



Scott Walker, Governor
Laura Gutiérrez, Secretary

CONTROLLED SUBSTANCES BOARD
West Allis Police Department
Hearing Room, 11301 W. Lincoln Avenue
West Allis, WI 53227
Contact: Erin Karow (608) 266-2112
November 9, 2018

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. ANNUAL HEARING WITH LAW ENFORCEMENT AGENCIES AND PROSECUTORS

1. Introduction

- a. Overview of Executive Order (EO) #228
- b. Background on the Wisconsin Controlled Substances Board

2. Overview of Scheduling Processes – Wisconsin Statutes § 961.11

3. Reporting Requirements for District Attorneys Regarding Controlled Substance Analogs – Wisconsin Statutes § 961.25

4. Discussion Regarding Drug Trends

- a. Presentation from the Wisconsin State Crime Lab Bureau
- b. Presentation from the Drug Enforcement Administration
- c. Open Discussion

5. Prescription Drug Monitoring Program (PDMP) Matters

- a. Input from Law Enforcement Regarding the Utilization of the PDMP

C. Approval of Minutes

- 1. September 14, 2018 **(4-6)**
- 2. October 9, 2018 Teleconference **(7-8)**

D. Administrative Matters - Discussion and Consideration

- 1. Staff Updates
- 2. Board Members
 - a. Yvonne Bellay – Dept. of Agriculture, Trade, and Consumer Protection Designee
 - b. Alan Bloom – Pharmacologist
 - c. Doug Englebert – Dept. of Health Services Designee
 - d. Philip Trapskin – Pharmacy Examining Board Designee

- e. Subhadeep Barman – Psychiatrist
- f. Peter Kallio – Board of Nursing Designee
- g. Leonardo Huck – Dentistry Examining Board Designee
- h. Tina Virgil – Attorney General Designee
- i. Timothy Westlake – Medical Examining Board Designee

E. PDMP Update – Discussion and Consideration (9)

- 1. **WI ePDMP Operations Update (10)**
 - a. Recent and Upcoming Releases
 - b. Status of Grants
 - c. Electronic Health Record (EHR) Integration Status
- 2. **WI ePDMP Events (11)**
- 3. **Quarterly Report Update (12-29)**
 - a. Q3 2018 Report Status Update
- 4. **Referral Update (30-42)**

F. Legislation and Rule Matters – Discussion and Consideration (43)

- 1. CSB 2.61 Relating to Scheduling MT-45 – Review Clearinghouse Comments **(44-51)**
- 2. CSB 2.62 Relating to Scheduling Parachloroisobutyl Fentanyl – Review of Clearinghouse Comments **(52-59)**
- 3. CSB 2.64 Scope Relating to Scheduling N-Ethylpentylone **(60-61)**
- 4. CSB 2.65 Scope Relating to Scheduling FDA Approved Cannabidiol Drugs **(62-63)**
- 5. Update on Legislation and Pending and Possible Rulemaking Projects

G. Board Member Reports

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

H. Special Use Authorizations – Discussion and Consideration

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

- 1. Introductions, Announcements, and Recognition
- 2. Informational Item(s)
- 3. Disciplinary Matters
- 4. Education Matters
- 5. Credentialing Matters
- 6. PDMP Update
- 7. Practice Questions
- 8. Legislation and Rule Matters
- 9. Liaison Report(s)
- 10. Speaking Engagement(s), Travel, or Public Relations Request(s)
- 11. Consulting with Legal Counsel

J. 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.).

K. Special Use Authorizations – Discussion and Consideration

L. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: JANUARY 11, 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
SEPTEMBER 14, 2018**

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

EXCUSED: Subhadeep Barman, Peter Kallio

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

CALL TO ORDER

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

ADOPTION OF AGENDA

Amendments to the Agenda:

- Add “Tina Virgil, Attorney General Designee”, to the list of Board Members

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

APPROVAL OF MINUTES OF AUGUST 8, 2018

MOTION: Philip Trapskin moved, seconded by Tina Virgil, to approve the minutes of the August 8, 2018 teleconference meeting as published. Motion carried unanimously.

LEGISLATION AND RULE MATTERS

Adopt CR 17-085 Relating to Scheduling AB-CHMINACA, AB-PINACA and THJ-2201

MOTION: Philip Trapskin moved, seconded by Leonardo Huck, to approve the Adoption Order for Clearinghouse Rule 17-085, relating to scheduling AB-CHMINACA, AB-PINACA and THJ-2201. Motion carried unanimously.

Adopt CR 17-086 Relating to Scheduling MAB-CHMINACA

MOTION: Philip Trapskin moved, seconded by Leonardo Huck, to approve the Adoption Order for Clearinghouse Rule 17-086, relating to scheduling MAB-CHMINACA. Motion carried unanimously.

Adopt CR 17-087 Relating to Scheduling 4-MePPP and a-PBP

MOTION: Philip Trapskin moved, seconded by Leonardo Huck, to approve the Adoption Order for Clearinghouse Rule 17-087, relating to scheduling 4-MePPP and a-PBP. Motion carried unanimously.

Adopt CR 17-088 Relating to Scheduling Synthetic Cannabinoids

MOTION: Philip Trapskin moved, seconded by Leonardo Huck, to approve the Adoption Order for Clearinghouse Rule 17-088, relating to scheduling Synthetic Cannabinoids. Motion carried unanimously.

Adopt CR 17-089 Relating to Scheduling 4-Fluororoisobutyryl Fentanyl

MOTION: Philip Trapskin moved, seconded by Leonardo Huck, to approve the Adoption Order for Clearinghouse Rule 17-089, relating to scheduling 4-Fluororoisobutyryl Fentanyl. Motion carried unanimously.

Review Clearinghouse Comments for CR 18-055 Relating to Oral Solutions Containing Dronabinol

MOTION: Philip Trapskin moved, seconded by Leonardo Huck, to accept all Clearinghouse comments for CR 18-055, relating to Oral Solutions Containing Dronabinol. Motion carried unanimously.

MOTION: Philip Trapskin moved, seconded by Yvonne Bellay, to authorize the Chair to approve the Legislative Report and Draft for CR 18-055, relating to Oral Solutions Containing Dronabinol, for submission to the Governor's Office and Legislature. Motion carried unanimously.

CSB 2.61, Relating to Scheduling MT-45

MOTION: Philip Trapskin moved, seconded by Tina Virgil, to approve the preliminary rule draft of CSB 2.61, relating to scheduling MT-45, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CSB 2.62, Relating to Scheduling Para-chloroisobutyryl Fentanyl

MOTION: Philip Trapskin moved, seconded by Tina Virgil, to approve the preliminary rule draft of CSB 2.62, relating to scheduling Para-chloroisobutyryl Fentanyl, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

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

MOTION: Philip Trapskin moved, seconded by Tina Virgil, to approve the scope statement for CSB 2.63, relating to scheduling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chair to approve the Scope Statement for implementation no less than 10 days after publication. Motion carried unanimously.

Affirmative Action Scheduling N-Ethylpentylone

MOTION: Philip Trapskin moved, seconded by Yvonne Bellay, to authorize the Chair to affirm the scheduling of N-Ethylpentylone as Schedule I, once the 30 days since the federal order has elapsed. Motion carried unanimously.

CSB 5, Relating to Approval of Pharmacies and Physicians That May Dispense Cannabidiol

MOTION: Timothy Westlake moved to authorize the Chair to approve the preliminary rule draft of CSB 5, relating to approving pharmacies and physicians that may dispense Cannabidiol, for posting of economic impact comments and submission to the Clearinghouse. Motion lost.

ADJOURNMENT

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

The meeting adjourned at 11:47 a.m.

**TELECONFERENCE/VIRTUAL
CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
OCTOBER 9, 2018**

PRESENT: Yvonne Bellay, Alan Bloom, Doug Englebert, Leonardo Huck, Philip Trapskin, Tina Virgil, and Timothy Westlake (*joined via teleconference at 2:04 p.m.*)

EXCUSED: Subhadeep Barman and Peter Kallio

STAFF: Erin Karow, Executive Director; Elizabeth Bronson, Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Kate Stolarzyk, Bureau Assistant; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chair, called the meeting to order at 2:01 p.m. A quorum of six (6) members was confirmed.

ADOPTION OF AGENDA

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

LEGISLATION AND ADMINISTRATIVE RULE MATTERS

**Approval of Pharmacies and Physicians to Dispense Federal Drug Administration (FDA)
Approved Cannabidiol**

MOTION: Philip Trapskin moved, seconded by Yvonne Bellay, to schedule by affirmative action drug products in finished dosage formulations that have been approved by the United States Food and Drug Administration that contain cannabidiol derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols as Schedule V controlled substances. The order shall take effect on October 15, 2018 to allow for publication in the Administrative Register. Motion carried unanimously.

(*Timothy Westlake joined via teleconference at 2:04 p.m.*)

MOTION: Alan Bloom moved, seconded by Timothy Westlake, to the Controlled Substances Board approves all Wisconsin licensed physicians and pharmacies to dispense Schedule V drug products in finished dosage formulations that have been approved by the United States Food and Drug Administration that contain cannabidiol derived from cannabis and no more than 0.1 percent residual tetrahydrocannabinols. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 2:06 p.m.

DRAFT

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Andrea Magermans and Sarah Bradley		2) Date When Request Submitted: 10/26/2018 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>																			
3) Name of Board, Committee, Council, Sections: Controlled Substances Board																					
4) Meeting Date: 11/9/18	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration																			
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session		8) Is an appearance before the Board being scheduled? <input checked="" type="checkbox"/> Yes, by PDMP Staff <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:																		
10) Describe the issue and action that should be addressed: <ol style="list-style-type: none"> 1. WI ePDMP Operations Update <ol style="list-style-type: none"> a. Recent and Upcoming Releases b. Status of Grants c. EHR Integration Status 2. WI ePDMP Events 3. Quarterly Report Update <ol style="list-style-type: none"> a. Q3 2018 Report Status Update 4. Referral update 																					
<table style="width: 100%; border: none;"> <tr> <td style="width: 40%;">11)</td> <td style="width: 20%; text-align: center;">Authorization</td> <td style="width: 40%;"></td> </tr> <tr> <td>Signature of person making this request</td> <td></td> <td style="text-align: right;">Date</td> </tr> <tr> <td colspan="3" style="border-top: 1px solid black; height: 20px;">Andrea Magermans 10/26/18</td> </tr> <tr> <td>Supervisor (if required)</td> <td></td> <td style="text-align: right;">Date</td> </tr> <tr> <td colspan="3" style="border-top: 1px solid black; height: 20px;"></td> </tr> <tr> <td colspan="3" style="border-top: 1px solid black; height: 20px;">Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date</td> </tr> </table>				11)	Authorization		Signature of person making this request		Date	Andrea Magermans 10/26/18			Supervisor (if required)		Date				Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date		
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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. 																					

2018 Release Summary

Wisconsin ePDMP

updated 10.31.2018

Release	Description
R8.0 January 2018	Healthcare Prescriber User <ul style="list-style-type: none"> • Addition of Prescriber Led Alert • Limit patient query results to 2 years of data • Prescriber Metrics Report comparison to others in specialty
R8.5 March 2018	Healthcare Prescriber User <ul style="list-style-type: none"> • Implement Password Expiration • Addition of audit log of Medical Coordinator view of Prescriber Metrics Pharmacy Submitter User <ul style="list-style-type: none"> • Improved messaging for fatal errors in ASAP processing Law Enforcement User <ul style="list-style-type: none"> • Addition of log of submitted alerts Public Statistics <ul style="list-style-type: none"> • Addition of raw data export
R9.0 June 2018	Healthcare Prescriber User <ul style="list-style-type: none"> • New Features for Prescriber Metrics Report <ul style="list-style-type: none"> ○ Map of distance travelled by patient ○ Graphic of payment type for dispensing ○ Drill down patient list for patient alert counts • Improved messaging for patient search results • Improved messaging for EHR related to interstate data Pharmacy Submitter User <ul style="list-style-type: none"> • Removal of zip code to city validation in ASAP file Public Statistics <ul style="list-style-type: none"> • Addition of MME per script graphic
R10.0 August 2018	Medical Coordinator User <ul style="list-style-type: none"> • Metrics detail added to prescriber grid • Improved functionality for managing DEA list Healthcare Prescriber User <ul style="list-style-type: none"> • Improved communication for pending MC request
R10.1 September 2018	Medical Coordinator Assistant User <ul style="list-style-type: none"> • New ePDMP role • Allows management of DEA list for Medical Coordinator by assistant Healthcare Prescriber User <ul style="list-style-type: none"> • Improved workflow for printing the Patient History Report

2018 – WI ePDMP Outreach Calendar

OCTOBER		NOVEMBER		DECEMBER	
1		1		1	
2		2		2	
3		3		3	
4	Greater Milwaukee Dental Association	4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10	Waukesha County Chapter of Medical Assistants	10	
11		11		11	
12		12	DSPS Secretary's Office PDMP Roundtable (Platteville)	12	
13		13		13	
14		14		14	WI Assoc. of Local Health Departments and Boards
15		15		15	
16	1. PDMP North Regional Meeting 2. DHS Tribal Consult	16		16	
17	PDMP North Regional Meeting	17		17	
18		18		18	
19		19		19	
20		20		20	
21		21		21	
22		22		22	
23	WI DOJ Opioid/Meth Forum	23		23	
24		24		24	
25		25		25	
26		26		26	
27		27		27	
28		28		28	
29		29		29	
30		30		30	
31				31	



Controlled Substances Board



WISCONSIN | **ePDMP**

Report 6

Quarter 3

July 1 – September 30, 2018

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
Trapskin, Philip	Pharmacy Board Representative
Virgil, Tina	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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Monitored Prescription Drug Dispensing Trend	7
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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 (PDMP). This report is intended to satisfy that requirement for the third quarter of 2018 and will primarily focus on analysis of PDMP data from Q3 2018 and the preceding 12 months.

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 the ability to obtain county-level detail.

User Satisfaction

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

During Q3 2018, DSPS staff have been reviewing the open-ended survey responses to identify priority areas for future WI ePDMP enhancements. Ideas proposed from WI ePDMP users via the survey and collected via general inquiries to DSPS will be developed into more formal proposals for consideration and additional feedback from WI ePDMP user focus groups. Priorities and details collected from the focus group will then determine the next round of user led enhancements for the WI ePDMP.

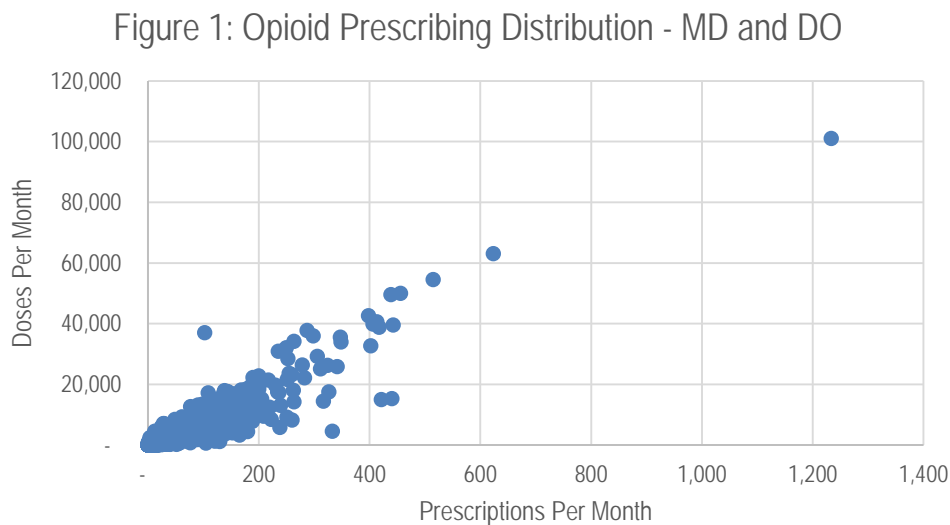
Impact on Referrals for Investigation

Pursuant to s. 961.385 (2) (f) and (3) (c), Wis. Stats., the CSB may refer to the appropriate licensing or regulatory board for discipline a pharmacist, pharmacy, or practitioner who fails to comply with the rules of the Prescription Drug Monitoring Program and may disclose PDMP data to relevant state boards and agencies if circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner, or patient. The CSB Referral Criteria Workgroup developed

recommendations for how the CSB could define suspicious or critically dangerous conduct or practices and presented their recommendations to the full Board.

Based on the recommendations, the Wisconsin Medical Examining Board (MEB), Dentistry Examining Board (DEB), and Board of Nursing (BON) all received summaries of the PDMP dispensing data specific to their professions at their August and September 2018 meetings. The data focused on opioid dispensing volume for the six-month time period of December 1, 2017 through May 31, 2018. The summaries took into consideration the specialty of the prescribers and provided information about the top controlled substances prescribed by the highest-volume prescribers, as well as information about the duration of the prescriptions.

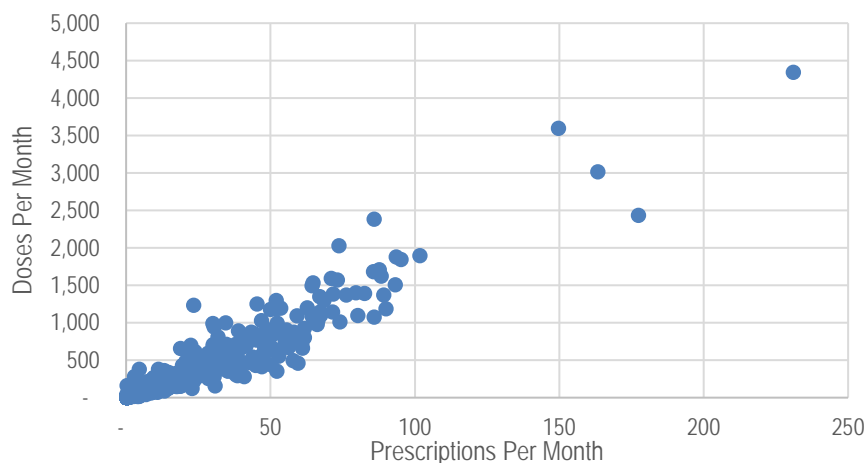
The data presented to the MEB resulted in the referral of the top seven physician prescribers based on opioid dispensing volume out of the approximately 15,000 opioid prescribers in the profession. Figure 1 below plots the distribution of physician prescribers, based on the average number of opioid prescriptions per month and the average number of opioid doses per month for the six-month period. The initial report presented to the MEB did not include physician assistant prescribers, so the MEB requested an updated report be presented at a future meeting including all physician and physician assistant prescribers.



The data presented to the DEB resulted in the referral of the top four dentistry prescribers based on opioid dispensing volume out of the approximately 3,000 opioid prescribers in the profession. Figure 2 below plots the distribution of dentistry prescribers, based on the average number of opioid prescriptions per month and the average number of opioid doses per month for the six-month period. Recognizing that opioid prescribing by dentists is unique and often falls within the exception to the requirement to review patient data in the PDMP for prescriptions lasting three days or less, the DEB also considered the WI ePDMP usage for prescribers who had prescriptions for an estimated duration of over three days. Among the highest 1% of opioid prescribers in the profession, those who had written

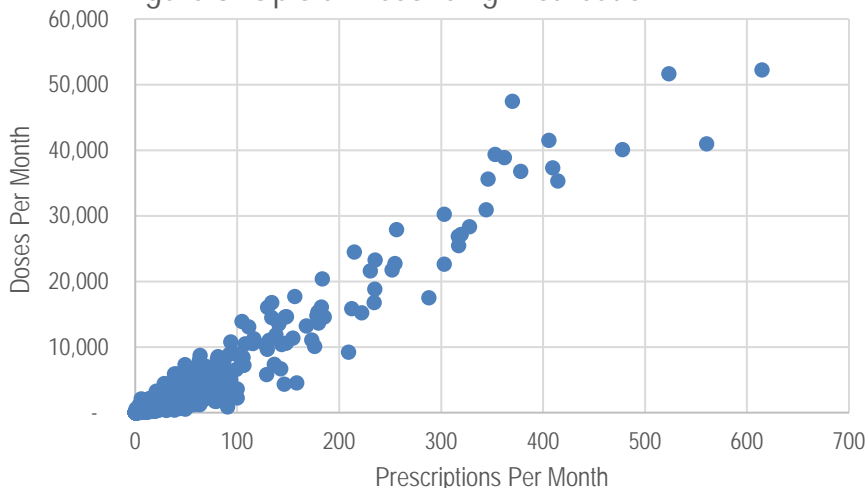
prescriptions for over three days but who had no indication of use of the WI ePDMP were also identified, which resulted in the referral of an additional 12 licensees.

Figure 2: Opioid Prescribing Distribution - DDS



The data presented to the BON resulted in the referral of the top four Advanced Practice Nurse Prescribers (APNP) based on opioid dispensing volume out of the approximately 3,700 APNPs who prescribed opioids during the six-month time period of the report. Figure 3 below plots the distribution of the prescribers, based on the average number of opioid prescriptions per month and the average number of opioid doses per month for the six-month period. The BON further requested additional targeted outreach for APNPs with an estimated WI ePDMP usage of less than 50% to educate these prescribers about the use of the PDMP and the tools available in the PDMP that can help promote safe prescribing practices.

Figure 3: Opioid Prescribing Distribution - APNP



The prescribers identified in all three professions were referred to the Division of Legal Services and Compliance at DSPS for further investigation.

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 opioids has decreased each quarter. A similar pattern can be seen with the dispensing of benzodiazepines, which have decreased each quarter starting in Q1 2017. Dispensing of stimulants has been variable by quarter between increased and decreased dispensing; however, Q3 2018 was the second consecutive quarter of decreased dispensing.

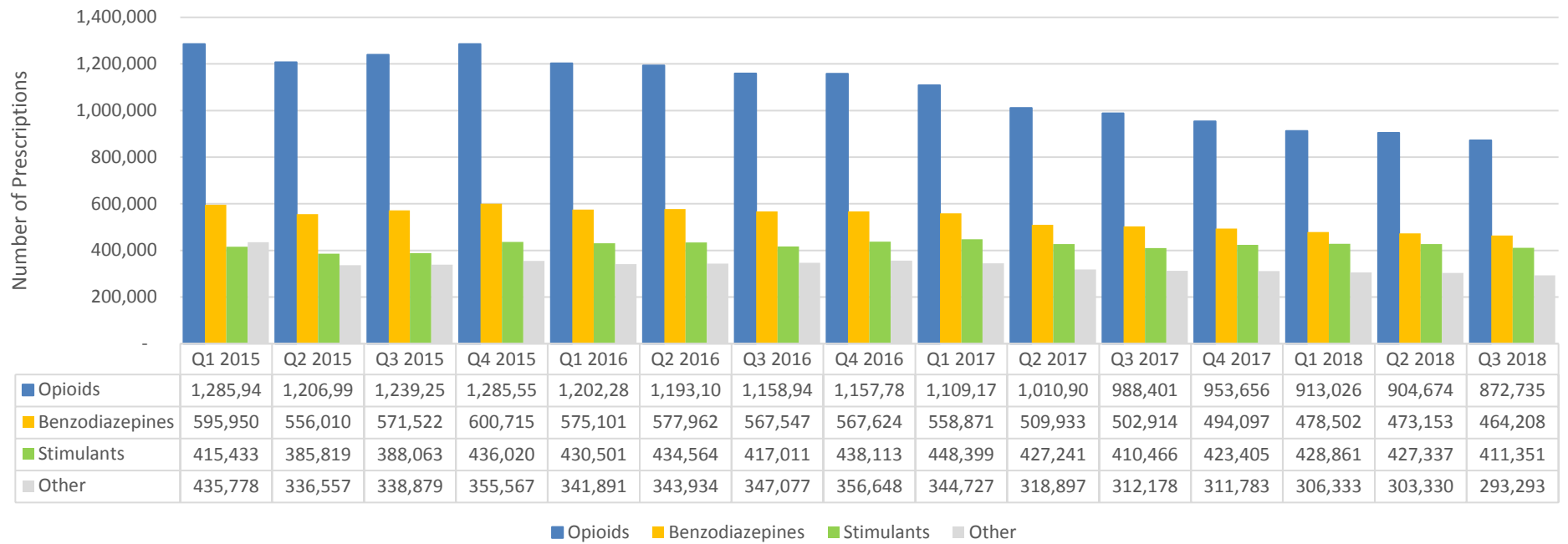
From Q2 2018 to Q3 2018 specifically, there was a 3% reduction in the number of monitored prescription drugs dispensed, a larger reduction than the previous quarter reduction of only 1%. This equates to an overall 6% reduction over the past 12 months and a 25% reduction when comparing the dispensing of monitored prescription drug dispensed in Q1 2015 to the dispensing in Q3 2018.

Opioid dispensing from Q2 2018 to Q3 2018 decreased 4%, a larger reduction than the previous quarter reduction of only 1%. This equates to a nearly 9% reduction over the past 12 months and a 32% reduction when comparing the number of opioid prescriptions dispensed in Q1 2015 to the dispensing in Q3 2018.

Benzodiazepine dispensing from Q2 2018 to Q3 2018 decreased 2%, compared to a 1% reduction in the previous quarter. This equates to an overall 6% reduction over the past 12 months and a 22% reduction when comparing the number benzodiazepine prescriptions dispensed in Q1 2015 to the dispensing in Q3 2018.

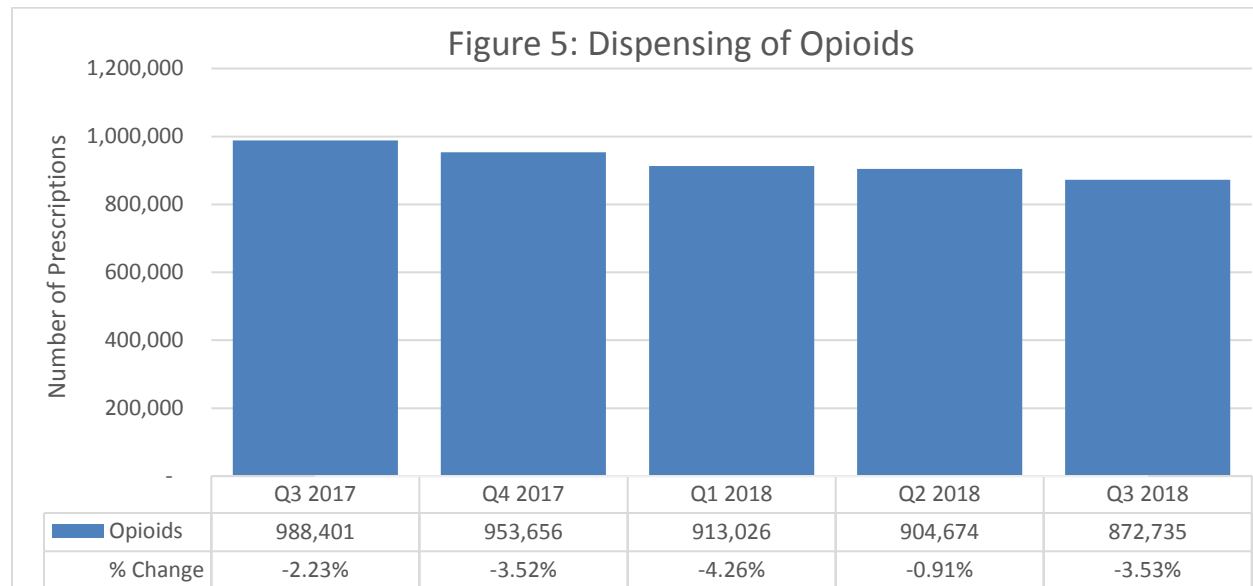
The 2015 – 2018 dispensing data per quarter by drug class can be seen in Figure 4, followed by detail for the last 12 months by drug class.

Figure 4: Dispensing of Monitored Prescriptions Drug by Quarter Q1 2015 - Q3 2018

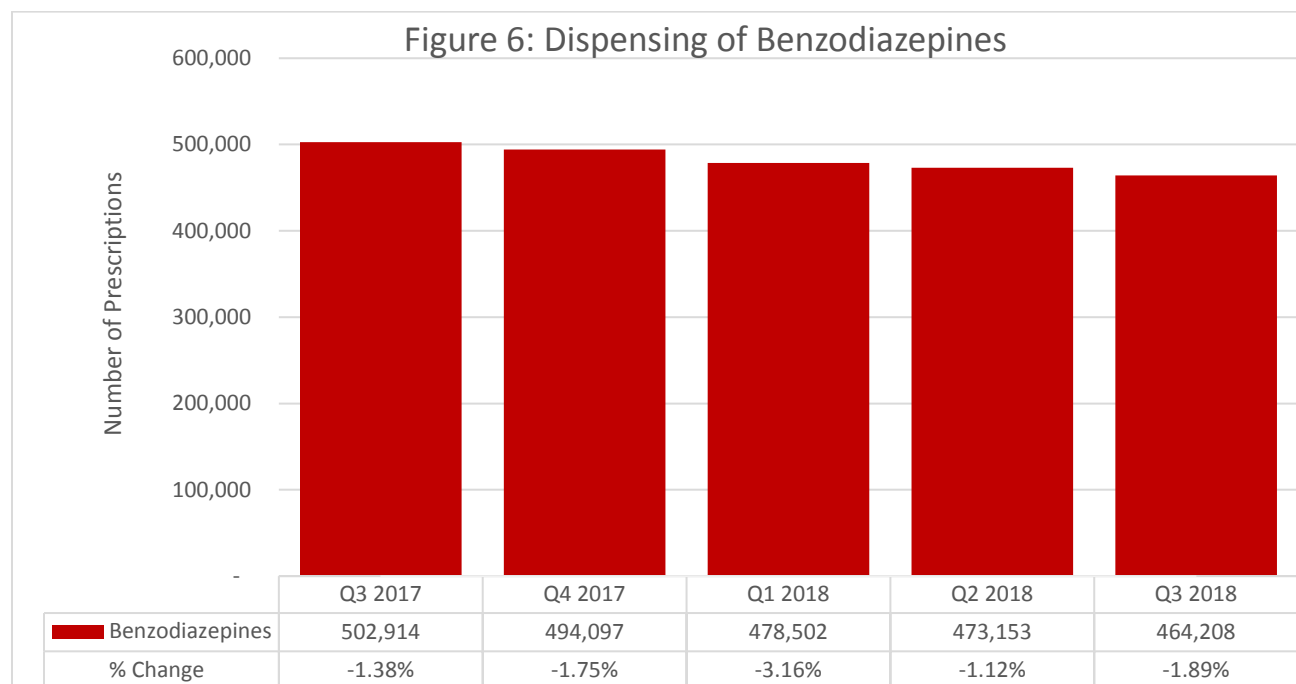


The following figures summarize dispensing by drug class for the past five quarters.

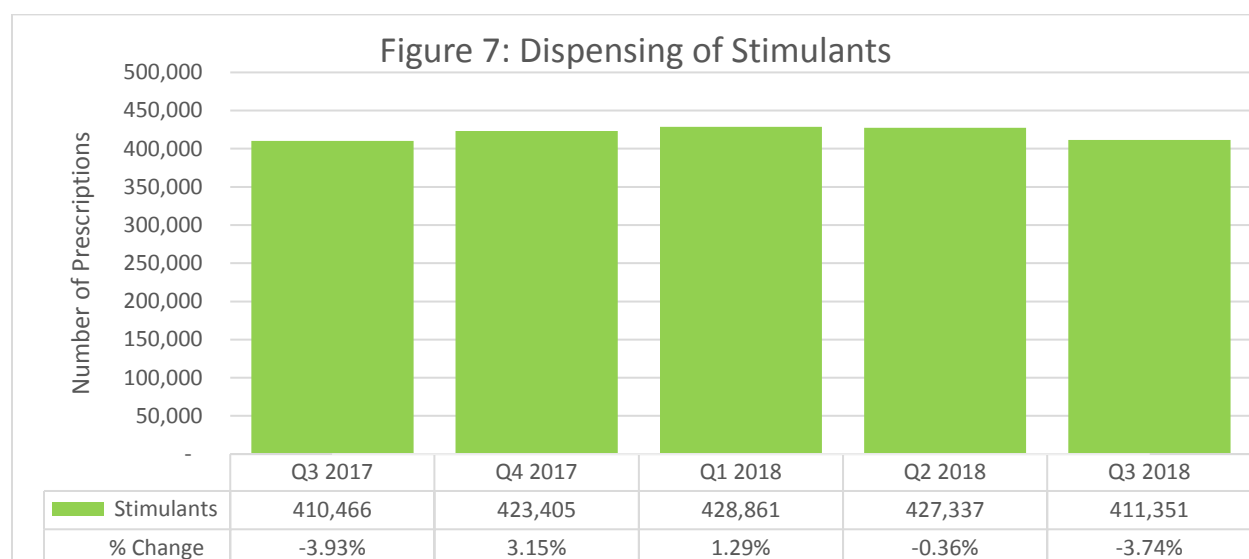
Opioids show a 4% reduction in the number of prescriptions dispensed from Q2 2018 to Q3 2018, for a total reduction of just under 9% over the past 12 months.



Benzodiazepines show a 2% reduction in the number of prescriptions dispensed from Q2 2018 to Q3 2018, for a total reduction of 6% over the past 12 months.



Dispensing of stimulants had been fluctuating between increased and decreased dispensing; however, Q3 2018 was the second consecutive quarter of decreased dispensing. There was a 4% reduction in the number of stimulant prescriptions dispensed from Q2 2018 to Q3 2018, for a total reduction of 3% over the past 12 months.



Top 15 Dispensed Monitored Prescription Drugs

Historically there has been no change to the drugs that fall under the 15 most dispensed monitored prescription drugs, but a notable change occurred in Q3 2018. Acetaminophen with Codeine was surpassed by Buprenorphine HCl-Naloxone HCl Dihydrate (Suboxone®) as the 15th most dispensed monitored prescription drug. Buprenorphine products are one of three FDA approved medications utilized to treat opioid use disorder as part of Medication-Assisted Treatment (MAT). However, it should be noted, federal regulation 42 CFR 8 prohibits federally funded opioid treatment programs from submitting dispensing data to state PDMPs. The dispensing data in the WI ePDMP only reflects Buprenorphine HCl-Naloxone HCl Dihydrate that is dispensed by a pharmacy and does not include dispensings that occur at an opioid treatment program.

For the third consecutive quarter, the top five monitored drugs dispensed no longer included Oxycodone HCl, resulting in only two opioids in the top five monitored prescription drugs. The top 15 monitored prescription drugs dispensed make up almost 88% of the dispensing records for any given quarter.

Table 1 below shows the top 15 most dispensed monitored prescription drugs in Q3 2018 compared to Q2 2018, ranked in order of the number of prescriptions dispensed in Q3 2018. Acetaminophen with Codeine has been included for comparison purposes.

Table 1: Top 15 Dispensed Monitored Prescription Drug by Dispensing					
	Drug Name	Drug Class	Q3 2018 Dispensing	Q2 2018 Dispensing	Percent Change
1	Hydrocodone-Acetaminophen	Opioid	291,990	302,404	-3.4%
2	Amphetamine- Dextroamphetamine	Stimulant	195,811	200,080	-2.1%
3	Tramadol HCl	Opioid	173,433	177,301	-2.2%
4	Lorazepam	Benzodiazepine	145,357	147,578	-1.5%
5	Alprazolam	Benzodiazepine	141,650	144,683	-2.1%
6	Oxycodone HCl	Opioid	136,760	142,469	-4.0%
7	Clonazepam	Benzodiazepine	120,946	123,401	-2.0%
8	Zolpidem Tartrate	Other	116,097	118,841	-2.3%
9	Oxycodone w/ Acetaminophen	Opioid	93,862	99,705	-5.9%
10	Methylphenidate HCl	Stimulant	90,497	96,624	-6.3%
11	Lisdexamfetamine Dimesylate	Stimulant	89,695	92,954	-3.5%
12	Pregabalin	Other	60,395	61,079	-1.1%
13	Diazepam	Benzodiazepine	49,514	50,704	-2.3%
14	Morphine Sulfate	Opioid	45,516	47,594	-4.4%
15	Buprenorphine HCl-Naloxone HCl Dihydrate	Opioid	39,374	37,886	+3.9%
15 (Q2)	Acetaminophen w/ Codeine	Opioid	36,571	38,297	-4.5%

Table 2 below shows the top 15 most dispensed monitored prescription drugs in Q3 2018 compared to Q2 2018, ranked in order of total quantity of pills or doses dispensed in Q3 2018, rather than number of prescription orders filled. Three of the top five monitored prescription drugs remain opioids. When measured by the number of doses rather than the number of prescriptions, Acetaminophen with Codeine remains in the top 15. Buprenorphine HCl-Naloxone HCl Dihydrate has been included in Table 2 for comparison purposes.

Table 2: Top 15 Dispensed Monitored Prescription Drug by Pill (Dose) Volume					
	Drug Name	Drug Class	Q3 2018 Pill (Dose)	Q2 2018 Pill (Dose)	Percent Change
1	Hydrocodone-Acetaminophen	Opioid	15,012,191	15,644,994	-4.0%
2	Tramadol HCl	Opioid	11,761,855	12,151,554	-3.2%
3	Oxycodone HCl	Opioid	9,916,310	10,626,154	-6.7%
4	Amphetamine- Dextroamphetamine	Stimulant	9,343,160	9,504,935	-1.7%
5	Alprazolam	Benzodiazepine	7,877,611	8,083,704	-2.5%
6	Clonazepam	Benzodiazepine	6,820,059	7,103,065	-4.0%
7	Lorazepam	Benzodiazepine	6,598,163	6,856,844	-3.8%
8	Oxycodone w/ Acetaminophen	Opioid	6,201,914	6,593,367	-5.9%
9	Pregabalin	Other	4,440,822	4,483,321	-0.9%
10	Methylphenidate HCl	Stimulant	4,183,438	4,419,971	-5.4%
11	Zolpidem Tartrate	Other	3,877,500	3,947,508	-1.8%
12	Lisdexamfetamine Dimesylate	Stimulant	2,807,524	2,900,347	-3.2%
13	Morphine Sulfate	Opioid	2,626,289	2,782,590	-5.6%
14	Diazepam	Benzodiazepine	1,956,016	2,038,674	-4.1%
15	Acetaminophen w/ Codeine	Opioid	1,547,412	1,609,476	-3.9%
16	<i>Buprenorphine HCl-Naloxone HCl Dihydrate</i>	<i>Opioid</i>	<i>1,281,850</i>	<i>1,255,298</i>	<i>+2.1%</i>

Data-Driven Alerts

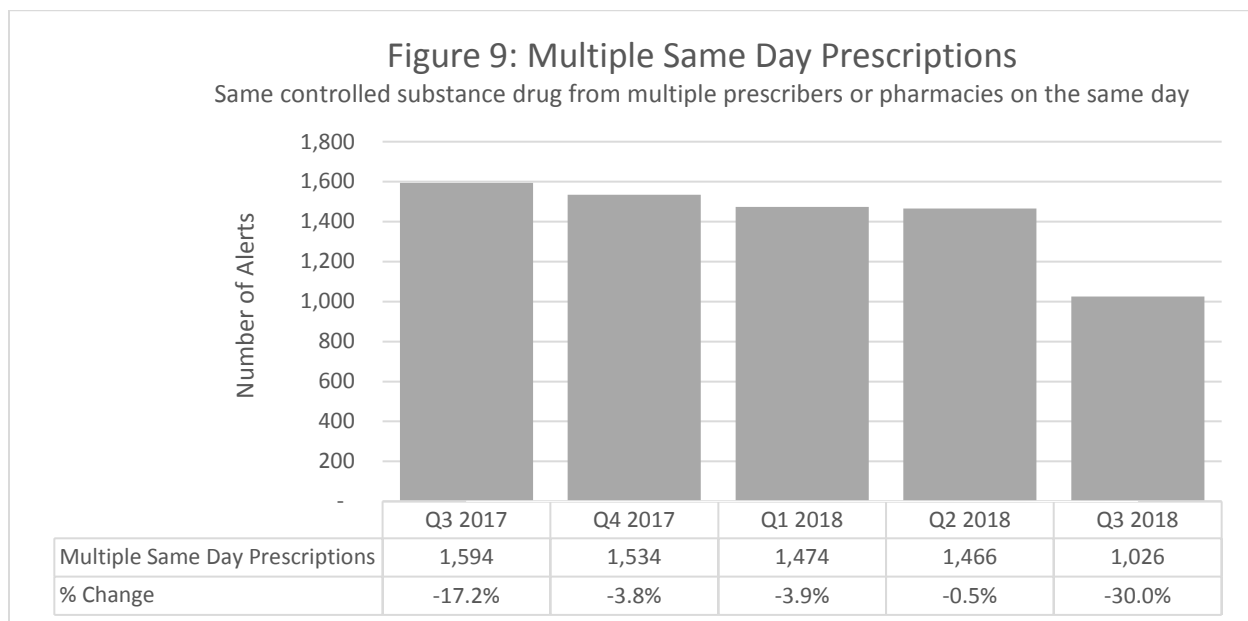
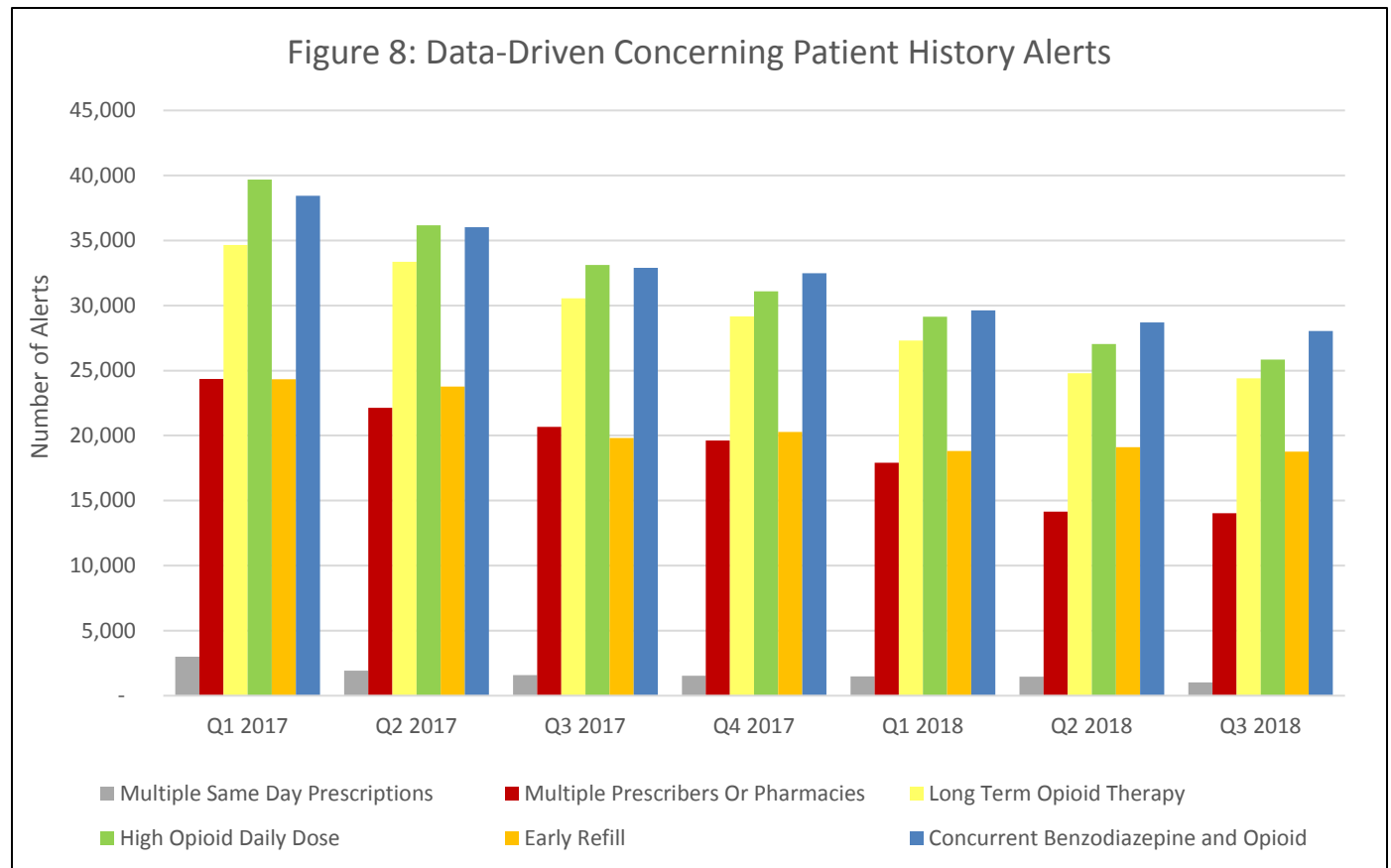
The WI ePDMP application uses sophisticated data analytics to assess a patient's monitored prescription drug history. Analytics are performed on the prescription history to identify and alert WI ePDMP users to potential indications of abuse, diversion, or overdose risk, such as high morphine milligram equivalent doses, overlapping benzodiazepine and opioid prescriptions, and multiple prescribers or dispensers.

The 6 types of concerning patient history alerts are:

1. **Multiple Prescribers or Pharmacies Alert**, which indicates that the patient has obtained prescriptions from at least 5 prescribers or 5 pharmacies within the previous 90 days. The 5 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, simply a flag for further inspection of the dispensing history.
2. **Long-Term Opioid Therapy with Multiple Prescribers Alert**, which indicates when a patient has been prescribed at least 1 opioid prescription from 2 or more prescribers for 90 or more days.
3. **Early Refill Alert**, which indicates when a patient has refilled a controlled substance prescription 2 or more days earlier than the expected refill date based on the estimated duration of the prescription calculated and reported by the pharmacy.
4. **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).
5. **Concurrent Benzodiazepine and Opioid Prescription Alert**, which indicates when a patient's active current prescriptions include both an opioid and a benzodiazepine.
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.

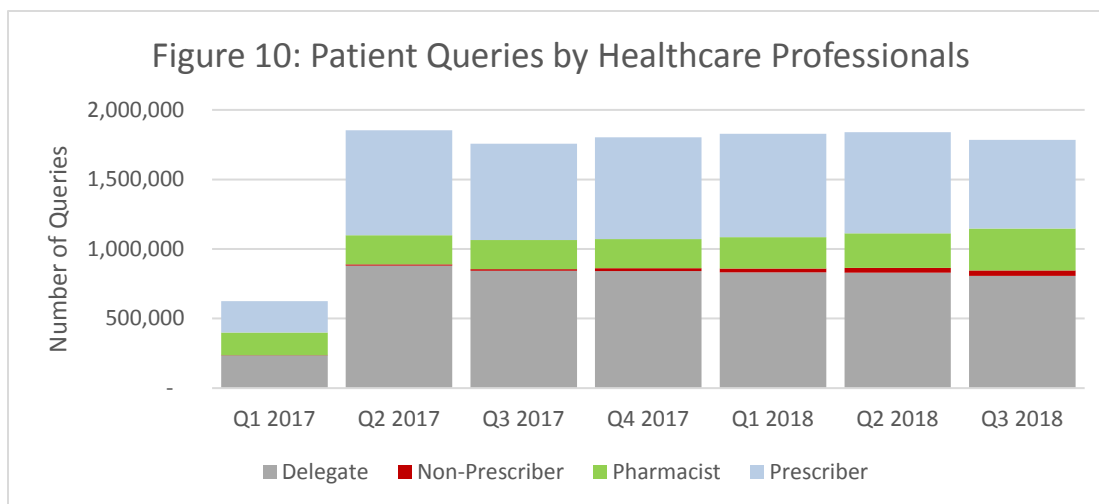
Overall, there was a nearly 17% reduction in the number of concerning patient history alerts over the last 12 months. All alert types declined between 1-5% from the previous quarter, apart from Multiple Same Day Prescriptions, which declined 30% from the previous quarter. The Multiple Same Day Prescription alerts account for the smallest portion of alerts for any given quarter.

Among higher volume alerts, High Opioid Daily Dose alerts decreased by 4%, Concurrent Benzodiazepine and Opioid alerts decreased by 2%, and Multiple Prescribers or Pharmacies, or “doctor shopping,” alerts decreased by just under 1%.

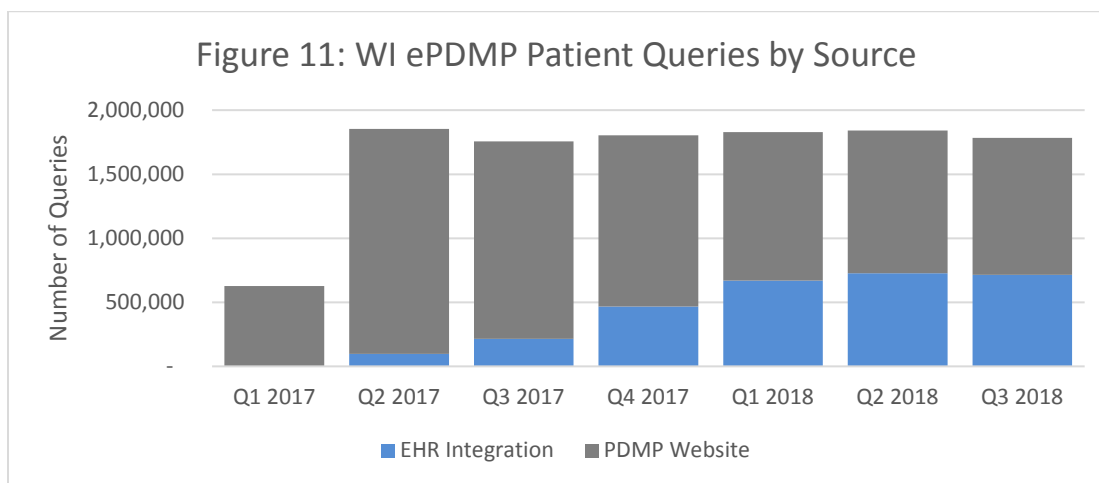


Disclosure of PDMP Data

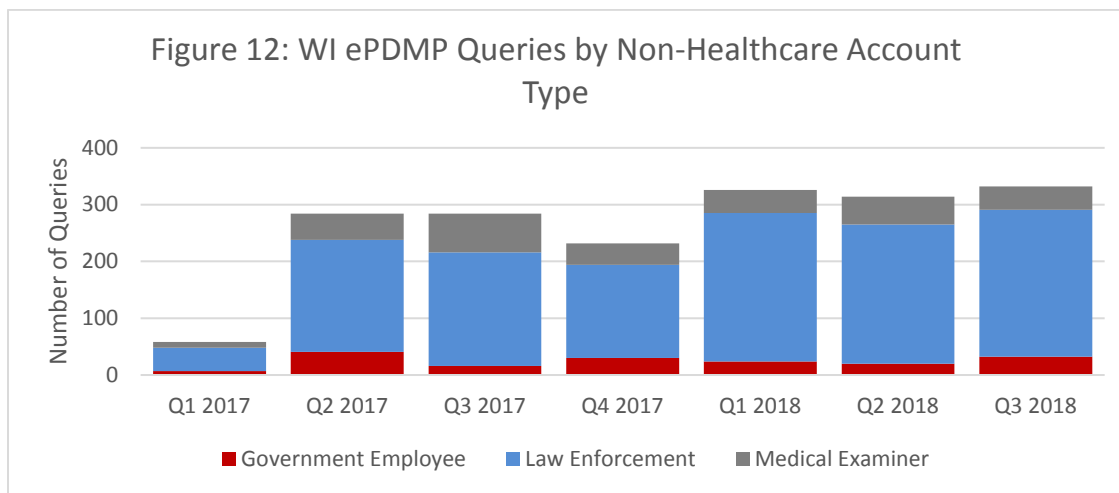
Between July 1 and September 30, 2018, healthcare users made a total of 1,783,813 patient queries. Breaking down the queries by user type shows that 45% of the queries were performed by delegates of prescribers or pharmacists, 36% were performed by prescribers, 17% by pharmacists, and 2% by other non-prescribing healthcare professionals.



As of September 30, 2018, healthcare professionals from fourteen health systems in Wisconsin have one-click access to the PDMP from within their EHR platform. In Q3 of 2018, 40% of patient queries were through the direct EHR integration, consistent with the previous quarter.



Authorized individuals from non-healthcare groups made 332 requests for PDMP data in Q3 of 2018, which was a slight increase from the 314 requests made in Q2 2018.

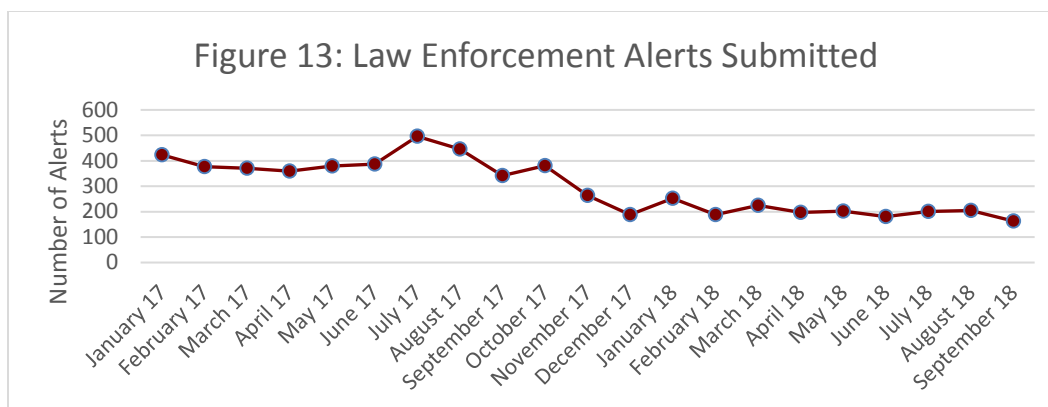


Law Enforcement Reports

Between July 1 and September 30, 2018, Wisconsin law enforcement agencies reported 568 events to the WI ePDMP 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.

There is no requirement for law enforcement agencies to submit their reports within a certain timeframe after the date of the event. Outreach for law enforcement agencies is ongoing as part of an effort to increase awareness of the requirement to submit to the PDMP and the value of the PDMP notifying the prescribers of the events for patients to whom they prescribe.



In 2018 the distribution of submission by report type remains consistent with the 2017 report type distribution:

- 38% of the reports submitted were reports of stolen controlled substance prescriptions
- 26% of the reports submitted were suspected violations of the Controlled Substances Act
- 31% of the reports submitted were suspected non-fatal opioid-related overdose events, and
- 4% of the reports submitted were suspected narcotic-related deaths.

Summary

The third quarter of 2018 shows a continuation of the encouraging decline in the number of monitored prescription drugs dispensed in Wisconsin and data-driven alerts generated by the WI ePDMP. The dispensing of opioids and benzodiazepines continues to decline each quarter, and stimulants have decreased in dispensing for two consecutive quarters.

Number of controlled substance prescriptions in Q3 2018 compared to Q1 2015:

- 25% decrease in the total number of monitored prescription drugs dispensed, which is over 690,000 fewer prescriptions
 - 32% decrease in the number of opioid prescriptions dispensed, which is over 413,000 fewer prescriptions
 - 22% decrease in the number of benzodiazepine prescriptions dispensed, which is over 131,700 fewer prescriptions
 - Considerable fluctuation stimulant prescriptions dispensed

Number of controlled substance prescriptions in past 12 months:

- Nearly 7% decrease in the total number of monitored prescription drugs dispensed, which is over 141,000 fewer prescriptions
 - Almost 9% decrease in the number of opioid prescriptions dispensed, which is over 80,900 fewer prescriptions
 - 6% decrease in the number of benzodiazepine prescriptions dispensed, which is over 29,800 fewer prescriptions
 - 3% decrease in the number of stimulants prescriptions dispensed, which is over 12,000 fewer prescriptions

Notable trends for Q3 2018:

- The top 15 monitored prescription drugs now includes a buprenorphine product. Dispensing of Buprenorphine HCl-Naloxone HCl Dihydrate (Suboxone®) increased by 4% over the previous quarter, surpassing Acetaminophen with Codeine in number of prescription order dispensed. Buprenorphine products are one of three medications commonly used as part of Medication-Assisted Treatment (MAT) for opioid use disorder.
- All six types of data-driven concerning patient history alerts continue to decline in frequency.

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.



WISCONSIN | ePDMP

Analysis of Monitored Prescription Drug Dispensings: MD/DO/PA

Prepared for:

Medical Examining Board October 2018 Meeting

The following report, prepared by the Wisconsin Department of Safety and Professional Services, is being provided as the result of the Controlled Substances Board Workgroup's effort to identify potentially suspicious or critically dangerous conduct or practices of a practitioner prescribing monitored prescription drugs. *An initial report provided to the Medical Examining Board in August of 2018 did not include PAs in the analysis. This amended report includes 2,581 PAs in the MD/DO analysis.*

Unless otherwise stated, the data in the report covers dispensing data submitted to the Wisconsin Prescription Drug Monitoring Program (PDMP) from December 1, 2017 – May 31, 2018.

Section 1: Prescribing of Opioids, MD/DO/PA

Profession: Physician - MD and DO, PA	
Total Number of Monitored Prescription Drugs Dispensed:	3,225,919
Total Number of Opioid Dispensings:	1,313,876
Total Number of Unique DEA Numbers Associated with Opioid Dispensings:	18,102

Figure 1: Opioid Prescribing Distribution - MD,DO and PA

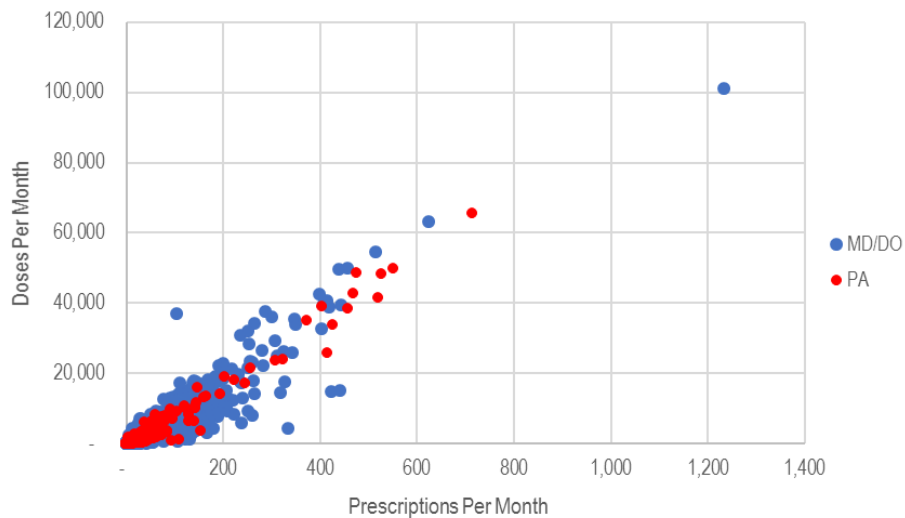
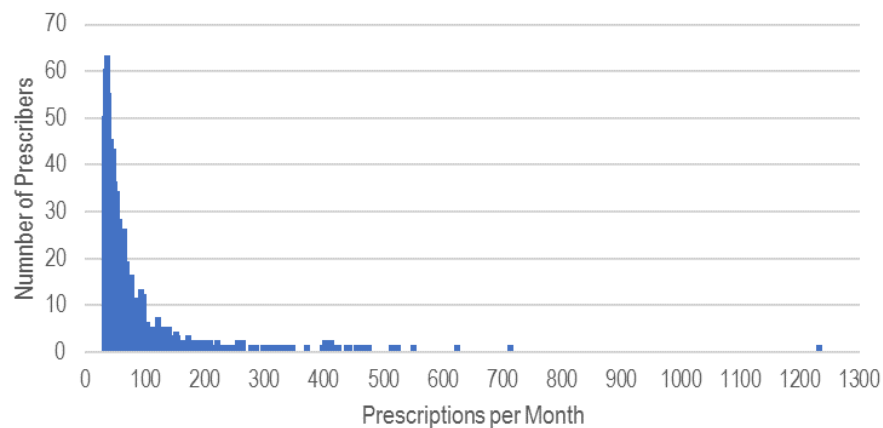


Figure 2: 90th Percentile Opioid Prescribing - MD,DO and PA*



*Top 10% of MD/DO/PA prescribers, based on average number of prescriptions filled/month. n = 1,809.
Average of ≥ 31.5 opioid prescription dispensings/month.

Section 2: Detail on Top Percentile (MD/DO—previously provided)

Top 23 MD/DO prescribers based on opioid prescriptions filled per month, December 1st, 2017 to May 31st, 2018, cutoff at average of approximately 300 opioid prescription dispensings/month. Highlighted rows indicate prescriber referrals from August 2018 meeting.

Table 1: Top Percentile MD/DO							
	Prescriber Detail		Monthly Average				
	Profession	Specialty	Opioid Orders	Percentile	Opioid Doses	Percentile	Avg Doses/ Opioid Script
1.	MD	Anesthesiology	1,233.7	100.00%	101,137.5	100.00%	82.0
2.	MD	Physical Medicine/Rehabilitation	623.3	99.99%	63,150.2	99.99%	101.3
3.	MD	Pain Management	514.8	99.98%	54,592.2	99.98%	106.0
4.	MD	Pain Management	456.2	99.98%	50,098.5	99.98%	109.8
5.	MD	Pain Management	442.5	99.97%	39,627.3	99.94%	89.6
6.	MD	Family Practice	440.3	99.96%	15,348.2	99.60%	34.9
7.	MD	Physical Medicine/Rehabilitation	438.7	99.96%	49,663.7	99.97%	113.2
8.	DO	Pain Management	421.5	99.95%	15,055.2	99.56%	35.7
9.	MD	Pain Management	417.0	99.94%	38,839.7	99.94%	93.1
10.	MD	Surgery- Neurological	413.3	99.94%	40,682.0	99.96%	98.4
11.	MD	Family Practice	406.5	99.93%	39,923.8	99.95%	98.2
12.	MD	Orthopedics	402.2	99.92%	32,736.0	99.89%	81.4
13.	MD	Physical Medicine/Rehabilitation	398.3	99.92%	42,638.3	99.96%	107.0
14.	MD	Pain Management	348.3	99.91%	33,982.0	99.90%	97.6
15.	MD	Orthopedics	347.3	99.90%	35,618.5	99.91%	102.5
16.	MD	Internal Medicine	341.7	99.90%	25,854.2	99.85%	75.7
17.	MD	Internal Medicine	333.2	99.89%	4,552.5	95.93%	13.7
18.	MD	Addiction Medicine	326.8	99.89%	17,575.0	99.67%	53.8
19.	MD	Pain Management	324.2	99.88%	26,292.2	99.85%	81.1
20.	MD	Oncology (including radiation oncology)	316.7	99.87%	14,533.5	99.53%	45.9
21.	MD	Rheumatology	311.7	99.87%	25,119.7	99.84%	80.6
22.	MD	Pain Management	305.5	99.86%	29,228.7	99.87%	95.7
23.	MD	Physical Medicine/Rehabilitation	298.5	99.85%	36,065.5	99.92%	120.8

Section 2: Detail on Top Percentile (including PA)

Top 36 MD/DO/PA prescribers based on opioid prescriptions filled per month, December 1st, 2017 to May 31st, 2018, cutoff at average of approximately 300 opioid prescription dispensings/month.

Highlighted rows indicate prescriber referrals from August 2018 meeting.

Table 1: Top Percentile MD/DO							
	Prescriber Detail		Monthly Average				
	Profession	Specialty	Opioid Orders	Percentile	Opioid Doses	Percentile	Avg Doses/ Opioid Script
1.	MD	Anesthesiology	1,233.7	100.00%	101,137.5	99.99%	82.0
2.	PA	Pain Management	714.3	99.99%	65,637.3	99.98%	91.9
3.	MD	Physical Medicine/Rehabilitation	623.3	99.98%	63,150.2	99.98%	101.3
4.	PA	Pain Management	551.3	99.98%	49,805.0	99.96%	90.3
5.	PA	Pain Management	525.3	99.97%	48,408.3	99.95%	92.1
6.	PA	Pain Management	519.3	99.97%	41,449.2	99.93%	79.8
7.	MD	Pain Management	514.8	99.96%	54,592.2	99.97%	106.0
8.	PA	Pain Management	475.0	99.96%	48,499.0	99.95%	102.1
9.	PA	Pain Management	468.8	99.95%	42,907.0	99.94%	91.5
10.	PA	Pain Management	458.0	99.95%	38,526.2	99.90%	84.1
11.	MD	Pain Management	456.2	99.94%	50,098.5	99.97%	109.8
12.	MD	Pain Management	442.5	99.93%	39,627.3	99.91%	89.6
13.	MD	Family Practice	440.3	99.93%	15,348.2	99.55%	34.9
14.	MD	Physical Medicine/Rehabilitation	438.7	99.92%	49,663.7	99.96%	113.2
15.	PA	Pain Management	425.3	99.92%	33,868.8	99.85%	79.6
16.	DO	Pain Management	421.5	99.91%	15,055.2	99.51%	35.7
17.	MD	Pain Management	417.0	99.91%	38,839.7	99.90%	93.1
18.	PA	Pain Management	413.7	99.90%	25,714.3	99.80%	62.2
19.	MD	Surgery- Neurological	413.3	99.90%	40,682.0	99.92%	98.4
20.	MD	Family Practice	406.5	99.89%	39,923.8	99.92%	98.2
21.	PA	Pain Management	402.5	99.88%	39,095.7	99.91%	97.1
22.	MD	Orthopedics	402.2	99.88%	32,736.0	99.85%	81.4
23.	MD	Physical Medicine/Rehabilitation	398.3	99.87%	42,638.3	99.93%	107.0
24.	PA	Pain Management	372.3	99.87%	35,174.8	99.87%	94.5
25.	MD	Pain Management	348.3	99.86%	33,982.0	99.86%	97.6
26.	MD	Orthopedics	347.3	99.86%	35,618.5	99.87%	102.5
27.	MD	Internal Medicine	341.7	99.85%	25,854.2	99.81%	75.7
28.	MD	Internal Medicine	333.2	99.85%	4,552.5	96.23%	13.7
29.	MD	Addiction Medicine	326.8	99.84%	17,575.0	99.62%	53.8
30.	MD	Pain Management	324.2	99.83%	26,292.2	99.81%	81.1
31.	PA	Pain Management	322.0	99.83%	24,108.5	99.79%	74.9
32.	MD	Oncology (including radiation oncology)	316.7	99.82%	14,533.5	99.49%	45.9
33.	MD	Rheumatology	311.7	99.82%	25,119.7	99.80%	80.6
34.	PA	Pain Management	306.5	99.81%	23,632.0	99.78%	77.1
35.	MD	Pain Management	305.5	99.81%	29,228.7	99.83%	95.7
36.	MD	Physical Medicine/Rehabilitation	298.5	99.80%	36,065.5	99.88%	120.8

Section 3: Pain Management Specialty Detail

MD/DO/PA opioid prescribers with Pain Management specialty, n = 132. State truncated mean for specialty = 120.1 prescriptions/month. State median for specialty = 45.8 prescriptions/month.

Figure 7: Opioid Prescribing Distribution - Pain Management

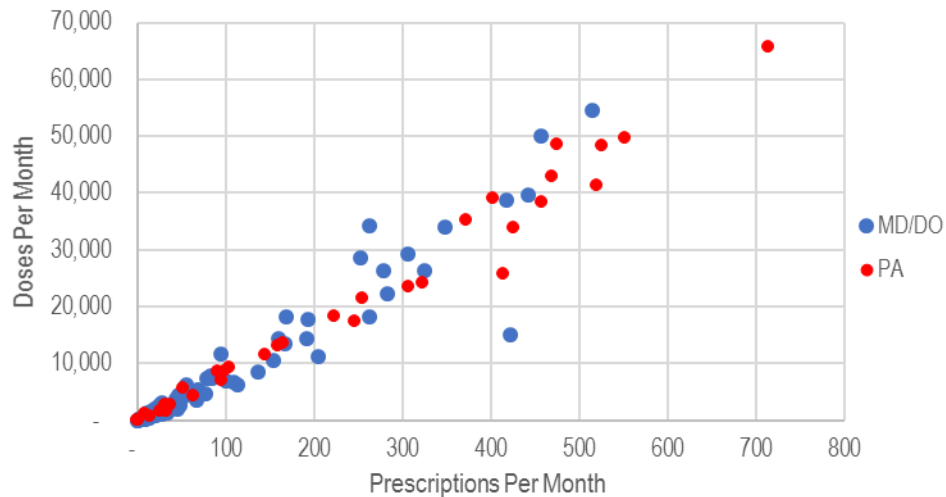
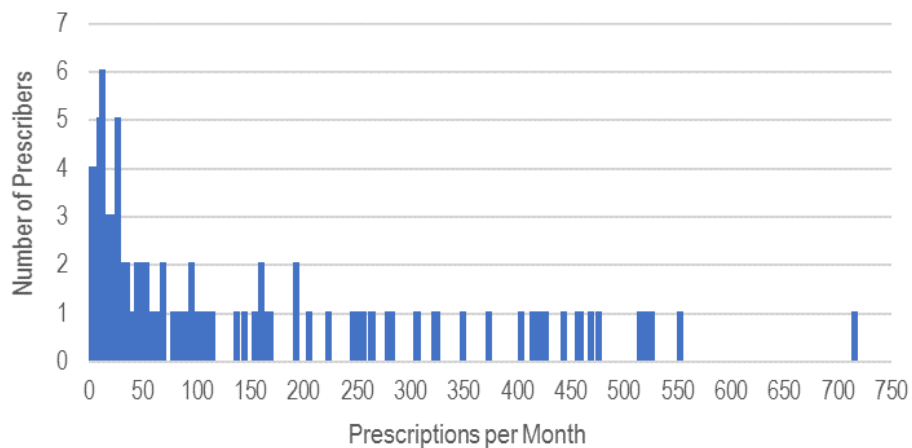


Figure 8: Overall Volume Opioid Prescribing - Pain Management



MD/DO/PA: Pain Management						
	Profession	Prescription/Month		Doses/Month		Doses/Prescription
State Median	MD/DO/PA	45.8		2,981.5		
State Mean Truncated	MD/DO/PA	120.1		10,017.2		
State-Level Dose/Prescription Ratio	MD/DO/PA					85.1
Prescriber Detail	Profession	Prescription/Month	Percentile	Doses/Month	Percentile	Doses/Prescription
1	PA	714.3	100.00%	65,637.3	100.00%	91.9
2	PA	551.3	99.23%	49,805.0	97.70%	90.3
3	PA	525.3	98.47%	48,408.3	96.18%	92.1
4	PA	519.3	97.70%	41,449.2	94.65%	79.8
5	MD	514.8	96.94%	54,592.2	99.23%	106.0
6	PA	475.0	96.18%	48,499.0	96.94%	102.1
7	PA	468.8	95.41%	42,907.0	95.41%	91.5
8	PA	458.0	94.65%	38,526.2	91.60%	84.1
9	MD	456.2	93.89%	50,098.5	98.47%	109.8
10	MD	442.5	93.12%	39,627.3	93.89%	89.6

NOTE: Including PAs in the analysis impacts the statewide comparison within specialty that was included in the August 2018 report. The table below summarizes the impact when PAs are included in the statewide analysis for Pain Management, and the tables on the following pages provide additional detail on the 7 PAs listed above.

Pain Management						
	MD/DO				MD/DO/PA	
	Prescription/ Month	Doses/ Month	Doses/ Prescription		Prescription/ Month	Doses/ Prescription
State Median	28.33	2,211.9			45.8	2,981.5
State Mean Truncated	80.06	6,666.73			120.1	10,017.2
State-Level Dose/Prescription Ratio			84.69			85.1

Prescriber 1						
Profession:	PA		Registered with the WI ePDMP:	Yes		
Specialty (self-reported):	Pain Management		Estimated ePDMP Usage:	62.3%		
Prescribing Summary: 12/1/2017 - 5/31/2018						
Dispensing Data	# of scripts	% of overall				
Opioids (includes buprenorphine)	4,526	90.16%	Number of Patients Prescribed Opioids by Prescriber:	1,617		
Stimulants	0	0%				
Benzodiazepines	45	0.90%				
Other	449	8.94%				
Opioid Dispensing	Prescriber	Peer %	State Median	State Mean (Truncated)	Doses/ Prescription	
Avg. Opioid Orders/Month	714.3	100%	45.8	120.1		
Avg. Opioid Doses/Month	65,637.3	100%	2,981.5	10,017.2		
Avg. Doses/Prescription	91.9				85.1	
	3 days or less	More than 3 days ≤ 10 days	More than 10 days ≤ 30 days	More than 30 days		
Days Supply Opioid Orders	3	23	4,493	7		
Top 5 Monitored Prescription Drugs Ordered by Prescriber (All Drug Classes)	Drug Name		Number of Dispensing	% of all Dispensing		
	Oxycodone HCl		2,830	56.37%		
	Morphine Sulfate		427	8.51%		
	Tramadol HCl		270	5.38%		
	Oxycodone w/ Acetaminophen		233	4.64%		
	Methadone HCl		212	4.22%		
Data Driven Alerts: As of 6/1/2018 (preceding 100 days)						
Alert Type				Number of Alerts		
Concerning Patient History	Concurrent Opioid/Benzo			207		
	High MME			866		

Prescriber 2						
Profession:	PA		Registered with the WI ePDMP:	Yes		
Specialty (self-reported):	Pain Management		Estimated ePDMP Usage:	100%		
Prescribing Summary: 12/1/2017 - 5/31/2018						
Dispensing Data	# of scripts	% of overall	Number of Patients Prescribed Opioids by Prescriber:	595		
Opioids (includes buprenorphine)	3,489	97.13%				
Stimulants	0	0%				
Benzodiazepines	0	0%				
Other	103	2.87%				
Opioid Dispensing	Prescriber	Peer %	State Median	State Mean (Truncated)	Doses/ Prescription	
Avg. Opioid Orders/Month	551.3	99.23%	45.8	120.1		
Avg. Opioid Doses/Month	49,805	97.70%	2,981.5	10,017.2		
Avg. Doses/Prescription	90.3				85.1	
	3 days or less	More than 3 days ≤ 10 days	More than 10 days ≤ 30 days	More than 30 days		
Days Supply Opioid Orders	4	137	3,345	3		
Top 5 Monitored Prescription Drugs Ordered by Prescriber (All Drug Classes)	Drug Name		Number of Dispensing	% of all Dispensing		
	Oxycodone HCl		2,248	62.58%		
	Morphine Sulfate		376	10.47%		
	Oxycodone w/ Acetaminophen		344	9.58%		
	Hydrocodone-Acetaminophen		189	5.26%		
	Methadone HCl		125	3.48%		
Data Driven Alerts: As of 6/1/2018 (preceding 100 days)						
Alert Type				Number of Alerts		
Concerning Patient History	Concurrent Opioid/Benzo			42		
	High MME			341		

Prescriber 3						
Profession:	PA		Registered with the WI ePDMP:	Yes		
Specialty (self-reported):	Pain Management		Estimated ePDMP Usage:	49.2%		
Prescribing Summary: 12/1/2017 - 5/31/2018						
Dispensing Data	# of scripts	% of overall				
Opioids (includes buprenorphine)	3,422	89.14%	Number of Patients Prescribed Opioids by Prescriber:	564		
Stimulants	45	1.17%				
Benzodiazepines	76	1.98%				
Other	296	7.71%				
Opioid Dispensing	Prescriber	Peer %	State Median	State Mean (Truncated)	Doses/ Prescription	
Avg. Opioid Orders/Month	525.3	98.47%	45.8	120.1		
Avg. Opioid Doses/Month	48,408.3	96.18%	2,981.5	10,017.2		
Avg. Doses/Prescription	92.1				85.1	
	3 days or less	More than 3 days ≤ 10 days	More than 10 days ≤ 30 days	More than 30 days		
Days Supply Opioid Orders	4	39	2,841	538		
Top 5 Monitored Prescription Drugs Ordered by Prescriber (All Drug Classes)	Drug Name		Number of Dispensing	% of all Dispensing		
	Oxycodone HCl		828	21.57%		
	Oxycodone w/ Acetaminophen		656	17.09%		
	Morphine Sulfate		543	14.14%		
	Hydrocodone-Acetaminophen		447	11.64%		
	Hydromorphone HCl		364	9.48%		
Data Driven Alerts: As of 6/1/2018 (preceding 100 days)						
Alert Type				Number of Alerts		
Concerning Patient History	Concurrent Opioid/Benzo			142		
	High MME			217		

Prescriber 4						
Profession:		PA		Registered with the WI ePDMP:	Yes	
Specialty (self-reported):		Pain Management		Estimated ePDMP Usage:	100%	
Prescribing Summary: 12/1/2017 - 5/31/2018						
Dispensing Data		# of scripts	% of overall	Number of Patients Prescribed Opioids by Prescriber:	683	
Opioids (includes buprenorphine)		3,364	90.72%			
Stimulants		8	0.22%			
Benzodiazepines		151	4.07%			
Other		185	4.99%			
Opioid Dispensing		Prescriber	Peer %	State Median	State Mean (Truncated)	Doses/ Prescription
Avg. Opioid Orders/Month		519.3	97.70%	45.8	120.1	
Avg. Opioid Doses/Month		41,449.2	94.65%	2,981.5	10,017.2	
Avg. Doses/Prescription		79.8				85.1
		3 days or less	More than 3 days ≤ 10 days	More than 10 days ≤ 30 days	More than 30 days	
Days Supply Opioid Orders		24	470	2,815	55	
Top 5 Monitored Prescription Drugs Ordered by Prescriber (All Drug Classes)		Drug Name		Number of Dispensing	% of all Dispensing	
		Hydrocodone-Acetaminophen		842	22.71%	
		Morphine Sulfate		740	19.96%	
		Oxycodone HCl		567	15.29%	
		Oxycodone w/ Acetaminophen		396	10.68%	
		Tramadol HCl		256	6.90%	
Data Driven Alerts: As of 6/1/2018 (preceding 100 days)						
Alert Type					Number of Alerts	
Concerning Patient History		Concurrent Opioid/Benzo			152	
		High MME			305	

Prescriber 6						
Profession:	PA		Registered with the WI ePDMP:	Yes		
Specialty (self-reported):	Pain Management		Estimated ePDMP Usage:	55.6%		
Prescribing Summary: 12/1/2017 - 5/31/2018						
Dispensing Data	# of scripts	% of overall				
Opioids (includes buprenorphine)	3,089	92.71%	Number of Patients Prescribed Opioids by Prescriber:	1,194		
Stimulants	1	0.03%				
Benzodiazepines	30	0.90%				
Other	212	6.36%				
Opioid Dispensing	Prescriber	Peer %	State Median	State Mean (Truncated)	Doses/ Prescription	
Avg. Opioid Orders/Month	475.0	96.18%	45.8	120.1		
Avg. Opioid Doses/Month	48,499.0	96.94%	2,981.5	10,017.2		
Avg. Doses/Prescription	102.1				85.1	
	3 days or less	More than 3 days ≤ 10 days	More than 10 days ≤ 30 days	More than 30 days		
Days Supply Opioid Orders	26	153	2,870	40		
Top 5 Monitored Prescription Drugs Ordered by Prescriber (All Drug Classes)	Drug Name		Number of Dispensing	% of all Dispensing		
	Oxycodone w/ Acetaminophen		923	27.70%		
	Hydrocodone-Acetaminophen		707	21.22%		
	Oxycodone HCl		484	14.53%		
	Morphine Sulfate		311	9.33%		
	Tramadol HCl		204	6.12%		
Data Driven Alerts: As of 6/1/2018 (preceding 100 days)						
Alert Type				Number of Alerts		
Concerning Patient History	Concurrent Opioid/Benzo			190		
	High MME			242		

Prescriber 7						
Profession:	PA		Registered with the WI ePDMP:	Yes		
Specialty (self-reported):	Pain Management		Estimated ePDMP Usage:	27.4%		
Prescribing Summary: 12/1/2017 - 5/31/2018						
Dispensing Data	# of scripts	% of overall				
Opioids (includes buprenorphine)	3,041	92.77%	Number of Patients Prescribed Opioids by Prescriber:	1,248		
Stimulants	0	0%				
Benzodiazepines	4	0.12%				
Other	233	7.11%				
Opioid Dispensing	Prescriber	Peer %	State Median	State Mean (Truncated)	Doses/ Prescription	
Avg. Opioid Orders/Month	468.8	95.41%	45.8	120.1		
Avg. Opioid Doses/Month	42,907.0	95.41%	2,981.5	10,017.2		
Avg. Doses/Prescription	91.5				85.1	
	3 days or less	More than 3 days ≤ 10 days	More than 10 days ≤ 30 days	More than 30 days		
Days Supply Opioid Orders	0	3	3,030	8		
Top 5 Monitored Prescription Drugs Ordered by Prescriber (All Drug Classes)	Drug Name		Number of Dispensing	% of all Dispensing		
	Oxycodone HCl		1,965	59.95%		
	Morphine Sulfate		297	9.06%		
	Oxycodone w/ Acetaminophen		176	5.37%		
	Methadone HCl		160	4.88%		
	Tramadol HCl		139	4.24%		
Data Driven Alerts: As of 6/1/2018 (preceding 100 days)						
Alert Type				Number of Alerts		
Concerning Patient History	Concurrent Opioid/Benzo			158		
	High MME			686		

Prescriber 8						
Profession:	PA		Registered with the WI ePDMP:	Yes		
Specialty (self-reported):	Pain Management		Estimated ePDMP Usage:	73.8%		
Prescribing Summary: 12/1/2017 - 5/31/2018						
Dispensing Data	# of scripts	% of overall				
Opioids (includes buprenorphine)	2,960	93.20%	Number of Patients Prescribed Opioids by Prescriber:	493		
Stimulants	12	0.38%				
Benzodiazepines	12	0.38%				
Other	192	6.05%				
Opioid Dispensing	Prescriber	Peer %	State Median	State Mean (Truncated)	Doses/ Prescription	
Avg. Opioid Orders/Month	458.0	94.65%	45.8	120.1		
Avg. Opioid Doses/Month	38,526.2	91.60%	2,981.5	10,017.2		
Avg. Doses/Prescription	84.1				85.1	
	3 days or less	More than 3 days ≤ 10 days	More than 10 days ≤ 30 days	More than 30 days		
Days Supply Opioid Orders	2	95	2,824	39		
Top 5 Monitored Prescription Drugs Ordered by Prescriber (All Drug Classes)	Drug Name		Number of Dispensing	% of all Dispensing		
	Oxycodone HCl		665	20.94%		
	Hydrocodone-Acetaminophen		584	18.39%		
	Oxycodone w/ Acetaminophen		531	16.72%		
	Morphine Sulfate		398	12.53%		
	Tramadol HCl		192	6.05%		
Data Driven Alerts: As of 6/1/2018 (preceding 100 days)						
Alert Type				Number of Alerts		
Concerning Patient History	Concurrent Opioid/Benzo			126		
	High MME			182		

**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: 26 October 2018 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>										
3) Name of Board, Committee, Council, Sections: Controlled Substances Board												
4) Meeting Date: 9 November 2018	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislative and Administrative Rule Matters <ol style="list-style-type: none"> 1. CSB 2.61 Relating to Scheduling MT-45 – Review Clearinghouse Comments 2. CSB 2.62 Relating to Scheduling Para-chloroisobutyl fentanyl – Review Clearinghouse Comments 3. CSB 2.64 Scope Relating to Scheduling N-Ethylpentylone 4. CSB 2.65 Scope Relating to Scheduling FDA Approved Cannabidiol Drugs 5. Updates on Legislation and Pending or Possible Rulemaking Projects 										
7) Place Item in: <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:										
10) Describe the issue and action that should be addressed:												
<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;"> 11) Authorization <div style="border-bottom: 1px solid black; margin-top: 10px;"> Sharon Henes </div> </td> <td style="width: 40%; border: none; text-align: right;"> <div style="border-bottom: 1px solid black; margin-top: 10px;"> 10/26/18 </div> </td> </tr> <tr> <td style="border: none;"> <small>Signature of person making this request</small> </td> <td style="border: none; text-align: right;"> <small>Date</small> </td> </tr> <tr> <td style="border: none;"> <div style="border-bottom: 1px solid black; margin-top: 10px;"> <small>Supervisor (if required)</small> </div> </td> <td style="border: none; text-align: right;"> <div style="border-bottom: 1px solid black; margin-top: 10px;"> <small>Date</small> </div> </td> </tr> <tr> <td colspan="2" style="border: none;"> <div style="border-bottom: 1px solid black; margin-top: 10px;"> <small>Executive Director signature (indicates approval to add post agenda deadline item to agenda)</small> </div> </td> <td style="border: none; text-align: right;"> <div style="border-bottom: 1px solid black; margin-top: 10px;"> <small>Date</small> </div> </td> </tr> </table>				11) Authorization <div style="border-bottom: 1px solid black; margin-top: 10px;"> Sharon Henes </div>	<div style="border-bottom: 1px solid black; margin-top: 10px;"> 10/26/18 </div>	<small>Signature of person making this request</small>	<small>Date</small>	<div style="border-bottom: 1px solid black; margin-top: 10px;"> <small>Supervisor (if required)</small> </div>	<div style="border-bottom: 1px solid black; margin-top: 10px;"> <small>Date</small> </div>	<div style="border-bottom: 1px solid black; margin-top: 10px;"> <small>Executive Director signature (indicates approval to add post agenda deadline item to agenda)</small> </div>		<div style="border-bottom: 1px solid black; margin-top: 10px;"> <small>Date</small> </div>
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Directions for including supporting documents: <ol style="list-style-type: none"> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting. 												

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.61 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 Nathaniel.Ristow@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.

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by October 30, 2018 to be included in the record of rule-making proceedings.

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)

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	2. Date 10 October 2018
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 2.61.	
4. Subject Scheduling MT-45	
5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	6. Chapter 20, Stats. Appropriations Affected
7. Fiscal Effect of Implementing the Rule <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget	
8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0.00	
10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Policy Problem Addressed by the Rule The United States Department of Justice, Drug Enforcement Administration scheduled MT-45 as a schedule I controlled substance effective December 13, 2017. The Wisconsin Controlled Substances Board took affirmative action on January 22, 2018 to similarly treat MT-45 as a schedule I controlled substance effective January 22, 2018. The Board is currently promulgating a final rule.	
12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments. This rule was posted for economic comments and none were received.	
13. Identify the Local Governmental Units that Participated in the Development of this EIA. None	
14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred) This rule will not have an economic or fiscal impact.	
15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion. In addition, it is in the best interest of Wisconsin citizens to schedule MT-45 as a controlled substance.	
16. Long Range Implications of Implementing the Rule MT-45 will be treated as a schedule I controlled substance.	
17. Compare With Approaches Being Used by Federal Government The federal government has scheduled MT-45 as a schedule I controlled substance.	
18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota) Our neighboring states have not scheduled MT-45 as a controlled substance.	

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

19. Contact Name

Sharon Henes

20. Contact Phone Number

(608) 261-2377

This document can be made available in alternate formats to individuals with disabilities upon request.

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- ☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes ☐ No



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Margit S. Kelley
Clearinghouse Assistant Director

Jessica Karls-Ruplinger
Legislative Council Acting Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **18-069**

AN ORDER to create CSB 2.61, relating to scheduling of MT-45.

Submitted by **CONTROLLED SUBSTANCES BOARD**

10-10-2018 RECEIVED BY LEGISLATIVE COUNCIL.

11-02-2018 REPORT SENT TO AGENCY.

SG:JN

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES ☐ NO ☒

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES ☐ NO ☒

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES ☐ NO ☒

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]

Comment Attached YES ☐ NO ☒

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES ☐ NO ☒

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES ☐ NO ☒

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached YES ☐ NO ☒

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.62 relating to scheduling of par-chloroisobutyl 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 Nathaniel.Ristow@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

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

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by October 30, 2018 to be included in the record of rule-making proceedings.

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)

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	2. Date 10 October 2018
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 2.62.	
4. Subject Scheduling para-chloroisobutyryl fentanyl	
5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	6. Chapter 20, Stats. Appropriations Affected
7. Fiscal Effect of Implementing the Rule <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget	
8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0.00	
10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Policy Problem Addressed by the Rule The United States Department of Justice, Drug Enforcement Administration scheduled para-chloroisobutyryl fentanyl as a schedule I controlled substance effective February 1 2018. The Wisconsin Controlled Substances Board took affirmative action on March 5, 2018 to similarly treat para-chloroisobutyryl fentanyl as a schedule I controlled substance effective March 12, 2018. The Board is currently promulgating a final rule.	
12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments. This rule was posted for economic comments and none were received.	
13. Identify the Local Governmental Units that Participated in the Development of this EIA. None	
14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred) This rule will not have an economic or fiscal impact.	
15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion. In addition, it is in the best interest of Wisconsin citizens to schedule para-chloroisobutyryl fentanyl as a controlled substance.	
16. Long Range Implications of Implementing the Rule Para-chloroisobutyryl fentanyl will be treated as a schedule I controlled substance.	
17. Compare With Approaches Being Used by Federal Government The federal government has scheduled para-chloroisobutyryl fentanyl as a schedule I controlled substance.	
18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)	

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Iowa has scheduled para-chloroisobutyryl fentanyl as a schedule I controlled substance. The other neighboring states have not scheduled para-chloroisobutyryl fentanyl.

19. Contact Name Sharon Henes	20. Contact Phone Number (608) 261-2377
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This document can be made available in alternate formats to individuals with disabilities upon request.

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- ☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes ☐ No



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Margit S. Kelley
Clearinghouse Assistant Director

Jessica Karls-Ruplinger
Legislative Council Acting Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **18-070**

AN ORDER to create CSB 2.62, relating to scheduling para-chloroisobutyl fentanyl.

Submitted by **CONTROLLED SUBSTANCES BOARD**

10-10-2018 RECEIVED BY LEGISLATIVE COUNCIL.

11-02-2018 REPORT SENT TO AGENCY.

MSK:JN

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES ☐ NO ☒

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES ☐ NO ☒

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES ☐ NO ☒

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]

Comment Attached YES ☐ NO ☒

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES ☐ NO ☒

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES ☐ NO ☒

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached YES ☐ NO ☒

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.64

Relating to: Scheduling of N-Ethylpentylone

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 N-Ethylpentylone as a Schedule I controlled substance. The Controlled Substances Board determines the scheduling of N-Ethylpentylone as a 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 August 31, 2018, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing N-Ethylpentylone into Schedule I of the federal Controlled Substances Act. The scheduling action was effective August 31, 2018. The Controlled Substances Board did not receive an objection to similarly treat N-Ethylpentylone as a Schedule I controlled substance under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the final order designating N-Ethylpentylone as a controlled substance.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat N-Ethylpentylone under ch. 961, Stats. by creating the following:

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

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

The Affirmative Action order, dated October 3, 2018, took effect on October 8, 2018 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

Rev. 3/6/2012

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 August 31, 2018, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing N-Ethylpentylone into Schedule I of the federal Controlled Substances Act. The scheduling action was effective on August 31, 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

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.65

Relating to: Scheduling of FDA approved cannabidiol drugs

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 US Food and Drug Administration approved cannabidiol as Schedule V controlled substance. The Controlled Substances Board determines the scheduling of US Food and Drug Administration approved cannabidiol as Schedule V controlled substances 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 September 28, 2018, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing US Food and Drug Administration approved cannabidiol into Schedule V of the federal Controlled Substances Act. The scheduling action was effective September 28, 2018.

Pursuant to s. 961.11 (4g), Stats., the Controlled Substances Board took affirmative action to similarly treat US Food and Drug Administration approved cannabidiol under ch. 961, Stats. by creating the following:

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

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

The Affirmative Action order, dated October 9, 2018, took effect on October 15, 2018 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(4g) Notwithstanding sub. (4), if cannabidiol is rescheduled or deleted as a controlled substance under federal law, the controlled substances board shall similarly treat cannabidiol under this chapter as soon as practically possible but no later than 30 days from the date of publication in the federal register of a final order rescheduling or deleting cannabidiol or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h). 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 rule making is omitted, rescheduling or deleting cannabidiol.

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 September 28, 2018, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing US Food and Drug Administration approved cannabidiol into Schedule V of the federal Controlled Substances Act. The scheduling action was effective on September 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