robert W. Carlson, MD
National Comprehensive Cancer Network

Clifford A. Hudis, MD
American Society of Clinical Oncology

Martha Liggett, Esq.
American Society of Hematology

Dear Dr. Carlson, Dr. Hudis, and Ms. Liggett,

Thank you for your letter regarding CDC's *Guideline for Prescribing Opioids for Chronic Pain*. CDC greatly appreciates your feedback regarding the interpretation of the Guideline, particularly with regard to patients undergoing cancer treatment, cancer survivors who have chronic pain, and individuals with sickle cell disease.

The Guideline was developed to provide recommendations for primary care clinicians who prescribe opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. Because of the unique therapeutic goals, and balance of risks and benefits with opioid therapy in such care, clinical practice guidelines specific to cancer treatment, palliative care, and end of life care should be used to guide treatment and reimbursement decisions regarding use of opioids as part of pain control in these circumstances.

The Guideline may apply to cancer survivors in specific conditions, namely, when these patients experience chronic pain after completion of cancer treatment, are in clinical remission, and are under cancer surveillance only. As you note, for select groups of cancer survivors with persistent pain due to past cancer or past cancer treatment, the relationship of benefits to risks in use of opioids for chronic pain is unique. Clinical practice guidelines addressing pain control for cancer survivors, such as the 2016 *American Society of Clinical Oncology Clinical Practice Guideline on Management of Chronic Pain in Survivors of Adult Cancers* and the 2018 *National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain*, have been published subsequent to release of CDC's *Guideline for Prescribing Opioids for Chronic Pain*. Such guidelines provide useful guidance on unique considerations for use of opioids for pain control in cancer survivors.

As you additionally note, unique considerations in sickle cell disease can change the balance of benefits and risks for the use of opioids in pain management. Given the challenges of managing the painful complications of sickle cell disease, clinical practice guidelines addressing use of opioids as part of pain control in patients with sickle cell disease should be used to guide treatment and reimbursement decisions. The CDC Guideline refers readers to NIH's *National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for guidance for management of sickle cell disease*. This resource can be found at <https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease>.



The Guideline is not intended to deny any patients who suffer with chronic pain from opioid therapy as an option for pain management. Rather, the Guideline is intended to ensure that clinicians and patients consider all safe and effective treatment options for patients. Clinical decision-making should be based on the relationship between the clinician and patient, with an understanding of the patient's clinical situation, functioning, and life context, as well as a careful consideration of the benefits and risk of all treatment options, including opioid therapy. CDC encourages physicians to continue to use their clinical judgment and base treatment on what they know about their patients, including the use of opioids if determined to be the best course of treatment. Providers should communicate frequently with their patients to discuss both the benefits and risks of opioid therapy and revisit treatment plans for pain regularly to achieve the most positive outcomes for patients.

CDC has developed translational materials and trainings for providers to continue to emphasize that the Guideline is intended for primary care physicians for the treatment of chronic pain. Some of these resources include:

- *Assessing Benefits and Harms of Opioid Therapy*: https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf.
- CDC Training Series *Applying CDC's Guideline for Prescribing Opioids*, a web-based training to help providers gain a deeper understanding of the Guideline. Trainings address a variety of topics, including provider-patient communication and decision-making on initiating opioids for chronic pain. <https://www.cdc.gov/drugoverdose/training/online-training.html>

Chronic pain is common and multidimensional, and patients deserve safe and effective pain management. Collaborative relationships between patients and providers are critical to provide optimal pain management. CDC will continue to emphasize what the Guideline and associated materials say about communication, patient engagement in decision-making, and maintenance of the patient-provider relationship.

CDC will revisit the Guideline as new evidence and recommendations become available to determine when gaps have been sufficiently closed to warrant an update. We value stakeholder input to assist with such an update.

Sincerely,

Deborah Dowell, MD, MPH
Chief Medical Officer
The National Center for Injury Prevention and Control
Centers for Disease Control and Prevention



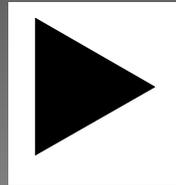
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As opioid prescriptions fall, investigation shows new drug spikes



MILWAUKEE -- Wisconsin doctors are prescribing fewer opioids, but state data reveals a spike in a different category of addictive drugs that medical professionals warn has become an emerging epidemic.

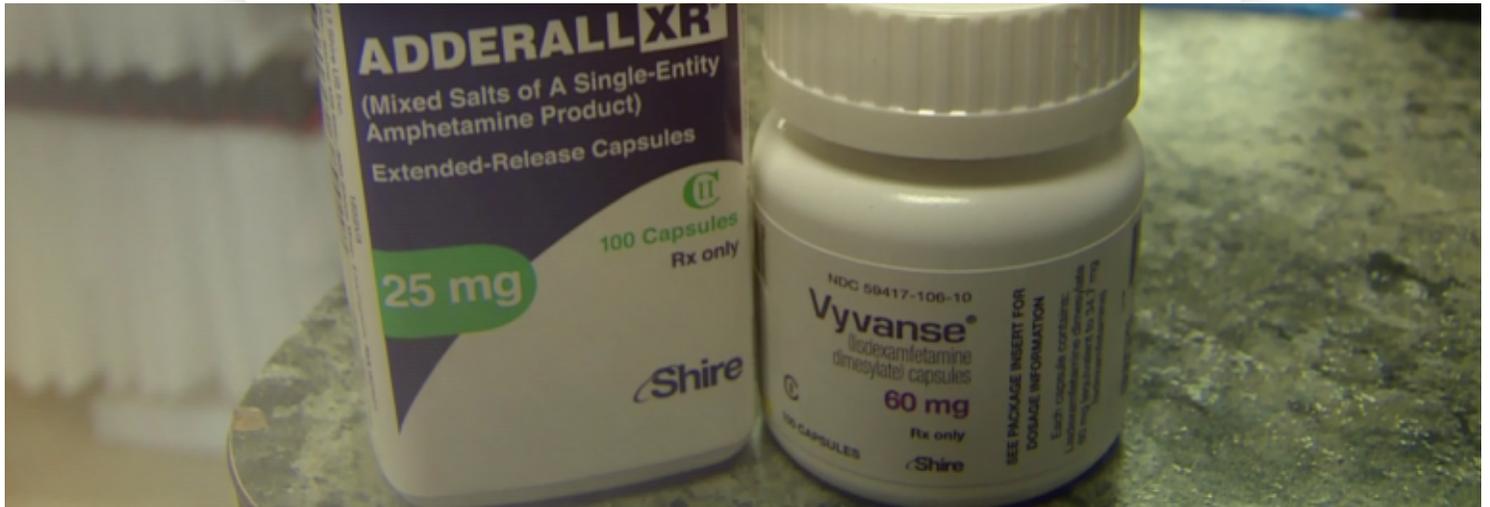
"They're not just a tablet that you're going to take, study for a test, and do well," CEO of Hayat Pharmacy Dr. Hashim Zaibak said, referring to stimulant medications like Adderall and Vyvanse, which are used to treat ADHD. "They're very, very addictive medications."



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"It's just too easy"

"I was in seventh grade when they prescribed Adderall," Jake Niesen said, speaking to FOX6 about his addiction and subsequent recovery.

Niesen says, at first, he did not like how the medication made him feel. A few years later, as classmates were experimenting with prescription medications, Niesen revisited Adderall.



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"I took double the dose, and so instantly I felt better about myself," Niesen said. "The consequences are not seen right away. So you just kind of push it off to the side as being a harmless drug."

The FOX6 Investigators also spoke with a woman who agreed to go on camera, but asked to go by the name "Christine" in order to protect future job opportunities.

"I was a freshman in college and I was having problems focusing," Christine said. "[Adderall] was able to have me live the party lifestyle, but also keep good grades in school."

"I was very naive," Christine added. "I didn't know about addiction."



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While Christine and Niesen have different stories, they described similar patterns they used to obtain stimulant medications.

"So there's typically a checklist," Niesen said. "You basically say certain things to get certain drugs. And the drug community coaches each other on how to do this."

"If you read off every symptom to a doctor, they want to believe you," Christine said. "It wasn't an issue for him to simply increase the dosage."



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"It's either a frown face or a smiley face," Niesen said. "And if you're frowning, you get a stronger prescription...it's just too easy to have access to do what you want."

"Even that wasn't enough," Christine said. "And then I turned to methamphetamine and eventually got in trouble with the law. It really brought me back down to my lowest point."

Christine and Niesen have worked hard in their recovery process, finding support in a local nonprofit called Just Listen. But both believe Wisconsin needs systemic change to prevent more people from falling into the patterns of addiction they've fought so hard to overcome.



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"Are we diagnosing more people?" Dr. Zaibak asked, referring to theories about why stimulant prescriptions are rising. "Are patients having more access to doctors? Or is it truly an overuse? It could be any of the above."

Pharmacists say they're noticing more stimulant prescriptions for patients on medications designed to treat opioid addiction, like Suboxone and Zubsolv.



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Of all the stimulants prescribed in Wisconsin, state data shows the biggest increase was in Lisdexamfetamine, often known as Vyvanse.



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"Really nothing's that safe," Niesen added. "If it has any abuse potential, it will be abused. We should be aware by now, so I don't understand how this is continuing."

State solutions

Wisconsin's Department of Safety and Professional Services' Controlled Substances Board says its focus has been on opioid prescriptions; specifically, with monitoring program alerts that help doctors and pharmacists identify risky behavior like medication overuse and "doctor shopping."

Wisconsin's Department of Safety and Professional Services says health care providers made approximately 20,000 drug monitoring patient queries per day in 2018; in 2016, that number was fewer than 5,000 per day.

"Because folks are looking at it more, they're becoming aware of more information and they can make better healthcare prescribing decisions," Controlled Substances Board Chair Doug Englebert said. "On the stimulant side, we haven't done so much of that. But we have been aware of the increase that's occurring."



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Englebert says the board is considering similar stimulant alerts for the monitoring program's future upgrades.

"Once you have something to review and find patterns, we can target some interventions," Englebert said, pointing to the success in reducing opioid prescriptions.

"Even though it's a prescription drug, there are safety concerns with these medications," Englebert added. "Age, race, social economics - doesn't matter. It's all over the place. It's a significant concern across the state."



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Pharmacists say solutions need to balance discouraging abuse without discouraging the patients who need medication.



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NEWS





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'Raising awareness:' Prescription take back event encourages people to dispose of drugs responsibly

HEALTH





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More deaths have been associated with kratom than previously known, CDC study finds

DOSE OF REALITY





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Bipartisan bill targets prescription drug costs in Wisconsin: 'Every day patients tell me they struggle'





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Blood pressure medication recall expands again to include losartan



Law enforcement officials begin sorting medication collected during 'Drug Take Back' events



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Wife of former Twin Lakes police captain, facing drug charges, pleads not guilty



NEWS

FDA OKs first medical device to treat ADHD in children



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Arraignment set for wife of former Twin Lakes police captain, facing drug charges



'Little cabin fever:' Some bar patrons, shoppers not discouraged by dangerous cold