



CONTROLLED SUBSTANCES BOARD

Contact: Chad Zadrazil (608) 266-2112
Room 121A, 1400 East Washington Avenue, Madison
July 13, 2016

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

AGENDA

9:30 A.M.

OPEN SESSION - CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1-3)**
- B. Approval of Minutes**
 - 1) **March 15, 2016 (4-7)**
 - 2) **April 20, 2016 (8)**
 - 3) **June 9, 2016 (9)**
- C. Administrative Matters**
 - 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. Franklin LaDien – Pharmacy Examining Board Designee
 - e. Gunnar Larson – Psychiatrist
 - f. Jeffrey Miller – Board of Nursing Designee
 - g. Jason Smith – Attorney General Designee
 - h. Wendy Pietz – Dentistry Examining Board Designee
 - i. Timothy Westlake – Medical Examining Board Designee
 - 3) Liaison Appointments
 - a. Prescription Drug Monitoring Program (PDMP) Liaison **(10-11)**
- D. Letter from GW Pharmaceuticals – Discussion and Consideration (12-14)**
- E. Waupaca County District Attorney’s Request Regarding Furanyl – Discussion and Consideration (15-35)**
- F. Update on the Wisconsin State Coalition for Prescription Drug Abuse Reduction – Discussion and Consideration (36)**

- G. **Controlled Substance Prescribing Guidelines (2015 Act 269) – Discussion and Consideration (37-47)**
- H. **DEA Registration Requirement Guidance Request – Discussion and Consideration (48-50)**
- I. **Prescription Drug Monitoring Program Operations – Discussion and Consideration (51-54)**
 - 1) Operations Statistics
 - 2) Pharmacy Compliance/Renewal
 - 3) Act 268 Update
- J. **PMPi Release – Discussion and Consideration (55-57)**
- K. **ePDMP Development Update – Discussion and Consideration (58)**
 - 1) ASAP Format Identification
 - 2) Promotion
 - 3) Survey of Users
 - 4) Demonstration
- L. **Annual and Quarterly Reports – Discussion and Consideration (59-61)**
 - 1) Annual Board Report: Wis. Stat. 961.36
 - 2) Quarterly PDMP Report: Wis. Stat. 961.385 (5) and (6)
- M. **Report Access – Discussion and Consideration (62)**
 - 1) Wisconsin Crime Lab Reports
 - 2) DEA Reports of Theft, Loss, and Diversion
- N. **Legislation and Rule Matters – Discussion and Consideration (63-87)**
 - 1) Adopt Clearinghouse Rule 15-068 Relating to the Exclusion of Naloxegol from Scheduling
 - 2) Adopt Clearinghouse Rule 15-083 Relating to Special Use Authorization Measurements
 - 3) Scope for CSB 2.40 Relating to Exclusion of [¹²³I]ioflupane
 - 4) Affirmative Action Order Relating to Butyryl Fentanyl and Beta-Hydroxythiofentanyl
 - 5) Proposals for Amending CSB 4 Relating to Prescription Drug Monitoring Program (Acts 266, 267 and 268)
 - 6) Update on Legislation and Possible or Pending Rule-Making Projects
- O. **Speaking Engagement(s), Travel, or Public Relations Request(s) – Discussion and Consideration (88)**
- P. Informational Items
- Q. Discussion and Consideration of Items Received After Preparation of the Agenda:
 - 1) Introductions, Announcements, and Recognition
 - 2) Presentations of Petition(s) for Summary Suspension
 - 3) Presentation of Proposed Stipulation(s), Final Decision(s) and Order(s)
 - 4) Presentation of Final Decision and Order(s)
 - 5) Informational Item(s)

- 6) DLSC Matters
- 7) Status of Statute and Administrative Rule Matters
- 8) Education and Examination Matters
- 9) Credentialing Matters
- 10) Practice Questions
- 11) Legislation / Administrative Rule Matters
- 12) Liaison Report(s)
- 13) Speaking Engagement(s), Travel, or Public Relations Request(s)
- 14) Consulting with Legal Counsel

R. 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.).

S. **Deliberation on Issuance of Order Suspending Access to the Prescription Drug Monitoring Program (89-97)**

- 1) 16 CSB 002
- 2) 16 CSB 003

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

T. Voting on Items Considered or Deliberated on in Closed Session, If Voting is Appropriate

ADJOURNMENT

The next scheduled meeting is September 20, 2016.

**CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
MARCH 15, 2016**

PRESENT: Alan Bloom, Yvonne Bellay, Doug Englebert, Franklin LaDien, Jeffrey Miller, Wendy Pietz, Tina Virgil, Timothy Westlake (*via GoToMeeting*)

EXCUSED: Gunnar Larson

STAFF: Chad Zadrazil – Managing Director; Nilajah Hardin - Bureau Assistant; Sharon Henes - Administrative Rules Coordinator; and other DSPS Staff

CALL TO ORDER

Doug Englebert called the meeting to order at 9:30 a.m. A quorum of eight (8) members was confirmed.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES OF FEBRUARY 5, 2016

MOTION: Franklin LaDien moved, seconded by Tina Virgil, to approve the minutes of February 5, 2016 as published. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Election Of Officers

Board Chair

NOMINATION: Alan Bloom nominated Doug Englebert for the Office of Board Chair.

Chad Zadrazil called for nominations three (3) times.

Doug Englebert was elected as Chair by unanimous consent.

Vice Chair

NOMINATION: Franklin LaDien nominated Alan Bloom for the Office of Vice Chair.

Chad Zadrazil called for nominations three (3) times.

Alan Bloom was elected as Vice Chair by unanimous consent.

Secretary

NOMINATION: Jeffrey Miller nominated Yvonne Bellay for the Office of Secretary.

Chad Zadrazil called for nominations three (3) times.

Yvonne Bellay was elected as Secretary by unanimous consent.

2016 OFFICER ELECTION RESULTS	
Board Chair	Doug Englebert
Vice Chair	Alan Bloom
Secretary	Yvonne Bellay

Appointment of Liaisons

2016 LIAISON APPOINTMENTS	
SUA Liaison(s)	Alan Bloom, Yvonne Bellay
SCOADA Liaison	Doug Englebert
Legislative Liaison	Timothy Westlake (Alternate: Doug Englebert)
PDMP Liaison	Tina Virgil (Alternate: Wendy Pietz)

MOTION: Jeffrey Miller moved, seconded by Tina Virgil, to affirm the Chair's appointment of liaisons for 2016. Motion carried unanimously.

Delegation of Authority

MOTION: Franklin LaDien moved, seconded by Jeffrey Miller, that the Board delegates authority to the Chair to sign documents on behalf of the Board. In order to carry out duties of the Board, the Chair has the ability to delegate this signature authority to the Board's Managing Director for purposes of facilitating the completion of assignments during or between meetings. Motion carried unanimously.

MOTION: Alan Bloom moved, seconded by Franklin LaDien, in order to facilitate the completion of assignments between meetings, the Board delegates its authority by order of succession to the Chair, highest ranking officer, or longest serving member of the Board, to appoint liaisons to the Department where knowledge or experience in the profession is required to carry out the duties of the Board in accordance with the law. Motion carried unanimously.

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

MOTION: Yvonne Bellay moved, seconded by Alan Bloom, to authorize the SCAODA liaison to vote on behalf of the Board at the State Council on Alcohol and Other Drug Abuse meetings. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Alan Bloom, to delegate authority to the Legislative Liaison(s) to address Board issues related to legislative matters excluding media requests. Motion carried unanimously. Motion carried unanimously.

LEGISLATION AND RULE MATTERS

Exclusion of [¹²³I]ioflupane

MOTION: Jeffrey Miller moved, seconded by Alan Bloom, to approve the preliminary rule draft of Clearinghouse Rule CSB 2 relating to Exclusion of [¹²³I]ioflupane for posting for economic impact comments and submission to the Clearinghouse. Motion carried. Abstained: Tina Virgil

Adoption of CR 15-070 Relating to Data Submission to the Prescription Drug Monitoring Program (PDMP) (Act 199)

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay, to approve the Adoption Order for Clearinghouse Rule 15-070 relating to Submission to the Prescription Drug Monitoring Program (PDMP). Motion carried unanimously.

KRATOM: REPORT OF FACTS ON ORIGINAL LEGISLATIVE SCHEDULING DECISION

MOTION: Timothy Westlake moved, seconded by Wendy Pietz, the Board determines that evidence does not exist that meets the requirements under Wis. Stats. § 961.11(1m) to change the schedule for Kratom (Mitragynine). Motion carried unanimously.

PRESCRIPTION DRUG MONITORING PROGRAM

Access Suspension Process

MOTION: Jeffrey Miller moved, seconded by Alan Bloom, to delegate DSPTS staff to gather preliminary information and follow up on reports of unauthorized access or other violations related to the disclosure of Prescription Drug Monitoring Program (PDMP) information. The Board also delegates DSPTS staff refer the report to the Board's PDMP liaison for determination of action as authorized under CSB § 4.09 (3). Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay, to authorize the designated Prescription Drug Monitoring Program (PDMP) Liaison(s) to make individual decisions on behalf of the Board when waiting for a Board meeting would unreasonably delay the development, testing, deployment, or operation of the PDMP. The Board also grants the PDMP liaison the authority to suspend access to the PDMP pursuant to CSB § 4.09 (3). Motion carried unanimously.

INFORMATIONAL ITEMS

MOTION: Jeffrey Miller moved, seconded by Yvonne Bellay, to acknowledge that on December 11, 2015 at the State Council on Alcohol and Drug Abuse (SCAODA) meeting, the Marijuana Ad-hoc Committee presented and made a motion to accept the Marijuana in Wisconsin Report. The motion failed and the report was not accepted by the SCAODA. Since the entire Controlled Substances Board was not able to review and discuss the report prior to voting, the Controlled Substances Board's liaison abstained from voting on the motion. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 11:48 a.m.

**CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
APRIL 20, 2016**

PRESENT: Alan Bloom (*via GoToMeeting*), Yvonne Bellay (*via GoToMeeting*), Doug Englebert, Franklin LaDien (*via GoToMeeting*), Gunnar Larson (*via GoToMeeting*), Wendy Pietz (*via GoToMeeting*), Tina Virgil (*via GoToMeeting*), Timothy Westlake

EXCUSED: Jeffrey Miller

STAFF: Chad Zadrazil – Managing Director; Nilajah Hardin - Bureau Assistant; Sharon Henes - Administrative Rules Coordinator; and other DSPS Staff

CALL TO ORDER

Doug Englebert called the meeting to order at 1:00 p.m. A quorum of eight (8) members was confirmed.

ADOPTION OF AGENDA

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

LEGISLATION AND RULE MATTERS

Scope Amending CSB 4 Relating to Prescription Drug Monitoring Program (PDMP)

MOTION: Timothy Westlake moved, seconded by Alan Bloom, to approve the Scope Statement on CSB 4 relating to Prescription Drug Monitoring Program (PDMP) for submission to the Governor’s Office and publication, and to authorize the Chair to approve the scope for implementation no less than 10 days after publication. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 1:04 p.m.

**CONTROLLED SUBSTANCES BOARD
VIRTUAL TELECONFERENCE MEETING MINUTES
JUNE 9, 2016**

PRESENT: Yvonne Bellay, Doug Englebert, Franklin LaDien, Jeffrey Miller, Timothy Westlake

EXCUSED: Alan Bloom, Gunnar Larson, Wendy Pietz, Jason Smith

STAFF: Chad Zadrazil – Managing Director; Andrea Magermans – Deputy Managing Director, Nilajah Hardin - Bureau Assistant; Sharon Henes - Administrative Rules Coordinator; and other DSPS Staff

CALL TO ORDER

Doug Englebert called the meeting to order at 2:00 p.m. A quorum of five (5) members was confirmed.

ADOPTION OF AGENDA

MOTION: Jeffrey Miller moved, seconded by Franklin LaDien, to adopt the agenda as published. Motion carried unanimously.

LEGISLATION AND RULE MATTERS

Adopt Clearinghouse Rule 15-101 Relating to Operation of Prescription Drug Monitoring Program

MOTION: Yvonne Bellay moved, seconded by Franklin LaDien, to approve the Adoption Order for Clearinghouse Rule 15-101 Relating to Operation of Prescription Drug Monitoring Program. Motion carried unanimously.

ADJOURNMENT

MOTION: Tim Westlake moved, seconded by Jeffrey Miller, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 2:04 p.m.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Nilajah Hardin, Bureau Assistant		2) Date When Request Submitted: 6/27/16	
		Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 07/13/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Administrative Matters Liaison Appointments Prescription Drug Monitoring Program (PDMP) Liaison	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: The Chair should appoint a new Prescription Drug Monitoring Program (PDMP) Liaison.			
11) Authorization <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <i>Nilajah D. Hardin</i> <hr/> Signature of person making this request </div> <div style="width: 35%; text-align: right;"> <i>06/27/16</i> <hr/> Date </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 60%;"> <hr/> Supervisor (if required) </div> <div style="width: 35%; text-align: right;"> <hr/> Date </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 60%;"> <hr/> Executive Director signature (indicates approval to add post agenda deadline item to agenda) </div> <div style="width: 35%; text-align: right;"> <hr/> Date </div> </div>			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

CONTROLLED SUBSTANCES BOARD
2016 ELECTIONS AND APPOINTMENTS

March 2016

2016 OFFICER ELECTION RESULTS	
Board Chair	Doug Englebert
Vice Chair	Alan Bloom
Secretary	Yvonne Bellay

2016 LIAISON APPOINTMENTS	
SUA Liaison(s)	Alan Bloom, Yvonne Bellay
SCOADA Liaison	Doug Englebert
Legislative Liaison	Timothy Westlake (Alternate: Doug Englebert)
PDMP Liaison	Tina Virgil (Alternate: Wendy Pietz)

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: 5/26/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 6/7/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Letter from GW Pharmaceuticals – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of GW Pharmaceuticals letter regarding rescheduling CBD.			



May 3, 2016

Chad Zadrazil
Executive Director
Controlled Substances Board
Department of Safety and Professional Services
1400 East Washington Ave., Room 112
Madison, WI 53703

Dear Mr. Zadrazil,

Please allow me to introduce myself. I am the Vice President of U.S. Professional Relations for GW Pharmaceuticals. GW is the developer of Epidiolex®, a pure cannabidiol (CBD) investigational product that is being studied as a potential anti-convulsive treatment for children with certain types of childhood-onset, medication-resistant epilepsies, including Dravet Syndrome and Lennox Gastaut Syndrome (LGS).

We have just announced that the results of our first study in Dravet Syndrome were highly statistically significant in favor of Epidiolex® over placebo. Epidiolex® achieved the primary endpoint of a significant reduction in convulsive seizures assessed over the entire treatment period compared with placebo ($p=0.01$). The results from our two trials in LGS will become available over the next few months, and the results from our second Dravet study will be available in the second half of the year. I include the press release announcing the first Dravet study results. Epidiolex® has both Orphan Drug Designation and Fast Track Designation from the U.S. Food and Drug Administration (FDA) in the treatment of Dravet syndrome and also Orphan designation for LGS.

Dravet Syndrome is a severe infantile-onset and highly treatment-resistant epileptic syndrome. Over time, people with Dravet Syndrome can develop multiple types of seizures and are prone to prolonged seizures called status epilepticus, which can be life threatening. Risk of premature death including SUDEP (sudden unexpected death in epilepsy) is elevated in people with Dravet Syndrome. Additionally, the majority will develop moderate to severe intellectual and development disabilities and require lifelong supervision and care. **There are currently no FDA-approved treatments**, and nearly all patients continue to have uncontrolled seizures and other medical needs throughout their lifetime.

Patients with Lennox Gastaut Syndrome commonly have frequent seizures of a wide variety, including convulsive, atonic seizures, which can cause abrupt falls and serious injury. LGS is also highly medication resistant. Most children with LGS experience some degree of impaired intellectual functioning or information processing, as well as developmental delays and behavioral disturbances. As you can see,

5800 Armada Drive Suite 210 Carlsbad, CA 92008

Telephone: 760-795-2200 - Facsimile: 760-795-2219 - www.gwpharm.com

there is a pressing need for new treatment options for patients with Dravet Syndrome and LGS. These syndromes have serious consequences for both the patients and for their families.

GW intends to file a New Drug Application with the FDA as soon as possible within the next year. Since Epidiolex has Fast Track status, we hope that the FDA will afford it a Priority Review cycle, which could result in approval within eight months of submission. Because CBD is a purified derivative of the cannabis plant, it is currently classified in Schedule I of the U.S. Controlled Substances Act (CSA). If Epidiolex® were approved by FDA, it would then be rescheduled by DEA to a lower schedule so that it could be prescribed. Under recent federal legislation, that rescheduling should be accomplished within 90 days of FDA approval. Almost all states have their own state controlled drug laws, and CBD is a Schedule I substance under those laws. ***Therefore, despite being approved by FDA and rescheduled by DEA, Epidiolex® could not be made available to patients in your state until it is also rescheduled under state law.*** In summary:

- Late 2016/beginning of 2017 - GW files a New Drug Application with FDA
- Potential FDA approval within 8 months of submission - based on Fast Track status and Priority Review Cycle
- 90 days after FDA approval - DEA reschedules Epidiolex® from Schedule I to lower schedule.
- Subsequently, the state reschedules Epidiolex® under state law similarly to DEA rescheduling.

We understand that your agency is responsible for implementing the administrative process that must occur in order for such rescheduling to take place. Therefore, we are reaching out to you with this information in order to minimize any delays in patient access in your state to a much-needed treatment option.

We would very much like to speak with you in the very near future to provide you with additional information about our research and answer any questions you might have about the development path of Epidiolex®. Thank you so much for considering our request.

Best wishes,

A handwritten signature in cursive script that reads 'Alice P. Mead'.

Alice P. Mead
Vice President, U.S. Professional Relations
GW Pharmaceuticals

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: 5/26/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 6/7/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Waupaca County District Attorney's Request Regarding Furanyl – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of Waupaca County DA request for emergency scheduling of Furanyl. 1) Wis. Stat. 961.25			

**Waupaca County District Attorney
John P. Snider**

Assistant District Attorneys:

James H. Fassbender
Brenda S. Freeman
Veronica Isherwood

Waupaca County Courthouse
811 Harding Street
Waupaca, WI 54981
Phone (715) 258-6444
Fax (715) 258-6436

**Victim/Witness
Assistance Program:**

Mary Lea St. Thomas
(715) 258-6445

May 2, 2016

Wisconsin Department of Safety and Professional Services
Controlled Substance Board
P.O. Box 8935
1400 E. Washington Avenue
Madison, WI 53708-8935

Re: Waupaca County Case #: 2016CF000097

To Whom It May Concern:

This office is currently prosecuting a case involving, among other things, delivery of Furanyl, described as an analog of the Schedule II synthetic opiate Fentanyl, listed at §961.16(3)(f), Wis. Stats. Enclosed please find a copy of the criminal complaint commencing said action. Also enclosed please find a copy of Wisconsin State Crime Laboratory Controlled Substances Analyst Katie Hoffmeyer's April 18, 2016 report, which report identifies one of the substances involved in our prosecution as Furanyl. I also enclose a recent article about Furanyl.

It is my understanding that a district attorney is required to provide information to this Board relevant to emergency scheduling of the above-referenced substance. It is intended that this communication satisfies this obligation, under §961.25, Wis. Stats., and serve as a request that the Wisconsin Controlled Substance Board review Fentanyl for emergency scheduling as contemplated under §961.11(4m), Wis. Stats. Please notify me of the specific procedure to be followed to have this request considered, or if you need any additional information.

Very truly yours,



John P. Snider
District Attorney
State Bar ID: 1014726

JPS:kms

Enclosures

**Waupaca County District Attorney
John P. Snider**

Assistant District Attorneys:

James H. Fassbender
Brenda S. Freeman
Veronica Isherwood

Waupaca County Courthouse
811 Harding Street
Waupaca, WI 54981
Phone (715) 258-6444
Fax (715) 258-6436

**Victim/Witness
Assistance Program:**

Mary Lea St. Thomas
(715) 258-6445

May 09, 2016

Wisconsin Department of Safety and Professional Services
Controlled Substance Board
PO Box 8935
1400 E. Washington Avenue
Madison, WI 53708-8935

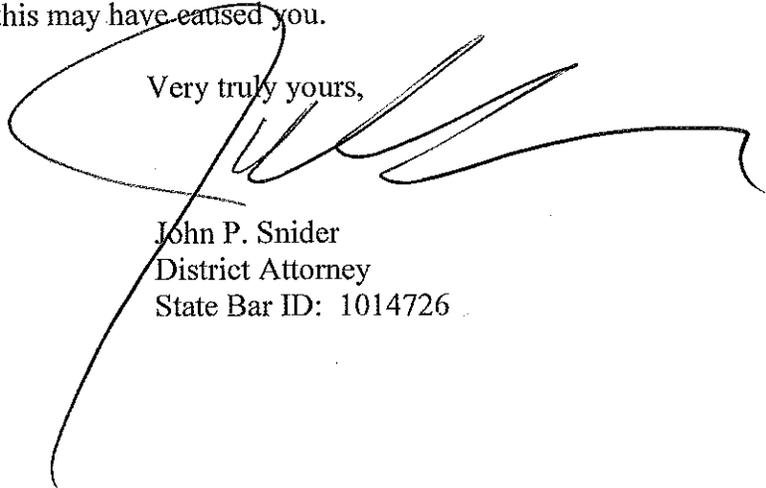
Re: Waupaca County Case #2016CF000097

To Whom It May Concern:

One of my secretaries typed a letter to you from me dated May 02, 2016 and stamped my name on the letter and put it in the office mail. However, there is a spelling error in the letter; wherever the words "Furanyl" and "Fentanyl" are used, the correct wording should be "Furanyl Fentanyl", all as one substance.

I am sorry for any confusion this may have caused you.

Very truly yours,



John P. Snider
District Attorney
State Bar ID: 1014726

JPS/mkw



Submitting Agency:

Sheriff Brad Hardel
Attn: Joshua Krueger
Waupaca County Sheriff's Office
1402 East Royalton Street
Waupaca WI 54981

Date: April 18, 2016

Case No: W16-974

Agency No: 16-04727

Laboratory Analyst:

Katie S. Hoffmeyer mg 4/18/16
Katie S. Hoffmeyer
(Controlled Substances Unit)

Case Name: Kabble, Cheyenne M. [V]

I do hereby certify this document, consisting of 1 page(s), to be a true and correct report of the findings of the State Crime Laboratory on the items examined as shown by this report. This report contains the conclusions of the above signed analyst.

Brad D. Schimel
ATTORNEY GENERAL

Eva Marie Plunk 04/21/2016
DESIGNEE

Item	Description / Source
A	One heat-sealed plastic bag containing a blue plastic grinder with 0.050 gram ± 0.003 gram of white powder material.
B	One heat-sealed plastic bag containing a pink plastic clipboard with slight white residue.
C	One heat-sealed plastic bag containing a cut yellow plastic straw with slight white residue.
D	One heat-sealed plastic bag containing a small ziplock plastic bag with: D1. Four orange oval tablets weighing 0.958 gram ± 0.003 gram and D2. One orange round tablet weighing 0.342 gram ± 0.003 gram.
E	One heat-sealed plastic bag containing a clear glass vial with 0.108 gram ± 0.003 gram of white powder material.

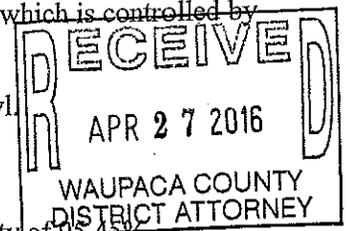
Examinations of the powder material from item A identified the presence of Oxymorphone and Alprazolam, which are controlled by Sections 961.16(2)(a)12 and 961.20(2)(a) of the Wisconsin Uniform Controlled Substances Act.

Examinations of the tablets from items D1 and D2 identified the presence of Amphetamine, which is controlled by Section 961.16(5)(a) of the Wisconsin Uniform Controlled Substances Act.

Examinations of the powder material from item E identified the presence of Furanyl Fentanyl.

Items B and C were examined visually only.

The uncertainty values for the reported weight(s) were calculated using a coverage probability of 95.45%.



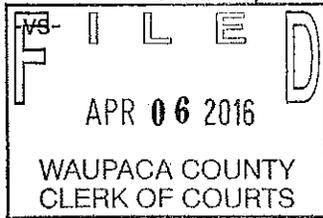
COPYING AND DISTRIBUTION OF THIS REPORT IS THE RESPONSIBILITY OF THE SUBMITTING AGENCY
The laboratory reserves the right to choose the items which will be tested and the methods which will be used to test them.



STATE OF WISCONSIN

COPY

Plaintiff,



Alexander M Madson
600 Korth Road
Clintonville, WI 54929
DOB: 05/26/1992
Sex/Race: M/W
Alias: Also Known As Alexander Matthew
Madson

**Amended
Criminal Complaint**

Court Case #: 2016CF000097

DA Case #: 2016WP000519

DA/ADA Assigned: John P. Snider

JUDGE ASSIGNED:

Defendant,

Deputy Craig Copes, Waupaca County Sheriff's Department
being first duly sworn, states that:

Count 1: DELIVERY OF SCHEDULE I OR II NARCOTICS

The above-named defendant on Sunday, April 03, 2016, in the Village of Embarrass, Waupaca County, Wisconsin, did deliver a controlled substance analog of a controlled substance included in schedule I or II which is a narcotic drug, to-wit: Furanylfentanyl, contrary to sec. 961.41(1)(a), 939.50(3)(e) Wis. Stats.

(PENALTY: Upon conviction for this offense, a Class E Felony, the defendant may be fined not more than Fifty Thousand Dollars (\$50,000), or imprisoned not more than fifteen (15) years, or both.

And the Court may suspend the defendant's operating privileges for not less than six (6) months nor more than five (5) years. If the defendant's driving privileges are already suspended, any suspension imposed must be served consecutively. Further, when a court imposes a fine, it shall impose a drug abuse program improvement surcharge in an amount of 75% of the fine and penalty assessment imposed.)

Count 2: MAINTAINING A DRUG TRAFFICKING PLACE - PTAC, AS A PARTY TO A CRIME

The above-named defendant on Sunday, April 03, 2016, in the Village of Embarrass, Waupaca County, Wisconsin, as a party to a crime, did maintain a dwelling which is resorted to by persons using controlled substances in violation of chapter 961 Wis. Stats., contrary to sec. 961.42(1), 939.50(3)(i), 939.05 Wis. Stats.

(PENALTY: Upon conviction for this offense, a Class I Felony, the defendant may be fined not more than Ten Thousand Dollars (\$10,000), or imprisoned not more than three (3) years and six (6) months, or both.

And the Court may suspend the defendant's operating privileges for not less than six (6) months nor more than five (5) years. If the defendant's driving privileges are already suspended, any suspension imposed must be served consecutively. Further, when a court imposes a fine, it shall impose a drug abuse program improvement surcharge in an amount of 75% of the fine and penalty assessment imposed.)

Count 3: PHYSICAL ABUSE OF CHILD

The above-named defendant on Sunday, April 03, 2016, in the Village of Embarrass, Waupaca County, Wisconsin, did recklessly cause bodily harm to a child, CMK, DOB 05/02/1999, contrary to sec. 948.03(3)(b), 939.50(3)(i) Wis. Stats.

(PENALTY: Upon conviction for this offense, a Class I Felony, the defendant may be fined not more than Ten Thousand Dollars (\$10,000), or imprisoned not more than three (3) years and six (6) months, or both.)

Count 4: OBSTRUCTING AN OFFICER

The above-named defendant on Sunday, April 03, 2016, in the Village of Embarrass, Waupaca County, Wisconsin, did knowingly obstruct an officer, while such officer was doing an act in an official capacity and with lawful authority,, contrary to sec. 946.41(1), 939.51(3)(a) Wis. Stats.

(PENALTY: Upon conviction for this offense, a Class A Misdemeanor, the defendant may be fined not more than Ten Thousand Dollars (\$10,000), or imprisoned not more than nine (9) months, or both.)

PROBABLE CAUSE:

This complaint is filed on information and belief based upon reports and statements compiled by the Waupaca Police Department.

On April 3, 2016, at 7:41 p.m., Deputy Josh Krueger of the Waupaca County Sheriff's Department was dispatched to 600 Korth Road, in the Village of Embarrass, County of Waupaca, State of Wisconsin, for a report of a 16 year old, C.M.K. (d.o.b. 05/02/99), who overdosed on what was reported as Xanax. It was reported she was unconscious, non-responsive, but breathing. It was reported by the caller, Alexander M. Madson (d.o.b. 05/26/92), the defendant, that he found her in this condition 15 minutes prior and thought she was sleeping. While en route, Deputy Krueger was advised that her breathing became labored.

Deputy Krueger arrived and saw the defendant outside. The defendant said he was freaking out and paramedics told him to grab a flat board from the ambulance. Deputy Krueger grabbed a flat board and brought it upstairs. When Deputy Krueger entered the apartment, he saw the paramedics working on C.M.K. She was still unresponsive and barely responded to sternum rubs from the paramedic. Another female in the apartment, Stephanie Hackbarth, said she was bartending when the call came out that a first responder in the bar heard. Hackbarth said the first responder asked her if that was her place, so she left work and came home to see what was going on.

Deputy Krueger asked the defendant what happened. The defendant said C.M.K. was in his and Hackbarth's bedroom when she slowly passed out and laid down on the bed. The defendant said this happened when he left the room to get a soda and was out of the room for approximately two minutes. The defendant said he tried to wake her and when she did not respond, he called 911. Deputy Krueger asked the defendant what she took. The defendant said he did not know. Deputy Krueger explained to the defendant this was not the time to lie and they needed to know what she had so they could properly work on C.M.K. The defendant said he did not know.

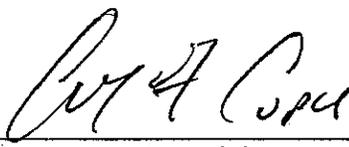
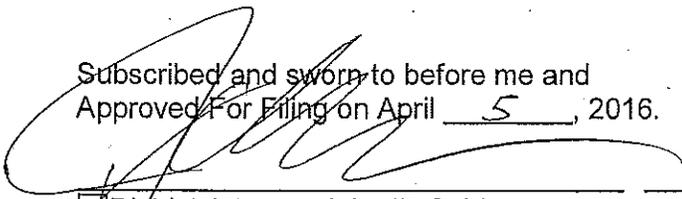
The bedroom door was wide open and when Deputy Krueger looked through the door, he saw a grinder and a glass pipe, both commonly used for marijuana use, on top of a desk, as well as a

small red clipboard with a white powdery substance and a straw next to them. Deputy Krueger asked the defendant again what C.M.K. took. Again, the defendant told Deputy Krueger he did not know and thought it was Xanax. Deputy Krueger asked the defendant how she was earlier in the night, and he said she was fine. The defendant said he picked her up and she was in good spirits. The defendant said they came to his place to hang out when all this happened. The defendant said C.M.K. did not in any way indicate she was depressed and wanted to harm herself. Stephanie Hackbarth said C.M.K. has been wanting to be romantic and she told the defendant he needed to tell her tonight to back off. Deputy Krueger asked the defendant if he told her to back off. The defendant said he did not and again, everything was fine with her. Paramedics administered Narcan to C.M.K. and moments later she came to and was confused. Deputy Krueger told the defendant that Narcan's purpose was to offset the effects of opiates and wanted to know what was taken. The defendant then admitted C.M.K. snorted Furanylfentanyl. The defendant admitted to snorting some as well. Furanylfentanyl (Fu-F) is an opioid analgesic that is an analog of fentanyl[1] sold online as a designer drug. The defendant said he bought the drug from a friend who told him he bought it on the Internet.

Further, the Hon. Raymond S. Huber granted a search warrant and Deputy Krueger went back to the residence where Deputy Zeamer and Sgt. Lewis had stayed awaiting the warrant. Found in the bedroom of Stephanie Hackbarth and the defendant under the warrant were:

- Item #003 Furanylfentanyl.
- Item #009 White crystal glass pipe in an eyeglass case and blue and yellow pipe in an eyeglass case.
- Item #011 Samsung Galaxy S4 Mini belonging to C.M.K.
- Item #012 Tin foil, circular mirror, Butane fuel, glass container with THC, glass pipe, rubber container with an odor of marijuana, plastic baggies, glass bowl with marijuana seeds with a sign on it that said "Fruity Pebbles," G hit, rolling paper and an empty unlabeled pill bottle.
- Item #013 E404 Amphetamine & Dextroamphetamine 30 Qty of 1, 9 973 Amphetamine & Dextroamphetamine Qty of 4, APO TI-4 Tizanidine Qty of 11, Dan Dan 3120 Qty of 4.
- Item #014 White water bong, small water bong.
- Item #015 Mushroom shaped glass pipe in eyeglass case.
- Item #016 Black and yellow glass pipe, two Mason jars with odor of marijuana.
- Item #017 Seven unlabeled pill bottles, one of those containing vape tips, various containers with marijuana odor, container with "roach" written on it with one partial marijuana cigarette, two water bong tips, skull pipe, blue rubber container with hash oil, glass container with unknown white powder.
- Item #018 VHT glass container with has oil, two Mason jars with leaves and stems with an odor of marijuana, both tested positive for tetrahydrocannabinols. One jar had 19.03 grams; the other jar had 9.01 grams. Zip lock baggie with leaves and seeds weighing in at 8.66 grams, and a green blade scale.
- Item #019 Black LG phone in black case.
- Item #020 Three plastic pill bottles with a marijuana odor.
- Item #021 Samsung Galaxy phone belonging to the defendant.

Subscribed and sworn to before me and
Approved For Filing on April 5, 2016.



- District Attorney John P. Snider
State Bar I.D. #: 1014726
- Assistant District Attorney
State Bar I.D. #:
- James H. Fassbender - 1005629
- Veronica Isherwood - 1022814
- Brenda S. Freeman - 1026150

Complainant

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Health

Chinese labs modify deadly fentanyl to circumvent ban on sales to US

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Rex Features via AP

A company that lists its headquarters in the Chinese city of Wuhan is offering a new version of potent fentanyl to US buyers.

By [David Armstrong @DavidArmstrongX](#)

April 26, 2016

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Chinese laboratories are producing and openly selling a new form of deadly fentanyl to get around China's recent export ban on the synthetic drug causing thousands of overdose deaths across the United States.

The slightly tweaked version of fentanyl — called furanyl fentanyl — is so new that it is not on the US government's list of controlled substances. That means the altered fentanyl, which was blamed for the March overdose of an Illinois man, is technically legal for drug dealers to sell.

The US Drug Enforcement Agency told STAT Monday that it is moving quickly to ban street sales of the new fentanyl product. The agency plans within days to classify furanyl fentanyl as an analog to fentanyl, which would mean the new drug would be treated in the same fashion as fentanyl, said DEA spokesman Russell Baer. He added that the producers of the new fentanyl are located in China and said the agency is planning similar action with other fentanyl analogs it has identified.

article continues after advertisement

Fentanyl can be legally prescribed by physicians, often to treat chronic pain. Any other sale of the drug is illegal.

The DEA is also working to place the new version of fentanyl on the permanent list of controlled substances, a move that requires review by the Food and Drug Administration, Baer said.

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The chemical structure of the new drug, and its effect on the body's central nervous central system, is nearly identical to that of fentanyl. China last fall banned more than 116 synthetic drugs, including other analogs of fentanyl. One of the most popular of those is called acetyl fentanyl.



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'Truly terrifying': Chinese suppliers flood US and Canada with deadly fentanyl

Once the ban was in place, fentanyl began to show up in the United States.

"Laboratories are automatically tweaking the formula to come up with the next analog," said Baer. "We will seek to put fentanyl on the list (of controlled substances), and then they will tweak one molecule, and in two months we will be discussing that one. It is a challenging process for us."

A laboratory company called Dharma Chemicals, or Dharmachem, that reports an address in a central China commercial district, recently told a STAT reporter by email that it was no longer selling the banned acetyl fentanyl, but that it "just added" fentanyl to "our catalogues." The company said the drug was being sold for "laboratory research."

The company was previously accused in a World Health Organization report of selling acetyl fentanyl over the Internet.

Fentanyl was recently identified as the cause of death in the fatal overdose of a 30-year-old man in Naperville, Ill., a suburb west of Chicago, according to an overdose database maintained by the Will County coroner. It appears to be the first public reporting of a case in which the new version of fentanyl caused a deadly overdose.



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US refuses to release records on Chinese companies linked to deadly fentanyl trade

In many areas of the United States and Canada, fentanyl is now causing more fatal overdoses than heroin. The drug is up to 100 times more potent than morphine and many times stronger than heroin. In some cases, fentanyl is being sold in pill form, often made to look like other prescription painkillers that fetch a higher price on the street. Fentanyl is also being added to heroin. Users are often unaware they are snorting or injecting the more powerful fentanyl.

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apply to a pseudoephedrine product unless it contains another schedule V substance.

(8) No person may sell a pseudoephedrine product to a person under 18 years of age, and no person under 18 years of age may purchase a pseudoephedrine product.

History: 1971 c. 219; 1973 c. 12 s. 37; 1981 c. 206; 1993 a. 482; 1995 a. 448 s. 228; Stats. 1995 s. 961.23; 2005 a. 14, 262; 2011 a. 146.

961.235 Records relating to sales of pseudoephedrine products. (1) In this section, “records of pseudoephedrine sales” means records required under s. 961.23 (4) with respect to the sale of a pseudoephedrine product.

(2) Records of pseudoephedrine sales may be kept in either a paper or electronic format and shall be maintained by the pharmacy for at least 2 years. Except as provided in sub. (3), only a pharmacist may have access to records of pseudoephedrine sales and information contained in those records.

(3) A pharmacist shall make records required under s. 961.23 (4) available to a law enforcement officer who requests them. Law enforcement officers may make those records available to other persons or redisclose information from those records to other persons only in connection with a criminal investigation or prosecution under this chapter.

History: 2005 a. 14, 262.

961.24 Publishing of updated schedules. The controlled substances board shall publish updated schedules annually. The failure of the controlled substances board to publish an updated schedule under this section is not a defense in any administrative or judicial proceeding under this chapter.

History: 1971 c. 219; 1993 a. 213; 1995 a. 448 s. 229; Stats. 1995 s. 961.24.

961.25 Controlled substance analog treated as a schedule I substance. A controlled substance analog, to the extent it is intended for human consumption, shall be treated, for the purposes of this chapter, as a substance included in schedule I, unless a different treatment is specifically provided. No later than 60 days after the commencement of a prosecution concerning a controlled substance analog, the district attorney shall provide the controlled substances board with information relevant to emergency scheduling under s. 961.11 (4m). After a final determination by the controlled substances board that the controlled substance analog should not be scheduled, no prosecution relating to that substance as a controlled substance analog may be commenced or continued.

History: 1995 a. 448.

SUBCHAPTER III

REGULATION OF MANUFACTURE, DISTRIBUTION, DISPENSING AND POSSESSION OF CONTROLLED SUBSTANCES

961.31 Rules. The pharmacy examining board may promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state.

History: 1971 c. 219; 1995 a. 448 s. 231; Stats. 1995 s. 961.31.

Cross-reference: See also ch. *Phar 8*, Wis. adm. code.

961.32 Possession authorization. (1) Persons registered under federal law to manufacture, distribute, dispense or conduct research with controlled substances may possess, manufacture, distribute, dispense or conduct research with those substances in this state to the extent authorized by their federal registration and in conformity with the other provisions of this chapter.

(2) The following persons need not be registered under federal law to lawfully possess controlled substances in this state:

(a) An agent or employee of any registered manufacturer, distributor or dispenser of any controlled substance if the agent or

employee is acting in the usual course of the agent’s or employee’s business or employment;

(b) A common or contract carrier or warehouse keeper, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

(c) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a schedule V substance.

(d) Any person exempted under federal law, or for whom federal registration requirements have been waived.

(e) A person actively engaged in the direct operation or implementation of a drug disposal program that is authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a).

History: 1971 c. 219, 336; 1983 a. 500 s. 43; 1993 a. 482; 1995 a. 448 s. 232; Stats. 1995 s. 961.32; 2013 a. 198.

A doctor or dentist who dispenses drugs to a patient within the course of professional practice is not subject to criminal liability. *State v. Townsend*, 107 Wis. 2d 24, 318 N.W.2d 361 (1982).

961.335 Special use authorization. (1) (a) Upon application the controlled substances board may issue a permit authorizing a person to manufacture, obtain, possess, use, administer, or dispense a controlled substance for purposes of scientific research, instructional activities, chemical analysis, or other special uses, without restriction because of enumeration.

(b) Except as provided in par. (c), no person may engage in any activity described under par. (a) without a permit issued under this section.

(c) 1. A person who is actively engaged in the direct operation or implementation of a drug disposal program that is authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a), may, without a permit issued under this section, obtain or possess a controlled substance for the purposes of operating and implementing the drug disposal program.

2. A person who is permitted under federal law to dispose of a controlled substance may, without a permit issued under this section, possess the controlled substance for the purpose of disposing of the controlled substance.

3. An individual who is designated and authorized to receive a permit under this section for a college or university department, research unit, or similar administrative organizational unit, and students, laboratory technicians, research specialists, or chemical analysts under his or her supervision, may, without an additional permit issued under this section, possess and use a controlled substance, for the purposes authorized in the permit received for the department or unit.

(2) A permit issued under this section shall be valid for one year from the date of issue.

(3) The fee for a permit under this section shall be an amount determined by the controlled substances board but shall not exceed \$25. No fee may be charged for permits issued to employees of state agencies or institutions.

(4) Permits issued under this section shall be effective only for and shall specify:

(a) The name and address of the permittee.

(b) The nature of the project authorized by the permit.

(c) The controlled substances to be used in the project, by name if included in schedule I, and by name or schedule if included in any other schedule, except that, for any permit issued to a state crime laboratory, the permit is effective for any controlled substance whether or not the name or schedule is specified.

(d) Whether dispensing to human subjects is authorized.

(5) A permit shall be effective only for the person, project, and, except as provided in sub. (4) (c), substances specified on its face and for additional projects which derive directly from the stated project. Upon application, a valid permit may be amended to add a further activity or to add further substances or schedules to the project permitted thereunder. The fee for such amendment

How Knockoff Fentanyl Dodges Cops



The synthetic opioid that killed Prince is part of a tangled international network of copycat drugs, and it's impossible for authorities to keep up.

A medical examiner announced on Thursday that [music legend Prince died](#) of a [self-administered dose of the synthetic opioid fentanyl](#), unleashing a torrent of headlines about the dangerously powerful narcotic that is [“sweeping the U.S.”](#)

Fentanyl isn't a new drug. It began its long run as a first-line surgical analgesic in 1968, and since the introduction of the transdermal patch in the 1990s, has become one of the most commonly prescribed narcotics for treating moderate-to-severe cancer pain.

However, its profile as a street drug has grown precipitously over the past several years, as America has found itself in the grips of a crippling epidemic of opioid abuse.

State and the federal lawmakers are now considering increasing mandatory prison penalties for fentanyl distribution—bucking a bipartisan trend toward drug sentencing reform.

On Tuesday morning, members of the Senate Judiciary Committee are holding [a hearing](#) titled “Deadly Synthetic Drugs: The Need to Stay Ahead of the Poison Peddlers,” to consider solutions to an increase of deaths attributed to synthetic drugs like “K2” (a synthetic cannabinoid also known as “Spice”) and fentanyl.



Authorities are now looking into where Prince obtained the fentanyl that killed him. If it came from a physician, the pop star would be among a small minority of drug abusers who obtain fentanyl either directly through, or diverted from, pharmaceutical channels. Instead, according to the Centers for Disease Control, most of the fentanyl taken off the street to date has been “[non-pharmaceutical fentanyl](#)” (NPF)—most of which is manufactured clandestinely in Mexico.

Recently, though, public health officials have been sounding the alarm about a troubling spate of overdose deaths tied to more arcane fentanyl *analogs*—as well as other synthetic opioid derivatives—that are shipped legally from facilities in China.

There are now more than 30 analogs of fentanyl alone, and a number of lesser known synthetic opioid analogs.

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Many exist in a regulatory gray area, and can be ordered wholesale via the internet if you know where to look. Some of these substances are so powerful that the United States [has reportedly](#) considered weaponizing them. Other nations already have. In 2002, Russian security forces used a gas believed to be an analog of fentanyl against Chechen terrorists who had taken over a packed theater in Moscow. The compound was so potent that at least 115 hostages also died in the “rescue” attempt.

Quasi-legal derivatives of fentanyl have been used by drug dealers to boost the potency of street heroin since at least the 1970s, when users began overdosing on heroin cut with an analog that medical investigators soon identified as alpha-methylfentanyl. The drug was developed by the same lab that synthesized fentanyl, but has no recognized medical use.

Back then, distribution of alpha-methylfentanyl was limited to California and drug markets in the Northeast—where it mixed easily with the highly refined heroin #4 powder common to those regions. It was frequently marketed under the street names “China White” and “Tango & Cash.”

Alpha-methylfentanyl was made a Schedule I controlled substance in the U.S. in 1981, but it continued to turn up in tainted batches of heroin well into the 1990s, along with an even more potent analog known as 3-methylfentanyl (TMF). TMF was outlawed in the U.S. in 1986, but it too surfaced sporadically for many more years.

According to [one study](#), fentanyl-related hospitalizations rose more than 641 percent from 1997 to 2004. Toxicologists were able to identify more than 10 unique fentanyl analogs causing users to get sick during that period. Over the next two years—from April 2005 through March 2007—officials blamed 1,013 deaths in six cities on non-pharmaceutical fentanyl analog. It was the largest NPF epidemic ever reported, according to the CDC.

Since most controlled substances banned under federal law are outlawed based on relatively rudimentary chemical properties, they can be easily altered to circumvent the law. In 1986, this prompted President Ronald Reagan to sign the “Federal Analogue Act,” which outlawed substances that are “substantially similar to the chemical structure of a controlled substance in schedule I or II.”

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However, the law left a loophole open for drugs that are “not intended for human consumption.”

Most synthetic opioids finding their way to illicit drug markets are part of a group of compounds known as “research chemicals” (RCs) that are reserved for industrial and medical trials but are largely untested in humans.

Chinese labs are reportedly exploiting that exception to flood the U.S. market with so-called novel narcotics—tweaked versions of existing drugs that fall under the radar of federal law.

While authorities struggle to keep up, a succession of newer fentanyl analogs have found their way onto the street—or “gone wild” as it’s known to the small but active group of RC enthusiasts who discuss experimenting with them in [online forums](#).

“Clever and well-informed drug distribution networks will likely take advantage of the legal loophole and profit by replacing or cutting a highly-regulated drug with this less regulated one,” said John Stogner, a criminologist at the University of North Carolina at Charlotte.

Police are now coming in contact with more illicit fentanyl and other “novel” opioids on the street than ever before. But authorities are unable to keep up with all the legal derivatives.

Last year police in Florida confiscated 2.5 pounds of a powerful, but still legal, synthetic opioid called W-18 during a raid on a suspected fentanyl trafficker. W-18 is said to be 10,000 times stronger than morphine (tests, however have only been conducted on mice); and it is suspected in several recent overdose deaths in Philadelphia.

Another synthetic opioid, U-47700—which was developed by the pharmaceutical manufacturer Upjohn in the 1970s—surfaced in the Dallas area in March. The drug is 7.5-times more powerful than morphine (making it

relatively weak in relation to other high-potency synthetics). Yet it's sent a number of users to the hospital, prompting medical professionals in Texas to issue a public warning.

"We've had calls recently from people concerned about this new drug," said Kristina Domanski, MD, a toxicologist with the North Texas Poison Center. "This seems to be a pretty new recycling of the drug which is intended as a research drug and not for use in humans."

Sweden and Finland have passed laws making U-47700 illegal, and last month Ohio Governor John Kasich added it to the state's list of scheduled substances ([PDF](#)). But there are currently no federal guidelines banning its sale in the U.S.

In 2015, a little-known analog known as acetylfentanyl was banned by the DEA two years after it first showed up in tablets tested in Maine. Two others fentanyl analogs—buprenorphine and beta-hydroxythiofentanyl—were subjected to emergency scheduling by the DEA only last month ([PDF](#)). On May 16, the DEA also emergency scheduled a relatively weak synthetic opioid known as AH-7921 after catching wind that it was gaining interest among drug enthusiasts in online chat rooms.

By that time, however, a legal replacement known as furanyl-fentanyl was already making headlines. Since the beginning of the year furanyl-fentanyl has been blamed for 10 overdose deaths in Pennsylvania and recently sent two North Dakota high school students to the emergency room.

One Chinese lab, which says it specializes in the sale of research chemicals, [lists a gram](#) of furanyl-fentanyl for \$80.

In May, Sen. Pat Toomey of Pennsylvania, which ranks third in the nation in fentanyl seizures, penned a letter to Secretary of State John Kerry urging the Obama administration to put pressure on China to "immediately stop the export of illicit fentanyl and dangerous analogues."

"Limiting the introduction of synthetic fentanyl and related analogues will help save lives and give those battling addiction another opportunity at recovery," Toomey stated. In his remarks he singled out "domestically unregulated" furanyl-fentanyl as a particular cause of concern.

In Philadelphia, where fentanyl-laced heroin has been blamed for periodic increases in drug fatalities for decades, fentanyl-related deaths spiked at the beginning of 2014 and continue to rise ([PDF](#)). Sources told The Daily Beast that dealers are, for the first time, openly marketing the drug for sale at half the price of a typical \$10 baggie of heroin. (Users report a "good rush" but complain about fentanyl's "short legs"—a reference to its limited window of effectiveness as compared to heroin.)

As the crackdown on prescription opioids pushes more users from the doctor's office to the street, distributors will be drawn to new and powerful opioid substitutes with little concern for where they come from.

And therein lies a conundrum: Limiting diversion of powerful painkillers from regulated pharmaceutical channels creates new unregulated avenues for satisfying demand. In most cases these secondary avenues are more dangerous than the original ones we are trying to shut down. It's a glaring oversight for a country that otherwise reveres the autonomous power of the "invisible hand" of the free market.

In response to China's recent export ban of [116 research chemicals](#), one online poster to a research chemical forum summed up: "If there's demand, it will be produced—legally or not. Worst thing is that from now on our stuff will come from catchy backyard labs without quality control. People will die. Way to go prohibition."

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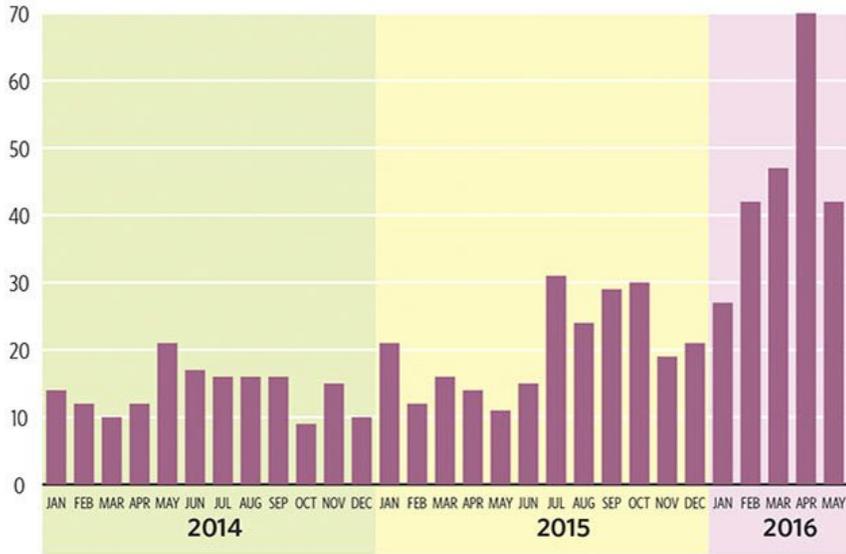
Fatal fentanyl

The drug that killed Prince blamed for spike in Dane County overdoses

by STEVEN POTTER
JUNE 9, 2016



Suspected opioid overdoses in Madison area



SOURCE: MADISON FIRE DEPT.

Heroin overdoses are up in Madison. Way, way up.

Last month, an opioid antidote, Narcan, was used 42 times to revive drug users who had overdosed, according to the Madison Fire Department. This compared to just 11 times in May of last year.

While that increase is alarming, it pales in comparison to the month before. In April 2015, Narcan was used 14 times to correct an opioid overdose, but in April of this year, drug users overdosed and were revived 70 times.

“These are just the cases that we know of,” says Ché Stedman, medical affairs division chief for the Madison Fire Department. His department’s data includes only overdoses where paramedics or someone else reported using an opioid antidote.

“It’s very likely — because there’s so much **more Narcan out there now** — that someone overdoses at home, [someone gives them] Narcan, and they never call us



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Week in Review: June 30-July, 6, 2016

Madison Matrix for June 30, 2016

Out of the sand trap

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about it," he adds. "So, we have no idea how many more of those there are."

The suspected cause of the increase in opiate (naturally occurring substances) or opioid (synthetically manufactured drugs) overdoses likely isn't an influx of new, inexperienced users or a larger-than-normal quantity of drugs coming into the area.

Instead, authorities say, it's an incredibly more potent opioid being mixed in with the heroin. Fentanyl, a fast-acting pain relief narcotic, became headline news last week when it was reported as the cause of Prince's death in April. Authorities believe this drug is now circulating in Madison, causing the spike in overdoses.

"The [drug] user pool is pretty steady, and their needs are pretty steady, so there's something in the supply that's causing this," says Madison Police Lt. Jason Freedman, commander of the Dane County Narcotics Task Force. "What we believe is happening is that fentanyl or something akin to fentanyl is being introduced with more regularity and in a higher quantity with standard heroin."

Freedman says fentanyl's strength is its selling point with addicts. "The addicts will seek out the most potent source because, frankly, that's more bang for the buck — it's almost rational," Freedman says. "If I know my buddy got something that's super, super potent, I'm going to seek that out even if I know it's more dangerous."

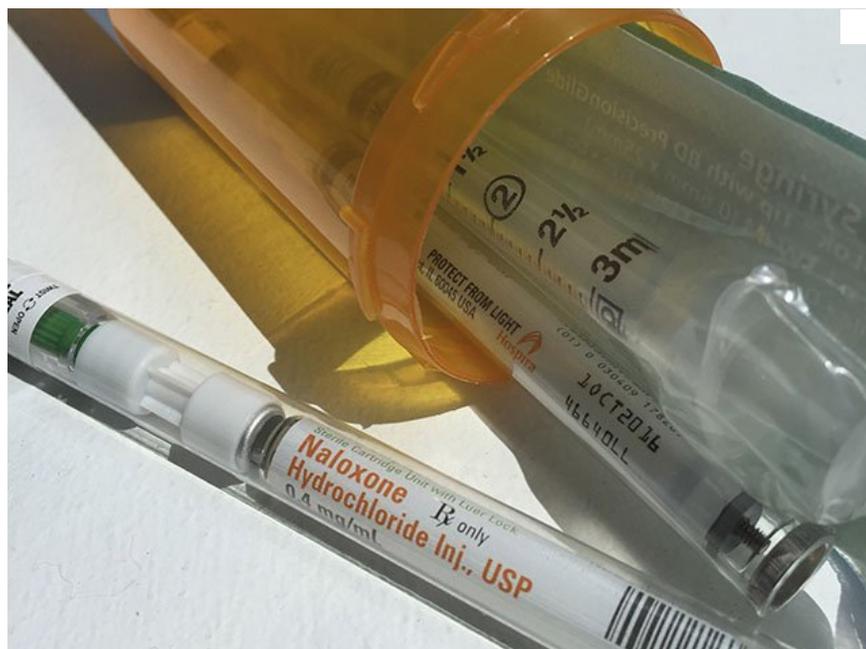
For about four years, paramedics have used fentanyl as a "go-to pain med," says Stedman. "We typically use it in pre-hospital [emergency situations] as a good pain control for our trauma patients."

"It's been used more predominantly in recent years because it doesn't mess with people's vital signs like morphine does," Stedman adds. "It's preferred because it's a cleaner drug."

But it's also much stronger, making it riskier to take recreationally. In October, the Centers for Disease Control warned public health agencies about an outbreak of fentanyl-laced heroin, stating it is "50-100 times more potent than morphine."

While local authorities believe fentanyl is causing the spike in overdoses, they aren't positive. Those who overdose on fentanyl typically need more Narcan to be revived.

"We can make a pretty reliable guess that these patients that we're giving two to three times more Narcan to is that it's likely because it's fentanyl-laced heroin," Stedman says. "But, we never know for sure."



CAROLYN FATH

Although overdoses are up, deaths are down, possibly due to increased availability of the antidote Narcan.

Freedman agrees that fentanyl-laced heroin is circulating in Madison. “If it looks like a duck, walks like a duck and sounds like a duck, it’s probably a duck,” he says.

The introduction of fentanyl-laced heroin to the already-ongoing opiate epidemic “is only driving things faster that are already going way too fast,” Freedman adds.

Other signals suggest a surge in fentanyl-laced heroin across the country. According to the federal Drug Enforcement Agency, fentanyl drug seizures have spiked. In 2012, fentanyl was confiscated 618 times, while just two years later, authorities seized it 4,585 times. About 80% of the drug was found in 10 states, including Ohio and Indiana in the Midwest.

Authorities suspect that fentanyl-laced heroin is being manufactured en masse by the drug cartels. “The vast majority of our heroin is coming from Chicago, and the vast majority of their heroin is coming from Mexico,” Freedman says. “So, the logical conclusion is that somewhere south of the border, at the point of manufacture, by the time it comes into the United States, it’s already been [mixed with fentanyl].”

Melissa Heinz, a supervisor with Public Health Madison & Dane County, says fentanyl is likely here to stay. “I think fentanyl in the heroin drug supply is the new normal,” she says. “I can’t imagine a reason why traffickers would move away from something that is so fabulously successful.”

This increases the need for prevention, treatment opportunities and Narcan availability, says Heinz, adding that “friends and family members should be prepared for the possibility [of an overdose] with an overdose response plan.”

Outreach groups, like the AIDS Resource Center of Wisconsin, work to provide such a plan. The center, which runs a needle exchange program to prevent the spread of communicable diseases, warns addicts about the potency of unknown narcotics.

“[We tell addicts] that if they’re purchasing the heroin from someone other than your usual source, do not do the same amount that you normally do from your regular source because of the purity issue,” says the center’s Scott Stokes.

He adds that the country has seen fentanyl before. “When we started the preventing fatal opiate overdose program, it was late 2005, and it was because there was a batch of heroin that was laced with fentanyl and there were 200 overdose deaths in the Midwest alone over the course of a weekend,” Stokes says.

Since 2006, ARCW’s fatal opiate overdose prevention program has trained more than 9,000 people how to administer naloxone — the drug in Narcan. The program is free, and those trained receive five doses of naloxone. Statewide, graduates of the program are credited with reviving 4,000 people who’ve overdosed since the program began, including 1,038 last year.

In Madison, naloxone is available for purchase at local pharmacies without a prescription. It ranges in price from \$40 to \$140, depending on the dosage and delivery device. It’s most commonly available as an injection but can also be given as a nasal spray, which is less effective.

Although overdoses might be on the rise, deaths associated with heroin are down locally. Fentanyl has been listed as a contributing factor in a handful of them, according to Barry Irmen, director of operations for the Dane County Medical Examiner’s Office.

In 2013, there were 40 deaths attributed to heroin. With four of those, fentanyl was considered as a possible factor. In 2015 and 2014, 26 and 29 deaths respectively were

caused by heroin, with fentanyl a factor only in one case each year. So far this year, there have been six deaths caused by heroin; in two of those fentanyl was found in the deceased's system.

Stedman fears there could be more because heroin use ramps up during summer.

"The highest months have always been July and August, and those [historically] have only been about 25 or 27 [opioid overdoses]," he says. "So, what we're afraid of right now is that if July is usually our highest month and we're already at 70 in April, what is that going to mean for July of 2016?"

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Narcan to the rescue

The Dane County District Attorney's office wants more people to have access to naloxone, better known by its trade name, Narcan, and recently began requiring addicts in the county's Opiate Initiative to train on how to use it.

Apr 29, 2015

Racial disparities persist in Wisconsin drug courts

Even before Dane County Circuit Judge Sarah O'Brien crunched the numbers, she knew something was amiss. Her strongest evidence: "The courtroom didn't look right when I walked in." O'Brien, who retired in 2012, was referring to the stark racial disparities in Dane County's drug court.

Aug 17, 2014

Young and sober: A thriving movement provides support for clean living in Madison

On a frigid December day in 2004, 17-year-old Aaron Meyer came home from drug and alcohol treatment. He'd already been to hell and back in his short life, but things were going to be different now. He felt alive with hope and possibility.

Apr 10, 2014

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Emergency room doctors dealing with more drug overdoses, including reactions to synthetic drugs

By Gordon Severson [CONNECT](#)
Posted: Jun 21, 2016 10:43 PM CDT
Updated: Jun 21, 2016 10:43 PM CDT

MADISON (WKOW)— The opiate epidemic has kept plenty of emergency room doctors on their toes in recent years. Many are seeing record-breaking amounts of fatal overdoses with users hooked on heroin and prescription medication.

Meanwhile, another drug is starting to become a problem for them as well. Doctors are seeing more patients coming in after taking synthetic drugs.

"These are sometimes sold in convenience stores where kids can just buy them, basically behind the counter," UW Health emergency room physician Dr. Aaron Kraut says.

Last week 27 News reported on a new statewide crackdown on synthetic drugs led by the Wisconsin Attorney General's Office and the Department of Justice.

Attorneys are currently pursuing a handful of cases, including a lawsuit filed earlier this month against a Madison convenience store owner. State officials say he's accused of selling packets of synthetic drugs at some of his 13 convenience store locations. Madison police seized more than 3,000 packets of these drugs in 2015 and conducted undercover buys nearly a year later at two of these locations.

"It's a real problem and we're seeing quite a bit of it here," Dr. Kraut says.

Over the last year or so, Kraut says he's dealt with more than a dozen cases of synthetic drug overdose. He hasn't seen any fatal overdoses here in Madison, but says back when he worked in Chicago he saw several serious cases while providing medical services at some of the massive musical festivals in downtown Chicago.

"Every year there would be two or three deaths, presumably linked to those synthetic agents," Dr. Kraut says.

These cases are difficult to deal with, because Kraut says the patients are often out of control. In many cases their actions pose a danger to themselves and several members of the medical staff.

There's also the added concern of treatment. Kraut says unlike opiates and heroin, there really isn't an antidote for these unpredictable synthetic drugs.

"We've got to make sure they're breathing okay, that their heart rate and blood pressure are alright, that their temperature is okay. Then we just give them loads and loads of medication to help them relax to make sure that we and the staff are safe," Dr. Kraut says.

Emergency room physicians at St. Mary's hospital have seen an increase in synthetic drug cases as well. Dr. Kyle Martin remembers one case in particular where a user had a severe, almost fatal reaction.

"A gentleman, who was running around the arboretum eating dirt, came in completely psychotic, was speaking in dragon at one point," Dr. Martin explains.

"His friend told us that he had taken some synthetic drugs."

Dr. Martin says there's an added concern when it comes to these synthetic drugs, because the users don't really know what they're getting. The potency ranges greatly since there are no regulations or oversight. He says the effects can range from a mild buzz, all the way up to a full on psychotic episode.

Doctors say the biggest concern right now is with the synthetic drug known as fentanyl, which is often added to heroin to make it even stronger. Madison Police say it can make the heroin up to ten times more potent. They say it's responsible for countless fatal overdoses across the country in recent months.

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1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: 5/26/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 6/7/16	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Update on the Wisconsin State Coalition for Prescription Drug Abuse Reduction – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the Wisconsin State Coalition for Prescription Drug Abuse Reduction.			

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4) Meeting Date: 6/7/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Controlled Substance Prescribing Guidelines (2015 Act 269) – Discussion and Consideration	
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10) Describe the issue and action that should be addressed: Discussion and consideration of Controlled Substances prescribing guidelines (2015 Act 269).			

State of Wisconsin



2015 Assembly Bill 660

Date of enactment: **March 17, 2016**

Date of publication*: **March 18, 2016**

2015 WISCONSIN ACT 269

AN ACT *to repeal* 448.05 (6) (at); *to renumber* 440.035; *to amend* 440.035 (title), 448.05 (6) (a), 448.07 (1) (b) and 452.12 (4); and *to create* 227.01 (13) (zk) and 440.035 (2m) of the statutes; **relating to:** guidelines for prescribing controlled substances and the examination authority of the Medical Examining Board.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 227.01 (13) (zk) of the statutes is created to read:

227.01 (13) (zk) Are guidelines issued under s. 440.035 (2m).

SECTION 2. 440.035 (title) of the statutes is amended to read:

440.035 (title) General duties and powers of examining boards and affiliated credentialing boards.

SECTION 3. 440.035 of the statutes is renumbered 440.035 (1m).

SECTION 4. 440.035 (2m) of the statutes is created to read:

440.035 (2m) The medical examining board, the podiatry affiliated credentialing board, the board of nursing, the dentistry examining board, or the optometry examining board may issue guidelines regarding best practices in prescribing controlled substances, as defined in s. 961.01 (4), for persons credentialed by that board who are authorized to prescribe controlled substances.

SECTION 5. 448.05 (6) (a) of the statutes, as affected by 2013 Wisconsin Act 240, is amended to read:

448.05 (6) (a) Except as provided in pars. (am), and (ar), ~~and (at)~~, the board shall examine each applicant it

finds eligible under this section in such subject matters as the board deems applicable to the class of license or certificate which the applicant seeks to have granted. Examinations may be both written and oral. In lieu of its own examinations, in whole or in part, the board may make such use as it deems appropriate of examinations prepared, administered, and scored by national examining agencies, or by other licensing jurisdictions of the United States or Canada. The board shall specify passing grades for any and all examinations required.

SECTION 6. 448.05 (6) (at) of the statutes, as created by 2013 Wisconsin Act 240, is repealed.

SECTION 7. 448.07 (1) (b) of the statutes is amended to read:

448.07 (1) (b) The board shall maintain the register required by s. 440.035 (4) (1m) (d), which shall be divided according to the activity for which the registrant is licensed or certified. The board shall make copies available for purchase at cost.

SECTION 8. 452.12 (4) of the statutes is amended to read:

452.12 (4) REGISTER OF BROKERS AND SALESPERSONS. The board shall include in the register the board maintains under s. 440.035 (4) (1m) (d) the names of all brokers and salespersons whose licenses were revoked

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

within the past 2 years. The register shall be available for purchase at cost.

shall be determined by the controlled substances board but shall not exceed \$5.

(6) Persons who possess a valid permit issued under this section are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

(7) The controlled substances board may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative or other proceeding to identify or to identify to the board the individuals who are the subjects of research for which the authorization was obtained.

(8) The controlled substances board may promulgate rules relating to the granting of special use permits including, but not limited to, requirements for the keeping and disclosure of records other than those that may be withheld under sub. (7), submissions of protocols, filing of applications and suspension or revocation of permits.

Cross-reference: See also ch. CSB 3, Wis. adm. code.

(9) The controlled substances board may suspend or revoke a permit upon a finding that there is a violation of the rules of the board.

History: 1971 c. 219; 1975 c. 110, 199; 1977 c. 26; 1995 a. 448 s. 233; Stats. 1995 s. 961.335; 2013 a. 198; 2015 a. 298.

961.337 Drug disposal programs. Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:

(1) The direct operation or implementation of a drug disposal program that is authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a).

(2) The transfer by the ultimate user, or by another person that lawfully possesses the controlled substance or controlled substance analog, of a controlled substance or controlled substance analog to a drug disposal program that has been authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a), and that accepts the controlled substance or controlled substance analog.

History: 2013 a. 198.

961.34 Controlled substances therapeutic research.

(1) Upon the request of any practitioner, the controlled substances board shall aid the practitioner in applying for and processing an investigational drug permit for marijuana under 21 USC 355 (i). If the federal food and drug administration issues an investigational drug permit, the controlled substances board shall approve which pharmacies can distribute the marijuana to patients upon written prescription. Only pharmacies located within hospitals are eligible to receive the marijuana for distribution. The controlled substances board shall also approve which practitioners can write prescriptions for the marijuana.

(2) (a) Upon the request of any physician, the controlled substances board shall aid the physician in applying for and processing an investigational drug permit under 21 USC 355 (i) for cannabidiol as treatment for a seizure disorder. If the federal food and drug administration issues an investigational drug permit, the controlled substances board shall approve which pharmacies and physicians may dispense cannabidiol to patients.

(b) If cannabidiol is removed from the list of controlled substances, or if cannabidiol is determined not to be a controlled substance, under schedule I of 21 USC 812 (c), the controlled substances board shall approve which pharmacies and physicians may dispense cannabidiol to patients as treatment for a seizure disorder.

History: 1981 c. 193; 1983 a. 189 s. 329 (18); 1985 a. 146 s. 8; 1995 a. 448 ss. 16 to 19; Stats. 1995 s. 961.34; 2013 a. 267.

Reefer Madness: Lighting Up in the Dairyland. Bailey. Wis. Law. Nov. 2014.

961.36 Controlled substances board duties relating to diversion control and prevention, compliance with controlled substances law and advice and assistance.

(1) The controlled substances board shall regularly prepare and make available to state regulatory, licensing and law enforcement agencies descriptive and analytic reports on the potential for diversion and actual patterns and trends of distribution, diversion and abuse within the state of certain controlled substances the board selects that are listed in s. 961.16, 961.18, 961.20 or 961.22.

(1m) At the request of the department of safety and professional services or a board, examining board or affiliated credentialing board in the department of safety and professional services, the controlled substances board shall provide advice and assistance in matters related to the controlled substances law to the department or to the board, examining board or affiliated credentialing board in the department making the request for advice or assistance.

(2) The controlled substances board shall enter into written agreements with local, state and federal agencies to improve the identification of sources of diversion and to improve enforcement of and compliance with this chapter and other laws and regulations pertaining to unlawful conduct involving controlled substances. An agreement must specify the roles and responsibilities of each agency that has information or authority to identify, prevent or control drug diversion and drug abuse. The board shall convene periodic meetings to coordinate a state diversion prevention and control program. The board shall assist and promote cooperation and exchange of information among agencies and with other states and the federal government.

(3) The controlled substances board shall evaluate the outcome of its program under this section and shall annually submit a report to the chief clerk of each house of the legislature, for distribution to the legislature under s. 13.172 (3), on its findings with respect to its effect on distribution and abuse of controlled substances, including recommendations for improving control and prevention of the diversion of controlled substances.

History: 1981 c. 200; 1987 a. 186; 1995 a. 305 ss. 2, 3; 1995 a. 448 s. 234; Stats. 1995 s. 961.36; 1997 a. 35 s. 339; 2011 a. 32.

961.37 Law enforcement duty. (1) A law enforcement officer shall report as provided in sub. (2) if the law enforcement officer, while acting in an official capacity, does any of the following:

(a) Encounters a situation in which the law enforcement officer reasonably suspects that a violation of this chapter involving a monitored prescription drug, as defined in s. 961.385 (1) (ag), is occurring or has occurred.

(b) Encounters an individual who the law enforcement officer believes is undergoing or has immediately prior experienced an opioid-related drug overdose, as defined in s. 256.40 (1) (d), or a deceased individual who the law enforcement officer believes died as a result of using a narcotic drug.

(c) Receives a report of a stolen controlled-substance prescription.

(2) A law enforcement officer under sub. (1) shall report to the law enforcement agency that employs him or her all of the following:

(a) The name and date of birth of all of the following, if applicable:

1. The individual who is suspected of violating this chapter.
2. The individual who experienced an opioid-related drug overdose.
3. The individual who died as a result of using a narcotic drug.
4. The individual who filed the report of a stolen controlled-substance prescription.

5. The individual for whom a prescription drug related to an event under subd. 1., 2., 3., or 4. was prescribed.

Wisconsin Opioid Prescribing Guideline Draft

Scope and purpose of the guideline: To help providers make informed decisions about acute and chronic pain treatment -pain lasting longer than three months or past the time of normal tissue healing. The guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care. Although not specifically designed for pediatric pain, many of the principals upon which they are based could be applied there, as well.

Opioids pose a potential risk to all patients. The guideline encourages providers to implement best practices for responsible prescribing which includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients.

1) Identify and treat the cause of the pain, use non-opioid therapies

Use non-pharmacologic therapies (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) and non-opioid pharmacologic therapies (such as acetaminophen and anti-inflammatories) for acute and chronic pain. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

2) Start low and go slow

When opioids are used, prescribe the lowest possible effective dosage and start with immediate-release opioids instead of extended-release/long-acting opioids. Only provide the quantity needed for the expected duration of pain.

3) Close follow-up

Regularly monitor patients to make sure opioids are improving pain and function without causing harm. If benefits do not outweigh harms, optimize other therapies and work with patients to taper or discontinue opioids, if needed.

What's included in the guideline?

The guideline addresses patient-centered clinical practices including conducting thorough assessments, considering all possible treatments, treating the cause of the pain, closely monitoring risks, and safely discontinuing opioids. The three main focus areas in the guideline include:

1) Determining when to initiate or continue opioids

- Selection of non-pharmacologic therapy, non-opioid pharmacologic therapy, opioid therapy
- Establishment of treatment goals
- Discussion of risks and benefits of therapy with patients

2) Opioid selection, dosage, duration, follow-up and discontinuation

- Selection of immediate-release or extended-release and long-acting opioids
- Dosage considerations
- Duration of treatment
- Considerations for follow-up and discontinuation of opioid therapy

3) Assessing risk and addressing harms of opioid use

- Evaluation of risk factors for opioid-related harms and ways to mitigate/reduce patient risk
- Review of prescription drug monitoring program (PDMP) data
- Use of urine drug testing
- Considerations for co-prescribing benzodiazepines
- Arrangement of treatment for opioid use disorder

Opioid Guideline Outline

1. Pain is a subjective experience and at present, physicians lack options to objectively quantify pain severity other than by patient reported measures including pain intensity. While accepting the patient's report of pain, the clinician must simultaneously decide if the magnitude of the pain complaint is commensurate with causative factors and if these have been adequately evaluated and addressed with non-opioid therapy.

2. In treating acute pain, if opioids are at all indicated, the lowest dose and fewest number of opioid pills needed should be prescribed. In most cases, less than 3 days' worth are necessary, and rarely more than 5 days' worth. Left-over pills in medicine cabinets are often the source for illicit opioid abuse in teens and young adults.

3. A practitioner's first priority in treating a patient in pain is to identify the cause of the pain and, if possible, to treat it. While keeping the patient comfortable during this treatment is important, it is critical to address to the extent possible the underlying condition as the primary objective of care.

- a. Patients unwilling to obtain definitive treatment for the condition causing their pain should be considered questionable candidates for opioids. If opioids are prescribed to such patients, documentation of clear clinical rationale should exist.
- b. Opioids should not be prescribed unless there is a medical condition present which would reasonably be expected to cause pain severe enough to require an opioid. For conditions where this is questionable, use of other treatments instead of opioids should be strongly considered.
- c. Consultation should be considered if diagnosis of and/or treatment for the condition causing the pain is outside of the scope of the prescribing practitioner.

4. Opioids should not necessarily be the first choice in treating acute or chronic pain.

- a. Acute pain: Evidence for opioids is weak. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments should be attempted prior to initiating opioid therapy. Although opioids could be simultaneously prescribed if it is apparent from the patient's condition that he/she will need opioids in addition to these. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.
- b. Acute pain lasting beyond the expected duration: A complication of the acute pain issue (surgical complication, nonunion of fracture, etc.) should be ruled out. If complications are ruled out, a transition to non-opioid therapy (tricyclic antidepressant, serotonin/norepinephrine re-uptake inhibitor, anticonvulsant, etc.) should be attempted.
- c. Chronic pain: Evidence for opioids is poor. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) should be utilized. Multiple meta-analyses demonstrate that the benefits of opioids are slight, while annualized mortality rates dramatically increased. There are few if any treatments in medicine with this poor a risk/benefit ratio, and there should be adequate clinical indication to indicate why chronic opioid therapy was chosen in a given patient. Note: There is no high-quality evidence to support opioid therapy longer than 6 months in duration. Despite this fact, it is considered acceptable although not preferable to continue patients on treatment who have been on chronic opioid therapy prior to this Guideline's release and who have shown no evidence of aberrant behavior.

- d. Patients unwilling to accept non-pharmacological and/or nonnarcotic treatments (or those providing questionably credible justifications for not using them) should not be considered candidates for opioid therapy.

5. Prescribing of opioids is discouraged in patients concurrently taking benzodiazepines or other respiratory depressants. Benzodiazepines triple the already extremely high increases in annual mortality rates from opioids. If they are used concurrently, clear clinical rationale must exist.

6. The use of oxycodone is discouraged. There is no evidence to support that oxycodone is more effective than other oral opioids, while there are multiple studies indicating that oxycodone is more abused and has qualities that would promote addiction to a greater degree than other opioids. As a result, oxycodone should not be considered first-line and should be used only in patients who cannot tolerate other opioids and who have been evaluated for and found not to demonstrate increased risk of abuse.

7. Patients presenting for chronic pain treatment should have a thorough evaluation, which may include the following:

- a. Medical history and physical examination targeted to the pain condition
- b. Nature and intensity of the pain
- c. Current and past treatments, with response to each treatment
- d. Underlying or co-existing diseases or conditions, including those which could complicate treatment (i.e., renal disease, sleep apnea, COPD, etc.)
- e. Effect of pain on physical and psychological functioning
- f. Personal and family history of substance abuse
- g. History of psychiatric disorders associated with opioid abuse (bipolar, ADD/ADHD, sociopathic, borderline, untreated/severe depression)
- h. Medical indication(s) for use of opioids.

8. Initiation of opioids for chronic pain should be considered on a trial basis. Prior to starting opioids, objective symptomatic and functional goals should be established with the patient. If after a reasonable trial these goals are not met, then opioids should be weaned or discontinued.

9. Practitioners should always consider the risk-benefit ratio when deciding whether to start or continue opioids. Risks and benefits should be discussed with patients prior to initiating chronic opioid therapy, and continue to be reassessed during that therapy. If evidence of increased risk develops, weaning or discontinuation of opioid should be considered. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be discontinued and the patient should be treated for withdrawal, if needed.

- a. Exceptions to this include patients with unstable angina and pregnant patients, especially in the 3rd trimester (withdrawal could precipitate pre-term labor).
- b. Components of ongoing assessment of risk include:
 - i. Review of the Prescription Drug Monitoring Program (PDMP) information
 - ii. Periodic urine drug testing – at least yearly in low risk cases, more frequently if evidence of increased risk (including chromatography) is strongly recommended
 - iii. Periodic pill counts – at least yearly and low risk cases, more frequently if evidence of increased risk
 - iiii. Violations of the opioid agreement

10. All patients on chronic opioid therapy should have informed consent consisting of:

- a. Specifically detailing significant possible adverse effects of opioids, including (but not limited to) addiction, overdose, and death
- b. Treatment agreement, documenting the behaviors required of the patient by the prescribing practitioner to ensure that they are remaining safe from these adverse effects

11. Initial dose titration for both acute and chronic pain should be with short-acting opioids. For chronic therapy, it would be appropriate once an effective dose is established to consider long-acting agents for a majority of the daily dose.

12. Opioids should be prescribed in the lowest effective dose. This includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients. If daily doses for chronic pain reach 50 morphine milligram equivalents (MMEs), additional precautions should be implemented (see #7.b. above). Given that there is no evidence base to support efficacy of doses over 90 MMEs, with dramatically increased risks, dosing above this level is strongly discouraged, and clear and compelling documentation to support such dosing should be present on the chart.

13. The use of methadone is not encouraged unless the practitioner has extensive training or experience in its use. Individual responses to methadone vary widely; a given dose may have no effect on one patient while causing overdose in another. Metabolism also varies widely and is highly sensitive to multiple drug interactions, which can cause accumulation in the body and overdose. For a given analgesic effect, the respiratory depressant effect is much stronger compared to other opioids. Finally, methadone can have a potent effect on prolonging the QTc, predisposing susceptible patients to potentially fatal arrhythmias.

14. Prescribing of opioids is very strongly discouraged for patients abusing illicit drugs. These patients are at extremely high risk for abuse, overdose, and death. If opioids are prescribed to such patients, a clear and compelling justification should be present.

15. During initial opioid titration, practitioners should re-evaluate patients every 1-4 weeks. During chronic therapy, patients should be seen at least every 3 months, more frequently if they demonstrate higher risk.

16. Practitioners should consider prescribing naloxone for home use in case of overdose for patients at higher risk, including:

- a. History of overdose (a relative contraindication to chronic opioid therapy)
- b. Opioid doses over 50 MMEs/day
- c. Clinical depression
- d. Evidence of increased risk by other measures (behaviors, family history, PDMP, UDS, risk questionnaires, etc.)

The recommended dose is 0.4 mg for IM or intranasal use, with a second dose available if the first is ineffective or wears off before EMS arrives. Family members can be prescribed naloxone for use with the patient.

17. All practitioners are expected to provide care for potential complications of the treatments they provide, including opioid use disorder. As a result, if a patient receiving opioids develops behaviors indicative of opioid use disorder, the practitioner should be able to assist the patient in obtaining addiction treatment, either by providing it directly (buprenorphine, naltrexone, etc. plus behavioral therapy) or referring them to an addiction treatment center which is willing to accept the patient. Simply discharging a patient from the provider's practice after prescribing the medication that led to the complication of opioid use disorder is not considered acceptable.

18. Discontinuing Opioid Therapy

A. If lack of efficacy of opioid therapy is determined discontinuation of therapy should be performed.

1. Opioid weaning can be performed by reducing the MED by 10% weekly until 5-10mg MED remain at which time the opioid can be fully discontinued
2. Prescription of clonidine 0.2 mg po BID or tizanidine 2mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.

B. If evidence of increased risk develops, weaning or discontinuation of opioid should be considered.

1. Opioid weaning can be performed by reducing the MED by 25% weekly until 5-10mg MED remain at which time the opioid can be fully discontinued
2. Prescription of clonidine 0.2 mg po BID or tizanidine 2mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.
3. Physicians can consider weekly or bi-monthly follow-up during the weaning process

C. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be immediately discontinued and the patient should be treated for withdrawal, if needed.

1. Exceptions to abrupt opioid discontinuation include patients with unstable angina and pregnant patients. These patients should be weaned from the opioid medications in a gradual manner with close follow-up

Draft of the Wisconsin Opioid Prescribing Guideline for the Emergency Department, Urgent Care and Procedural Settings

1. A physician's first priority in treating a patient in pain is to identify the cause of the pain and, if possible, to treat it. While keeping the patient comfortable during this treatment is important, it is critical to address to the extent possible the underlying condition as the primary objective of care. Physicians should base treatment on their clinical judgement, and appropriate pain management frequently does not require the use of opioids.
2. In treating acute illness or injury, opioid analgesics should not be first-line therapy, but may be appropriate after the use of non-opioid management has been optimized.
3. Pain from acute trauma or chronic degenerative diseases can usually be managed without opioids prior to surgery. Surgical patients using opioids preoperatively have higher complications rates, require more narcotics postoperatively, and have lower satisfaction rates with poorer outcomes following surgery.
4. If opioids are at all indicated, the lowest dose and fewest number of opioid pills needed should be prescribed. In most cases, less than 3 days' worth are necessary, and should be written for the lowest dose that is effective. It is also recommended to write 2 separate prescriptions for smaller amounts of opioids with specific refill dates, rather than a single large prescription. Most patients do not fill the second prescription, so this strategy limits potential opioid leftovers and misuse.
5. Oxycodone, hydromorphone, and methadone have high abuse potential and the physician should consider using non-narcotics such as anti inflammatories, acetaminophen, or tramadol.
6. Patients should not receive opioid prescriptions from multiple physicians. ED/urgent care physicians should, in general, not prescribe opioids for chronic pain. A dedicated provider outside the ED/urgent care setting such as a primary care or pain specialist should provide all opioids to treat any patient's chronic pain.
7. Patients with chronic non-cancer pain should not receive IV or IM opioid injections in the ED/urgent care for chronic pain conditions.
8. For emergency/urgent care physicians and in treating procedural pain, it is best practice to not prescribe long acting opioid agents such as oxycontin, extended release morphine or methadone.
9. Emergency/urgent care physicians should not replace lost or stolen prescriptions for controlled substances.

10. Emergency/urgent care physicians should not fill prescriptions for patients who have run out of controlled substances. Refills are to be arranged with the primary care or specialist prescribing physician.
11. Accessing PDMP data prior to prescribing is required by state law in cases where more than 3 days worth of controlled substances are written. It is also best practice to check the PDMP if there are any questions or concerns about use or abuse.
12. Opioid pain medication use is not encouraged for dental and back pain whether acute or chronic. Non-opioid alternatives such as dental block and/or non-steroidal anti-inflammatory drugs are available.
13. Opioid pain medications are not best practice in treating migraines, gastro-paresis and chronic abdominal or pelvic pain.
14. Physicians should consider drug screening as needed to guide treatment decisions.
15. Patients with suspected opioid use disorder-like behavior should be referred to the appropriate available psychiatric crisis service or other treatment/detoxification resources.
16. Patients suspected of multiple visits for pain, problematic or dishonest behavior (abusive, altering prescriptions, false reports) or use of multiple hospitals/physicians for pain can be reviewed and the patient notified that they will no longer be provided opioids in the ED.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: 5/26/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 6/7/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? DEA Registration Requirement Guidance – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of WVMA’s request for guidance regarding DEA registration requirements and record keeping obligations.			

Please respond to: Capitol Square Office
Direct line: 608-252-9358
Email: jkl@dewittross.com

April 26, 2016

VIA FIRST CLASS MAIL & EMAIL (Chad.Zadrazil@wisconsin.gov)

Mr. Chad Zadrazil, Executive Director
Wisconsin Controlled Substances Board
Department of Safety and Professional Services
1400 East Washington Avenue, Room 121B
PO Box 8366
Madison, WI 53708

RE: Request for Guidance on Controlled Substance Act & Applicable DEA Registration Requirements

Dear Mr. Zadrazil:

I am writing on behalf of the Wisconsin Veterinary Medical Association ("WVMA") to ask for clarification for WVMA members regarding several Drug Enforcement Administration ("DEA") registration requirements and record keeping obligations for controlled substances under Wisconsin law.

The WVMA respectfully requests that the Controlled Substances Board provide guidance with respect to the following three issues:

1. Whether Wis. Stat. § 961.32, Wisconsin's Controlled Substances Act, requires every licensed Wisconsin veterinarian who "administers" or "dispenses" a controlled substance (other than by issuance of a prescription) to obtain his/her own DEA registration?
2. Whether, under Wisconsin law, a Wisconsin veterinary hospital/clinic may obtain its own DEA registration? In other words, in Wisconsin, may a veterinary clinic obtain a clinic DEA registration number?
3. Does Wisconsin law specify how long a licensed Wisconsin veterinarian is required to maintain logs of controlled substances that he/she administers, dispenses, or prescribes? If not, what law does control in Wisconsin with regard to maintenance or retention of these logs?

Mr. Chad Zadrazil, Executive Director
Controlled Substances Board
Department of Safety and Professional Services
April 26, 2016
Page 2

We realize that responding to one or more of these questions may require contacting DEA or coordinating your response with DEA. However, because we have struggled with getting guidance from DEA on these issues recently, we are directing them to you.

I appreciate your time and attention to these important regulatory matters affecting veterinary professionals in Wisconsin. Please do not hesitate to contact me directly at (608) 252-9358 if you have questions regarding any of the issues raised in this letter.

Very truly yours,

DeWitt Ross & Stevens s.c.



Jordan K. Lamb

JKL:jav

cc: Kim Brown Pokorny, Executive Director, WVMA (via email: kpokorny@wvma.org)

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

AGENDA REQUEST FORM

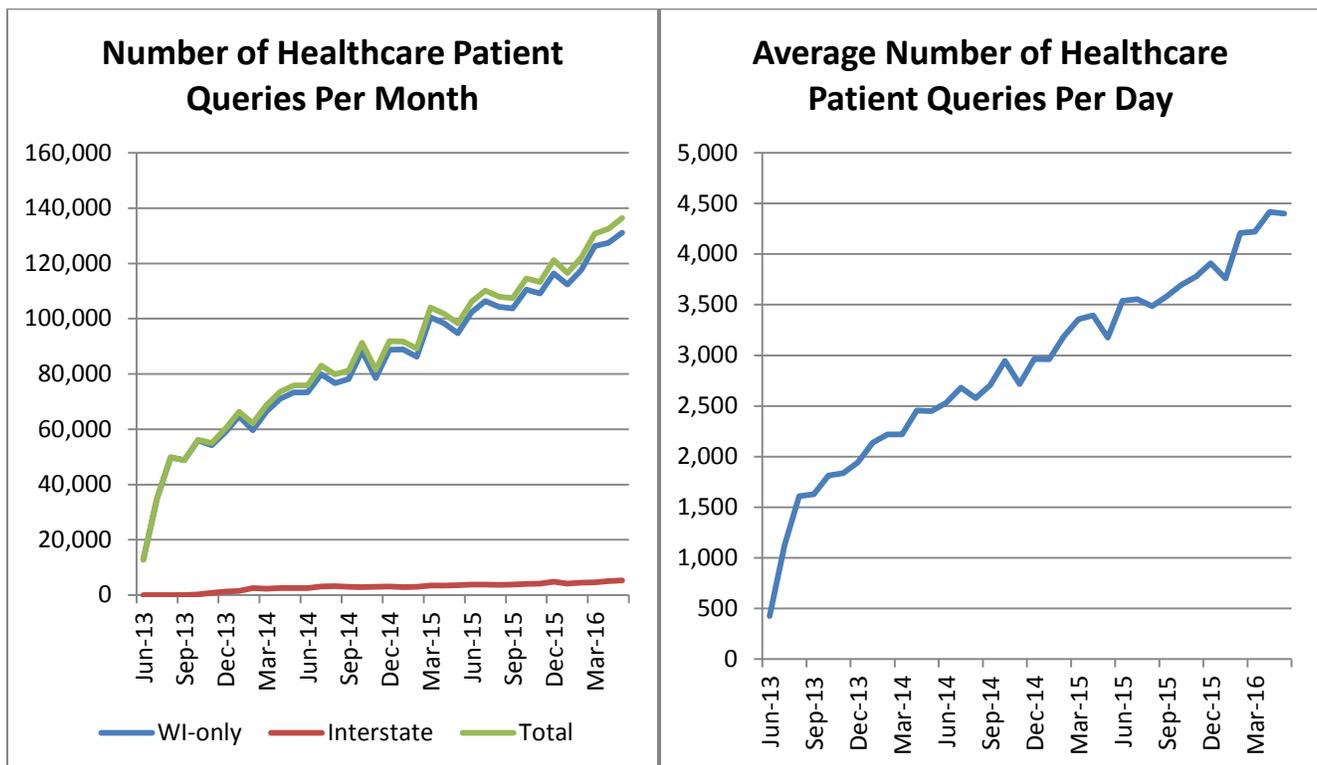
1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: 5/26/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 6/7/16	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 Operations – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the current PDMP. <ul style="list-style-type: none"> • Operational Statistics • Pharmacy compliance/renewal • Act 268 update 			



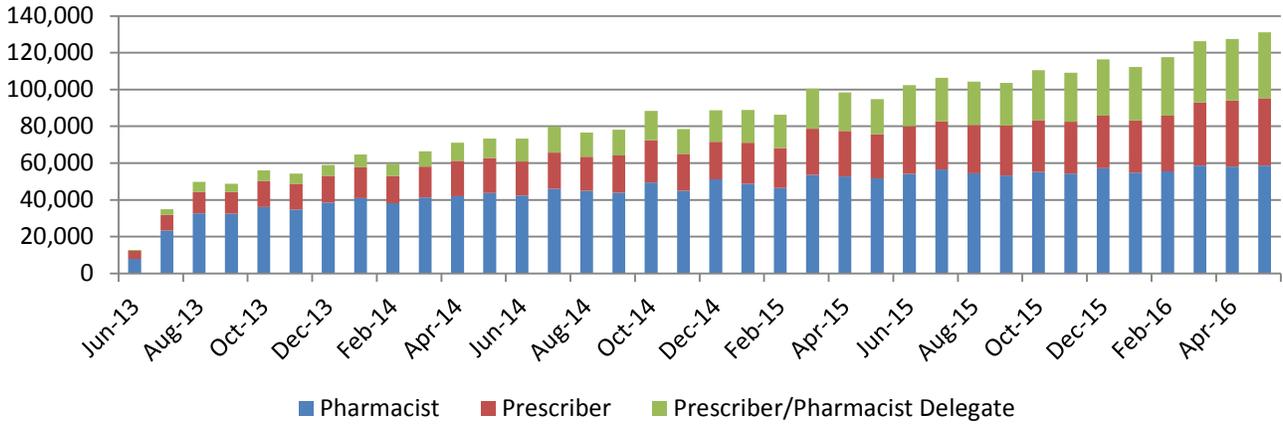
Operational Statistics of the WI PDMP

Compiled on June 1, 2016

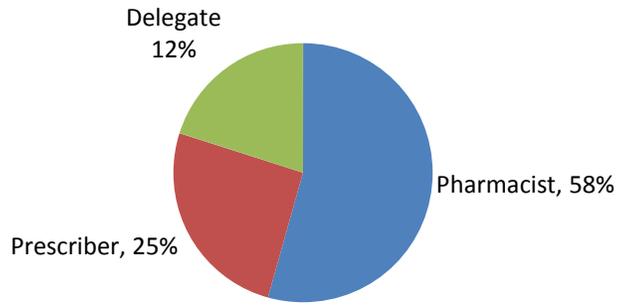
- Approximately 37 million R_x records in the database
- Approximately 1,800 dispensers actively submitting data
- Approximately 15,600 healthcare users have query accounts
- Healthcare users have created over 3 million recipient queries since June 1, 2013
 - In addition, healthcare users have created approximately 102,000 interstate queries since October 1, 2013
- Healthcare Users have initiated nearly 1,600 PDMP Alerts since July 1, 2013



Healthcare Patient Queries Performed by User Group

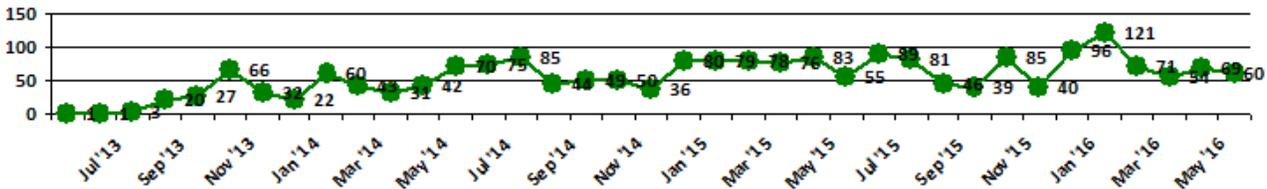


Healthcare Patient Queries Performed by User Group



- Approximately 200 law enforcement and government users with query accounts.
- Law enforcement and government requests:

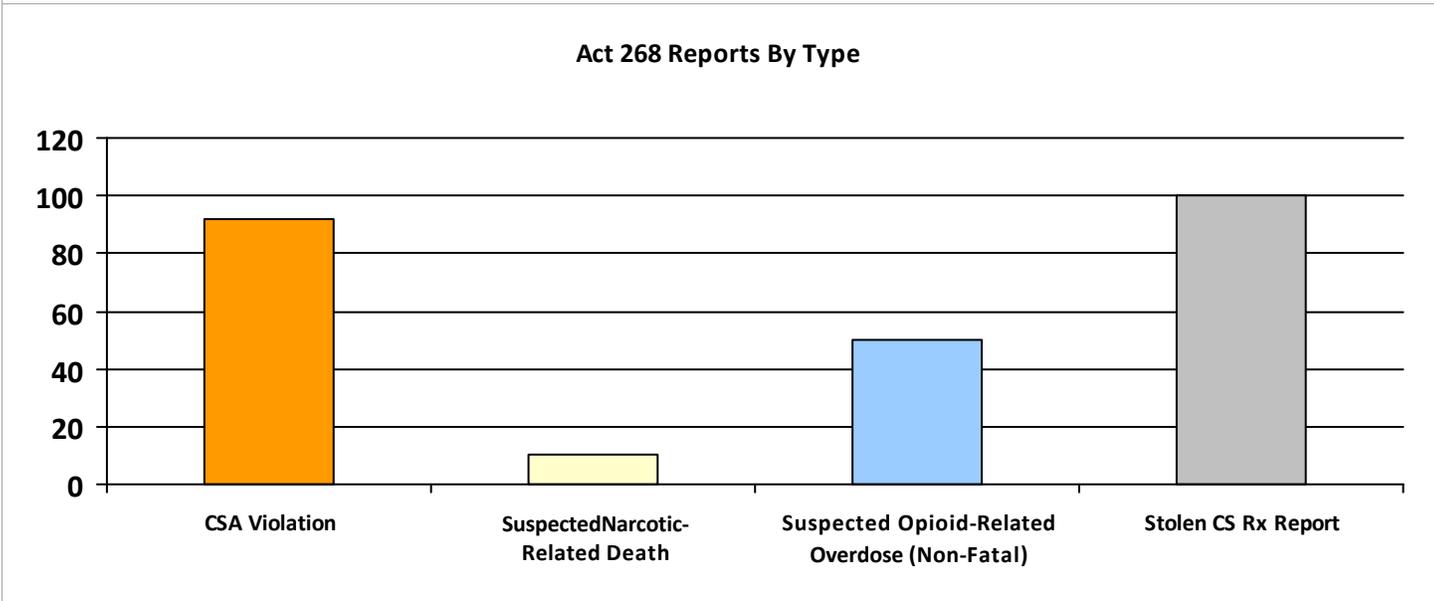
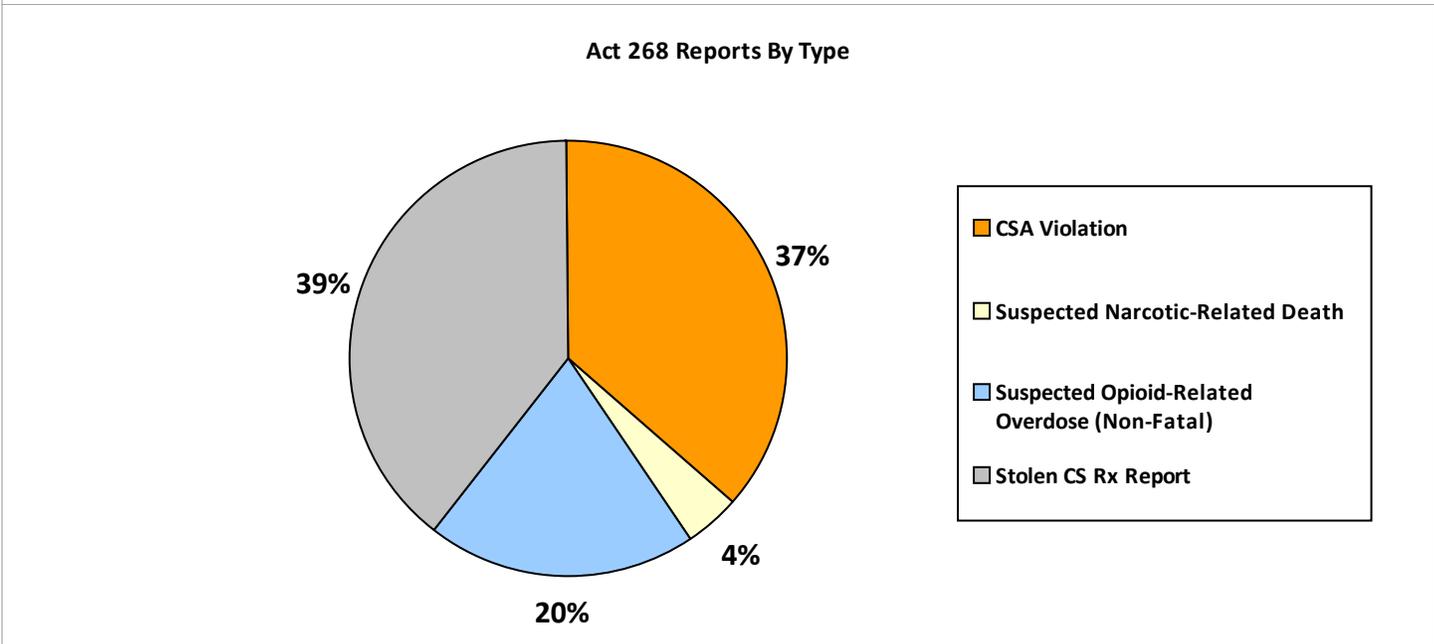
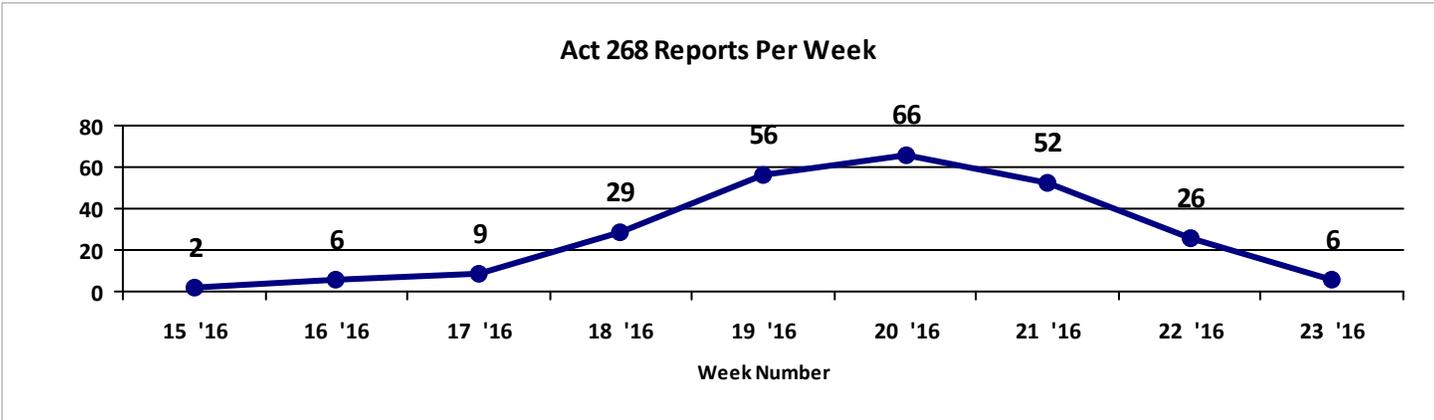
Requests By Month





Act 268 Reports

Total Act 268 Reports Submitted: **252** as of: 6/1/2016



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

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3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 7/13/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PMPi Release – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the release about the PMP InterConnect from the National Association of Boards of Pharmacy.			



News Release

FOR IMMEDIATE RELEASE

June 16, 2016

**For more information contact:
Amy Suhajda, Communications Manager
847/391-4405; custserv@nabp.net**

NABP PMP InterConnect Will Remain Free to Participating States Past 2018

The National Association of Boards of Pharmacy® (NABP®) is pleased to announce that it will provide state prescription monitoring programs (PMPs) with access to NABP's PMP InterConnect® at no cost so states can focus their resources and federal grants to support PMP operations.

Currently, 42 states have executed memorandums of understanding to be part of PMP InterConnect, 33 PMPs are active, and 40 states are expected to be active by the end of 2016. PMPs supply health care providers and appropriate law enforcement agencies with access to a record of patients' controlled substance medication histories. PMP InterConnect enhances the benefits of state PMPs by allowing authorized users in the United States to access PMP data from across state lines, for a more complete patient record.

"NABP PMP InterConnect is the only national network of state-based PMPs. It furthers the mission of the boards of pharmacy and NABP, as well as other state agencies, to protect public health by assisting health care providers in identifying doctor shopping and diversion of controlled substances, as well as confirming which patients are legitimately receiving such prescriptions," notes NABP President Hal Wand, MBA, RPh.

(— more —)

*National Association of Boards of Pharmacy • 1600 Feehanville Drive • Mount Prospect, IL 60056-6014
847/391-4406 • (F) 847/391-4502 • www.nabp.net*

The commitment by NABP to fully support PMP InterConnect will remove any resource roadblocks that states face to identifying patients with prescription drug abuse and misuse problems, especially if those patients are crossing state lines to obtain drugs. Participating state PMPs that use this highly secure communications exchange platform (which does not store data) have access to information that can be an effective means of combating drug diversion and drug abuse nationwide.

Launched in 2011, PMP InterConnect is currently processing more than 2.7 million requests and 4.5 million responses per month for consolidated multistate PMP reports. For more information about PMP InterConnect, visit the Programs section of the NABP website.

NABP is the independent, international, and impartial Association that assists its state member boards and jurisdictions for the purpose of protecting the public health.

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

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4) Meeting Date: 6/7/16	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? ePDMP Development Update – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the development of the ePDMP. <ul style="list-style-type: none"> • ASAP format Identification • Promotion • Demonstration 			

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

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4) Meeting Date: 6/7/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Annual and Quarterly Reports – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the annual Board report requirements of 961.36 and quarterly PDMP report requirements of 961.385 (5) and (6).			

shall be determined by the controlled substances board but shall not exceed \$5.

(6) Persons who possess a valid permit issued under this section are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

(7) The controlled substances board may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative or other proceeding to identify or to identify to the board the individuals who are the subjects of research for which the authorization was obtained.

(8) The controlled substances board may promulgate rules relating to the granting of special use permits including, but not limited to, requirements for the keeping and disclosure of records other than those that may be withheld under sub. (7), submissions of protocols, filing of applications and suspension or revocation of permits.

Cross-reference: See also ch. CSB 3, Wis. adm. code.

(9) The controlled substances board may suspend or revoke a permit upon a finding that there is a violation of the rules of the board.

History: 1971 c. 219; 1975 c. 110, 199; 1977 c. 26; 1995 a. 448 s. 233; Stats. 1995 s. 961.335; 2013 a. 198; 2015 a. 298.

961.337 Drug disposal programs. Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:

(1) The direct operation or implementation of a drug disposal program that is authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a).

(2) The transfer by the ultimate user, or by another person that lawfully possesses the controlled substance or controlled substance analog, of a controlled substance or controlled substance analog to a drug disposal program that has been authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a), and that accepts the controlled substance or controlled substance analog.

History: 2013 a. 198.

961.34 Controlled substances therapeutic research.

(1) Upon the request of any practitioner, the controlled substances board shall aid the practitioner in applying for and processing an investigational drug permit for marijuana under 21 USC 355 (i). If the federal food and drug administration issues an investigational drug permit, the controlled substances board shall approve which pharmacies can distribute the marijuana to patients upon written prescription. Only pharmacies located within hospitals are eligible to receive the marijuana for distribution. The controlled substances board shall also approve which practitioners can write prescriptions for the marijuana.

(2) (a) Upon the request of any physician, the controlled substances board shall aid the physician in applying for and processing an investigational drug permit under 21 USC 355 (i) for cannabidiol as treatment for a seizure disorder. If the federal food and drug administration issues an investigational drug permit, the controlled substances board shall approve which pharmacies and physicians may dispense cannabidiol to patients.

(b) If cannabidiol is removed from the list of controlled substances, or if cannabidiol is determined not to be a controlled substance, under schedule I of 21 USC 812 (c), the controlled substances board shall approve which pharmacies and physicians may dispense cannabidiol to patients as treatment for a seizure disorder.

History: 1981 c. 193; 1983 a. 189 s. 329 (18); 1985 a. 146 s. 8; 1995 a. 448 ss. 16 to 19; Stats. 1995 s. 961.34; 2013 a. 267.

Reefer Madness: Lighting Up in the Dairyland. Bailey. Wis. Law. Nov. 2014.

961.36 Controlled substances board duties relating to diversion control and prevention, compliance with controlled substances law and advice and assistance.

(1) The controlled substances board shall regularly prepare and make available to state regulatory, licensing and law enforcement agencies descriptive and analytic reports on the potential for diversion and actual patterns and trends of distribution, diversion and abuse within the state of certain controlled substances the board selects that are listed in s. 961.16, 961.18, 961.20 or 961.22.

(1m) At the request of the department of safety and professional services or a board, examining board or affiliated credentialing board in the department of safety and professional services, the controlled substances board shall provide advice and assistance in matters related to the controlled substances law to the department or to the board, examining board or affiliated credentialing board in the department making the request for advice or assistance.

(2) The controlled substances board shall enter into written agreements with local, state and federal agencies to improve the identification of sources of diversion and to improve enforcement of and compliance with this chapter and other laws and regulations pertaining to unlawful conduct involving controlled substances. An agreement must specify the roles and responsibilities of each agency that has information or authority to identify, prevent or control drug diversion and drug abuse. The board shall convene periodic meetings to coordinate a state diversion prevention and control program. The board shall assist and promote cooperation and exchange of information among agencies and with other states and the federal government.

(3) The controlled substances board shall evaluate the outcome of its program under this section and shall annually submit a report to the chief clerk of each house of the legislature, for distribution to the legislature under s. 13.172 (3), on its findings with respect to its effect on distribution and abuse of controlled substances, including recommendations for improving control and prevention of the diversion of controlled substances.

History: 1981 c. 200; 1987 a. 186; 1995 a. 305 ss. 2, 3; 1995 a. 448 s. 234; Stats. 1995 s. 961.36; 1997 a. 35 s. 339; 2011 a. 32.

961.37 Law enforcement duty. (1) A law enforcement officer shall report as provided in sub. (2) if the law enforcement officer, while acting in an official capacity, does any of the following:

(a) Encounters a situation in which the law enforcement officer reasonably suspects that a violation of this chapter involving a monitored prescription drug, as defined in s. 961.385 (1) (ag), is occurring or has occurred.

(b) Encounters an individual who the law enforcement officer believes is undergoing or has immediately prior experienced an opioid-related drug overdose, as defined in s. 256.40 (1) (d), or a deceased individual who the law enforcement officer believes died as a result of using a narcotic drug.

(c) Receives a report of a stolen controlled-substance prescription.

(2) A law enforcement officer under sub. (1) shall report to the law enforcement agency that employs him or her all of the following:

(a) The name and date of birth of all of the following, if applicable:

1. The individual who is suspected of violating this chapter.
2. The individual who experienced an opioid-related drug overdose.
3. The individual who died as a result of using a narcotic drug.
4. The individual who filed the report of a stolen controlled-substance prescription.

5. The individual for whom a prescription drug related to an event under subd. 1., 2., 3., or 4. was prescribed.

ers, pharmacists, and others to whom the board may make disclosures under par. (c).

(2m) (a) The rules promulgated under sub. (2) may not require that a record submitted to the board before 2 years after April 9, 2014, contain the name recorded under s. 450.11 (1b) (bm).

(b) After consultation with representatives of licensed pharmacists and pharmacies, and subject to the approval of the secretary of safety and professional services, the board may delay the requirement that a record submitted to the board contain the name recorded under s. 450.11 (1b) (bm) for an additional period beyond the date specified in par. (a).

(3) (a) A pharmacy, pharmacist, or practitioner is immune from civil or criminal liability or professional discipline arising from the pharmacy's, pharmacist's, or practitioner's compliance in good faith with this section or with rules promulgated under this section.

(b) Nothing in this section may be construed to require a pharmacy or pharmacist to obtain, before dispensing a monitored prescription drug to a patient, information about the patient that has been collected pursuant to the program established under sub. (2).

NOTE: Par. (b) is shown as amended eff. 4–1–17 by 2015 Wis. Act 266. Prior to 4–1–17 it reads:

(b) Nothing in this section may be construed to require a pharmacy, pharmacist, or practitioner to obtain, before prescribing or dispensing a monitored prescription drug to a patient, information about the patient that has been collected pursuant to the program established under sub. (2).

(4) Records generated under the program under this section are not subject to inspection or copying under s. 19.35.

(5) (a) Beginning with the 3rd calendar quarter of 2016, no later than 30 days after the end of each calendar quarter, the board shall conduct a review of the program under this section to evaluate the actual outcomes of the program compared with projected outcomes, as determined by the board. The board's review shall include an evaluation of all of the following:

1. The satisfaction with the program of pharmacists, pharmacies, practitioners, and other users of the program.

2. The program's impact on referrals of pharmacists, pharmacies, and practitioners to licensing or regulatory boards for discipline and to law enforcement agencies for investigation and possible prosecution.

(b) This subsection does not apply after October 30, 2020.

(6) Beginning with the 3rd calendar quarter of 2016, no later than 30 days after the end of each calendar quarter, the board shall provide a report to the department of safety and professional services that includes all of the following:

(a) The results of the board's review under sub. (5). This paragraph does not apply after October 30, 2020.

(b) An assessment of the trends and changes in the use of monitored prescription drugs in this state.

(c) The number of practitioners, by profession, and pharmacies submitting records to the board under the program in the previous quarter.

(d) A description of the number, frequency, and nature of submissions by law enforcement agencies under s. 961.37 (3) (a) in the previous quarter.

(e) A description of the number, frequency, and nature of requests made in the previous quarter for disclosure of records generated under the program.

(f) The number of individuals receiving prescription orders from 5 or more practitioners or having monitored prescription drugs dispensed by 5 or more pharmacies within the same 90-day period at any time over the course of the program.

(g) The number of individuals receiving daily morphine milligram equivalents of 1 to 19 milligrams, 20 to 49 milligrams, 50 to 99 milligrams, and 100 or more milligrams in the previous quarter.

(h) The number of individuals to whom both opioids and benzodiazepines were dispensed within the same 90-day period at any time over the course of the program.

(7s) (a) The board may contract with an analytics firm to augment the program under this section with an analytics platform that provides data integration, advanced analytics, and alert management capabilities to detect problematic behaviors of practitioners, pharmacies, pharmacists, and patients.

(b) If the board augments the program under this section as specified in par. (a), the goals of that augmentation shall include all of the following:

1. Allowing the board, with the assistance of the analytics firm, to identify past patterns of abuse, addiction, or criminal activity.

2. Proactively improving painkiller prescribing, informing clinical practice, and protecting patients at risk.

3. Measuring program outcomes at an individual level to minimize the abuse of monitored prescription drugs in this state.

(c) For purposes of this subsection, the board may disclose records generated under the program to an analytics firm with which the board contracts.

History: 2009 a. 362; 2011 a. 260 s. 81; 2013 a. 3, 20, 124, 199; 2015 a. 55; 2015 a. 55 ss. 4477, 4737f to 4731k; Stats. 2015 s. 961.385; 2015 a. 195, 266, 267, 268.

Cross-reference: See also ch. CSB 4, Wis. adm. code.

961.39 Limitations on optometrists. An optometrist who is allowed under s. 449.18 (1) to use therapeutic pharmaceutical agents and under s. 449.18 (6) (am) 2. b. to dispense a contact lens that delivers a therapeutic pharmaceutical agent:

(1) May not prescribe, dispense, or administer a controlled substance included in schedule I or II.

(2) May prescribe, dispense, or administer only those controlled substances included in schedules III, IV, and V that are permitted for prescription or administration under the rules promulgated under s. 449.18 (6) (cm).

(2m) Notwithstanding sub. (1), may prescribe, dispense, or administer any of the following, if permitted for prescription or administration under the rules promulgated under s. 449.18 (6) (cm):

(a) Not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with a four-fold or greater quantity of an isoquinoline alkaloid of opium.

(b) Not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Shall include with each prescription order all of the following:

(a) A statement that he or she is allowed under s. 449.18 (1) to use therapeutic pharmaceutical agents.

(b) The indicated use of the controlled substance included in schedule III, IV, or V so prescribed or the indicated use of the controlled substance under sub. (2m) (a) or (b) so prescribed.

(4) May not dispense other than as provided under s. 449.18 (6) (am) 2.

History: 1989 a. 31; 1995 a. 448 s. 241; Stats. 1995 s. 961.39; 2005 a. 297; 2009 a. 168; 2015 a. 34.

961.395 Limitation on advanced practice nurses.

(1) An advanced practice nurse who is certified under s. 441.16 may prescribe controlled substances only as permitted by the rules promulgated under s. 441.16 (3).

(2) An advanced practice nurse certified under s. 441.16 shall include with each prescription order the advanced practice nurse prescriber certification number issued to him or her by the board of nursing.

(3) An advanced practice nurse certified under s. 441.16 may dispense a controlled substance only by prescribing or administering the controlled substance or as otherwise permitted by the rules promulgated under s. 441.16 (3).

History: 1995 a. 448.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: 5/26/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 6/7/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Report Access – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of access to reports: <ul style="list-style-type: none"> • Wisconsin Crime Lab Reports • DEA Reports of Theft, Loss, and Diversion 			

**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: 27 June 2016 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 13 July 2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislation and Rule Matters – Discussion and Consideration 1. Adopt CR 15-068 Relating to the Exclusion of Naloxegol from Scheduling 2. Adopt CR 15-083 Relating to Special Use Authorization Measurements 3. Scope for CSB 2.40 Relating to Exclusion of [¹²³I]ioflupane 4. Affirmative Action Order Relating to Butyryl Fentanyl and Beta-Hydroxythiofentanyl 5. Proposals for amending CSB 4 Relating to Prescription Drug Monitoring Program (Acts 266, 267 and 268) 6. Update on Pending and Possible Rulemaking Projects	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both		8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:
10) Describe the issue and action that should be addressed:			
11) Authorization			
<i>Sharon Henes</i>		<i>27 June 2016</i>	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 15-068)

ORDER

An order of the Controlled Substances Board to create CSB 2.39 relating to exclusion of naloxegol.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

Statutory authority: s. 961.11 (4), Stats.

Explanation of agency authority:

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: n/a

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

On January 23, 2015, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing naloxegol from schedule II of the federal Controlled Substances Act. The scheduling action was effective January 23, 2015.

Plain language analysis:

The Controlled Substances Board did not receive an objection to excluding naloxegol as a schedule II under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on March 25, 2015 to similarly exclude naloxegol under chapter 961 effective April 1, 2015 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule amends 961.16(2)(a)(intro), Stats. which excludes naloxegol from schedule II.

Comparison with rules in adjacent states:

Illinois: Illinois does not exclude naloxegol from scheduling.

Iowa: Iowa does not exclude naloxegol from scheduling.

Michigan: Michigan does not exclude naloxegol from scheduling.

Minnesota: Minnesota has a bill to exclude naloxegol from scheduling.

Summary of factual data and analytical methodologies:

The methodology was to remove naloxegol from scheduling to conform with the federal Controlled Substances Act.

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

This rule was posted for 14 days for economic comments and none were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jeff.Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

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

TEXT OF RULE

SECTION 1. CSB 2.39 is created to read:

CSB 2.39 Exclusion of naloxegol. Section 961.16(2)(a)(intro), Stats., is amended to read:
961.16(2)(a)(intro) Opium and substances derived from opium, and any salt, compound, derivative or preparation of opium or substances derived from opium. Apomorphine, dextrorphan, nalbuphine, butorphanol, nalmefene, naloxegol, naloxone and naltrexone and their respective salts and the isoquinoline alkaloids of opium and their respective salts are excluded from this paragraph. The following substances, and any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:

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

(END OF TEXT OF RULE)

Dated _____

Agency _____

Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 15-083)

ORDER

An order of the Controlled Substances Board to amend CSB 3.04 (6) (a) and (b) and 3.07 (1) (c), relating to measurements of controlled substances for purposes of special use authorizations.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.335, Stats.

Statutory authority: s. 961.335(8), Stats.

Explanation of agency authority:

The controlled substances board may promulgate rules relating to the granting of special use permits including, but not limited to, requirements for the keeping and disclosure of records other than those that may be withheld under sub. (7), submissions of protocols, filing of applications and suspension or revocation of permits. s. 961.335(8), Stats.

Related statute or rule: CSB 3

Plain language analysis:

This rule indicates the controlled substances are to be measured in total weight in grams for solid controlled substances and in volume and concentration for liquid controlled substances for purposes of inventory list, records and application purposes.

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

Federal regulations require any person who possess, manufactures, distributes or dispenses any controlled substances to register with the U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control.

Comparison with rules in adjacent states:

Illinois: Illinois controlled substance license (other) does not indicate a requirement for total weight or volume of the controlled substances for purposes of inventory list, records or application process.

Iowa: Iowa registration for independent activities does not indicate a requirement for total weight or volume of the controlled substances for purposes of inventory list, records or application process.

Michigan: Michigan licenses for controlled substances do not indicate a requirement for total weight or volume of the controlled substances for purposes of inventory list, records or application process.

Minnesota: Minnesota controlled substance registration does not indicate a requirement for total weight or volume of the controlled substances for purposes of inventory list, records or application process.

Summary of factual data and analytical methodologies:

The current rule indicates weight in grams regardless of the state of the liquid. A more accurate reflection of how the substances are measured includes volume for liquid controlled substances. Therefore, the Board is updating the rule to take into consideration the state of the controlled substance and the method for which each state of matter is measured.

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

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 Jeff.Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

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

TEXT OF RULE

SECTION 1. CSB 3.04 (6) (a) and (b) are amended to read:

CSB 3.04 (6) (a) An inventory listing the total weight in grams if solid, or volume and concentration if liquid, of each controlled substance in the lab or intended for purchase for the lab.

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

SECTION 2. CSB 3.07 (1) (c) is amended to read:

CSB 3.07 (1) (c) The total weight in grams if solid, or volume and concentration if liquid, of each controlled substance on hand.

SECTION 3. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____

Agency _____

Chair
Controlled Substances Board

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2

Relating to: Removing [¹²³I]ioflupane as a controlled substance

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 proposed rule is exclude naloxegol as a controlled substance

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 11, 2015, the U.S. Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [¹²³I]ioflupane from the federal Controlled Substances Act. The scheduling action was effective September 11, 2015. The Controlled Substances Board did not receive an objection to similarly remove [¹²³I]ioflupane from schedule II under ch. 961, Stats within 30 days of the date of publication in the federal register of the final order removing [¹²³I]ioflupane as a controlled substance.

Pursuant to s. 961.11(4), Stats, the Controlled Substances Board took affirmative action to similarly treat [¹²³I]ioflupane under chapter 961, Stats. by creating the following:

CSB 2.40 Exclusion of [¹²³I]ioflupane.

Sections 961.16(2)(b) is amended to read:

961.16(2)(b) *Coca leaves and any salt, compound, derivative or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [¹²³I]ioflupane is excluded from this paragraph. The following substances and any of their salts, esters, isomers and salts of esters and isomers that are theoretically possible within the specific chemical designation, are included in this paragraph.*

The Affirmative Action order, dated October 13, 2015, took effect on October 19, 2015 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(2) After considering the factors enumerated in sub. (1m), the controlled substances board shall make findings with respect to them and promulgate a rule controlling the substance upon finding that the substance has a potential for abuse.

961.11(4) If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30-day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling,

temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2).

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

25 hours

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

Pharmacists, prescribers, courts, police 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 11, 2015, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [¹²³I]ioflupane from schedule II of the federal Controlled Substances Act. The scheduling action was effective September 11, 2015.

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

Chair

Date Submitted

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On May 12, 2016, the United States Food and Drug Administration, Drug Enforcement Administration published its final rule in the Federal Register scheduling Butyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutyramide) and Beta-hydroxythiofentanyl (*N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide) as Schedule I of the federal Controlled Substances Act. The scheduling action is effective May 12, 2016.
2. The Controlled Substances Board did not receive an objection to similarly treating Butyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutyramide) and Beta-hydroxythiofentanyl (*N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide) as schedule II under ch. 961, Stats. within 30 days of the date of publication in the federal register.
3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.15 and omitting the notice of proposed rule making, scheduling Butyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutyramide) and Beta-hydroxythiofentanyl (*N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide) as Schedule I controlled substances.

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats butyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutyramide) and beta-hydroxythiofentanyl (*N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide) under chapter 961, Stats. by creating the following:

CSB 2.41 Scheduling of beta-hydroxythiofentanyl and butyryl fentanyl. Sections 961.14 (2) (eu) and (ey) are created to read:

961.14 (2) (eu) Beta-hydroxythiofentanyl (N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide)

(ey) Butyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide)

This order shall take effect on July 18, 2016 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated _____

Doug Englebert, Chair
Controlled Substances Board

TEXT OF RULE

SECTION 1. CSB 4.01 is amended to read:

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

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

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

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

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

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

(3s) “Audit trail” means the log that contains information about each time the PDMP system discloses PDMP data and monitored prescription drug history reports.

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

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

SECTION 4. CSB 4.01 (7) is amended to read:

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

SECTION 5. CSB 4.01 (11c) and (11n) are created to read:

CSB 4.01 (11c) “Healthcare Professional” means a pharmacist, practitioner, registered nurse licensed under s. 441.06, Stats., substance abuse counselor, as defined in s. 440.88 (1) (b), or individual authorized under s. 457.02 (5m) to treat alcohol or substance dependency or abuse as a specialty.

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

SECTION 6. CSB 4.01 (11r) and (12) (a) 1. are amended to read:

CSB 4.01 (11r) “Managing pharmacist” ~~has the meaning given in s. Phar 1.02 (6)~~ means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

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

SECTION 7. CSB 4.01 (11w) and (12m) are created to read:

CSB 4.01 (11w) “Medical coordinator” means a person who medically coordinates, directs, supervises, or establishes standard operating procedures for a healthcare professional.

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

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

SECTION 8. CSB 4.01 (13) is amended to read:

CSB 4.01 (13) “Patient” has the meaning given in s. ~~450.01 (14)~~ 961.385 (1) (aj), Stats.

SECTION 9. CSB 4.01 (14) is repealed.

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

CSB 4.01 (15) “PDMP information data” means ~~any of the following: The data the information~~ compiled and stored analyzed by the ~~board~~ PDMP system from dispensing data submitted to it by dispensers.

SECTION 11. CSB 4.01 (15) (b) is repealed.

SECTION 12. CSB 4.01 (15b) and (15e) are created to read:

CSB 4.01 (15b) “PDMP system” means the web-based application and analytics platform that facilitates the submission of dispensing data and the access to and the obtaining of relevant monitored prescription drug history reports and relevant PDMP data.

(15e) “Personally identifiable information” means information that can be associated with a particular patient through one or more identifiers or other information or circumstances.

SECTION 13. CSB 4.01 (15g), (15r), (16), (17) and (18) are amended to read:

CSB 4.01 (15g) “Pharmacist” has the meaning given in s. 961.385 (1) (aL), Stats. For the purposes of this program, the board recognizes a pharmacist licensed by another state that engages in the practice of pharmacy within the contiguous borders of this state as a person authorized to engage in the practice of pharmacy.

(15r) “Pharmacist delegate” means an agent of a pharmacist to whom the pharmacist has delegated the task of accessing ~~PDMP information~~ monitored prescription drug history reports, audit trails or PDMP data.

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

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

(18) “Practitioner delegate” means an agent or employee of a practitioner to whom the practitioner has delegated the task of accessing ~~PDMP information~~ monitored prescription drug history reports, audit trails or PDMP data.

SECTION 14. CSB 4.01 (21m) is created to read:

CSB 4.01 (21m) “Prosecutorial unit” has the meaning given in s. 978.001 (2), Stats.

SECTION 15. CSB 4.03 (2) is repealed.

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

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

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

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

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

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

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

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

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

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

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

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

NOTE: The guide for dispensers which specifies the data standards in version 4 release 2 of the ASAP implementation guide for prescription monitoring programs and other electronic formats identified by the board may be obtained online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) A healthcare professional may only disclose a monitored prescription drug history report about a patient obtained pursuant to sub. (1) in the following situations:

- (a) To the patient as part of treating or rendering assistance to the patient.
- (b) To another healthcare professional or a medical coordinator for consultation about the health of the patient or as part of treating or rendering assistance to the patient.
- (c) To a law enforcement agency as required by s. 146.82, Stats.

SECTION 27. CSB 4.093 is created to read:

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

- (1) Practitioners may access relevant monitored prescription drug history reports, audit trails, and PDMP data about themselves and their practitioner delegates.
- (2) Healthcare professionals may access audit trails about themselves and their practitioner delegates or pharmacist delegates.
- (3) Medical coordinators may access monitored prescription drug history reports, PDMP data, and audit trails about a healthcare professional whom the medical coordinator coordinates, directs, or supervises or for whom the medical coordinator establishes standard operating procedures that contain no personally identifiable information about a patient if the medical coordinator is conducting any of the following activities:
 - (a) Evaluating the job performance of the healthcare professional.
 - (b) Performing quality assessment and improvement activities, including outcomes evaluation or development of clinical guidelines for the healthcare professional.
- (4) To obtain access to monitored prescription drug history reports, audit trails, and relevant PDMP data as authorized in sub. (1) and (2), healthcare professionals, pharmacist delegates, and practitioner delegates shall do one of the following:
 - (a) Create an account with the PDMP system.
 - (b) Create an account with a prescription monitoring program operated by a relevant agency in another jurisdiction with which the board exchanges monitored prescription drug history reports or PDMP data pursuant to s. CSB 4.14.
 - (c) Create an account with a pharmacy or other entity at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports or that is connected to and lawfully obtains data from the state-designated entity under ch. 153, Stats.
 - (d) Create an account with a hospital or other entity at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports or that is connected to and lawfully obtains data from the state-designated entity under ch. 153, Stats.
- (5) To obtain access to monitored prescription drug history reports, audit trails, and PDMP data about a healthcare professional, a medical coordinator shall create an account with the PDMP system.

SECTION 28. CSB 4.097 is created to read:

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

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

- (a) The healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator is suspected of attempting to access, accessing, or disclosing a monitored prescription drug history report, PDMP data, or audit trail in violation of s. 146.82 or 961.385, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records.
 - (b) The healthcare professional is no longer licensed in this state or in another state and recognized by this state as a person to whom the board may grant access pursuant to s. CSB 4.09 or 4.093.
 - (c) The board, or other licensing board, or regulatory agency takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.
 - (d) A licensing board or equivalent regulatory agency in another jurisdiction takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.
 - (e) The federal department of justice, drug enforcement administration takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.
 - (f) The healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator is convicted of a crime substantially related to the prescribing or dispensing of a monitored prescription drug.
 - (g) The pharmacist delegate or practitioner delegate is no longer delegated the task of accessing monitored prescription drug history reports or PDMP data.
 - (h) The medical coordinator no longer coordinates, directs, supervises, or establishes standard operating procedures for a healthcare professional.
- (2) The board may temporarily suspend access to monitored prescription drug history reports, PDMP data, and audit trails upon discovering circumstances that indicate a healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator has performed any of the actions identified in sub. (1) (a).

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

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

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

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

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

(2) To request a review, the pharmacist dispenser, health care professional, pharmacist delegate, practitioner, or practitioner delegate, or medical coordinator shall file a written request

with the board within 20 days after the mailing of the notice of the action in sub. (1). The request shall be in writing and include all of the following:

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

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

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

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

SECTION 32. CSB 4.105 is created to read:

CSB 4.105 Practitioners' requirement to review monitored prescription drug history reports. (1) Practitioners shall review relevant PDMP data or the monitored prescription drug history report about a patient before the practitioner issues a prescription order for the patient unless any of the following conditions are met:

- (a) The patient is receiving hospice care, as defined in s. 50.94 (1) (a).
- (b) The prescription order is for a number of doses that is intended to last the patient 3 days or less and is not subject to refill.
- (c) The monitored prescription drug is lawfully administered to the patient.
- (d) The practitioner is unable to review the patient's monitored prescription drug history reports before issuing a prescription order for the patient due to an emergency.
- (e) The practitioner is unable to review the patient's records under their program because the PDMP system is not operation or due to other technological failure that the practitioner reports to the board.

(2) The board may refer a practitioner that fails to review relevant monitored prescription drug history reports or PDMP data about a patient prior to issuing a prescription order for that patient to the appropriate licensing or regulatory board for discipline, or the appropriate law enforcement agency for investigation and possible prosecution.

SECTION 33. CSB 4.11 (title), (1) and (2) (intro) and (c), (5) (intro), (a) and (c), (6) (intro), (a) and (c), (7) (intro), (a) and (c), (8) (intro), (a) and (c), (9), and (10) are amended to read:

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

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

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

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

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

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

(5) The board shall disclose the minimum necessary amount of ~~PDMP~~ information necessary in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of a federal or state governmental agency in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

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

(6) The board shall disclose the minimum necessary amount of ~~PDMP~~ information necessary in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of the department who is charged with investigating dispensers, dispenser delegates, pharmacists, pharmacist delegates, practitioners, and practitioner delegates in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

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

(7) The board shall disclose the minimum necessary amount of ~~dispensing data~~ necessary information in a monitored prescription drug history report about a patient or patient address to a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is

being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

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

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

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

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

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

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

(10) The board shall disclose the minimum necessary amount of ~~PDMP~~ information in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of a law enforcement ~~authority in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records~~ agency or prosecutorial unit if the designated staff does all of the following:

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

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

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

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

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

SECTION 34. CSB 4.11 (10) (c) (note) is repealed.

SECTION 35. CSB 4.12 (title) and (1) are amended to read:

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

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

SECTION 36. CSB 4.12 (2) is repealed.

SECTION 37. CSB 4.12 (2m) is created to read:

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

- (a) The submission of dispensing data to the PDMP database.
- (b) The creation of monitored prescription drug history reports about specific patients, practitioners, and dispensers.
- (c) The access to and the obtaining of monitored prescription drug history reports and PDMP data.

SECTION 38. CSB 4.12 (3) is repealed and recreated to read:

CSB 4.12 (3) The board shall maintain audit trails that contain all of the following information:

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

SECTION 39. CSB 4.12 (4), (4g), (4r), and (5) are repealed.

SECTION 40. CSB 4.12 (6) (intro) and (a) are amended to read:

CSB 4.12(6) ~~Board and department staff~~ Staff assigned administrative duties over the PDMP, vendors, and other agents of the board shall only have access to the minimum amount of PDMP ~~information~~ data necessary for all of the following purposes:

- (a) The design, implementation, operation, and maintenance of the program, including the PDMP database and PDMP system, as part of the assigned duties and responsibilities of their employment.

SECTION 41. CSB 4.12 (6) (am) is created to read:

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

SECTION 42. CSB 4.12 (6) (c) is amended to read:

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

SECTION 43. CSB 4.12 (6) (cg) and (cr) are created to read:

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

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

SECTION 44. CSB 4.13 is amended to read:

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

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

criminal penalties for discipline, or the appropriate law enforcement agency for investigation and possible prosecution.

SECTION 45. CSB 4.14 (title) and (1) (intro) are amended to read:

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

SECTION 46. CSB 4.15 (1) and (5) (intro) are amended to read:

CSB 4.15 (1) The board may review dispensing data, monitored prescription drug history reports, PDMP information data, and data compiled pursuant to s. CSB 4.12 to determine whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist, pharmacy, practitioner, or patient.

(5) Upon determining that circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacy, practitioner, or patient, the Board may disclose ~~PDMP information~~ monitored prescription drug history reports, audit trails, and PDMP data to any of the following:

SECTION 47. 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)

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2

Relating to: Additions to schedules in chapter 961

Rule Type: Both Permanent and Emergency

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

The Waupaca County District Attorney's office has provided the Controlled Substances Board with information relevant to emergency scheduling and the commencement of a prosecution concerning a controlled substance analog pursuant to s. 961.25, Stats. Furanyl Fentanyl is an analog of the controlled substance schedule II drug, Fentanyl.

The Controlled Substances Board finds that scheduling of furanyl fentanyl on an emergency basis is necessary to avoid an imminent hazard to the public safety. The substances are not included in any other schedule and no exemption or approval is in effect for the substance under 21 USC 355.

The Controlled Substances Board considered the following factors in making the finding of an imminent hazard to the public safety: the history and current pattern of abuse; the scope, duration and significance of abuse; and the risk to the public health.

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

The objective is to schedule furanyl fentanyl (*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide) as a Schedule I controlled substance.

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:

Currently Wisconsin has not scheduled furanyl fentanyl as a Schedule I controlled substance. Furanyl fentanyl is a synthetic opioid. Last fall China banned other analogs of fentanyl resulting in the development of a new analog, furanyl fentanyl. Furanyl fentanyl is more potent than morphine and heroin. It is sold in pill form as well as being added to heroin. Deadly overdoses have been reported due to furanyl fentanyl. There are documented cases of furanyl fentanyl being used in the state of Wisconsin.

The Drug Enforcement Administration issued a nationwide alert on fentanyl as a threat to health and public safety on March 18, 2015. The Centers for Disease Control and Prevention issued an official health advisory on fentanyl-related overdose fatalities on October 26, 2015.

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(4m) The controlled substances board, by rule and without regard to the requirements of sub. (1m), may schedule a controlled substance analog as a substance in schedule I regardless of whether the substance is substantially similar to a controlled substance in schedule I or II, if the board finds that scheduling of the substance on an emergency basis is necessary to avoid an imminent hazard to the

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public safety and the substance is not included in any other schedule or no exemption or approval is in effect for the substance under 21 USC 355. Upon receipt of notice under s. 961.25, the board shall initiate scheduling of the controlled substance analog on an emergency basis under this subsection. The scheduling of a controlled substance analog under this subsection expires one year after the adoption of the scheduling rule. With respect to the finding of an imminent hazard to the public safety, the board shall consider whether the substance has been scheduled on a temporary basis under federal law or factors under sub. (1m) (d), (e) and (f), and may also consider clandestine importation, manufacture or distribution, and, if available, information concerning the other factors under sub. (1m). The board may not promulgate a rule under this subsection until it initiates a rule-making proceeding under subs. (1), (1m), (1r) and (2) with respect to the controlled substance analog. A rule promulgated under this subsection lapses upon the conclusion of the rule-making proceeding initiated under subs. (1), (1m), (1r) and (2) with respect to the substance.

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

100 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:

Furanyl fentanyl is not currently scheduled under the Controlled Substances Act. The U.S. Department of Justice Drug Enforcement Administration in May 2016 scheduled two different fentanyl analogs.

8. Anticipated economic impact of implementing the rule:

Minimal to none

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

Chair Signature

Date Submitted

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: 5/26/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 6/7/16	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Speaking Engagement(s), Travel, or Public Relations Request(s) – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of travel updates and upcoming travel opportunities.			