



CONTROLLED SUBSTANCES BOARD

Contact: Chad Zadrazil (608) 266-2112
Room 121B, 1400 East Washington Avenue, Madison
October 6, 2015

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

AGENDA

9:30 A.M.

OPEN SESSION - CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1-3)**
- B. Approval of Minutes of August 14, 2015 (4-6)**
- 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. Patrick Mitchell – Attorney General Designee
 - h. Wendy Pietz – Dentistry Examining Board Designee
 - i. Timothy Westlake – Medical Examining Board Designee
 - 3) Liaison Appointments **(7-8)**
 - 4) Upcoming Meetings
- D. 9:30 A.M. PUBLIC HEARING: Clearinghouse Rule 15-070 Relating to Submission of Data to Prescription Drug Monitoring Program (PDMP) (9)**
- E. Prescription Drug Monitoring Program – Discussion and Consideration**
 - 1) PDMP Operations Statistics **(10-12)**
 - 2) PDMP Dispenser Compliance Audit **(13-15)**
 - 3) PDMP Referral Process **(16)**
 - 4) Minnesota PDMP Letter Regarding Interstate Data **(17-21)**

- 5) 2015 Harold Rogers PDMP Implementation and Enhancement Grant Award (**22-24**)
- 6) 2015 CDC Prescription Drug Overdose: Prevention for States Grant (**25-28**)
- 7) WIE-PDMP Scope (**29-43**)
- 8) WIE-PDMP Schedule (**44-45**)

F. HOPE Draft Bills – Discussion and Consideration (46-65)

G. Legislation and Rule Matters – Discussion and Consideration (66-85)

- 1) Adopt CR 15-007, Relating to Rescheduling Hydrocodone Combination Products (**67-69**)
- 2) Adopt CR 15-008, Relating to Scheduling Tramadol (**70-72**)
- 3) Adopt CR 15-009, Relating to Scheduling Suvorexant (**73-75**)
- 4) Clearinghouse Report for CR 15-068, Relating to Exclusion of Naloxegol
- 5) Federal Exclusion of Ioflupane (**76-79**)
- 6) Draft Amending CSB 3, Relating to Special Use Authorization (**80**)
- 7) Proposals for Amending CSB 4, Relating to Prescription Drug Monitoring Program Operation (**81-85**)
- 8) Update on Legislation and Possible or Pending Rule-Making Projects

H. Kratom (Mitragynine) Scheduling – Discussion and Consideration (86-89)

I. National Governors Association (NGA) Policy Academy Review – Discussion and Consideration (90-93)

J. Board Goals – Discussion and Consideration (94)

K. Speaking Engagement(s), Travel, or Public Relations Request(s) – Discussion and Consideration

L. Informational Items – Discussion and Consideration

- 1) Heroin, Opiate Prevention and Education (HOPE) – PDMP Article – Informational Only (**95-97**)
- 2) CVS Naloxone Article – Informational Only (**98-100**)

M. 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

N. 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), and 440.205, 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.).

O. Credentialing Matters

P. Case Closures

Q. Deliberation of Items Received After Preparation of the Agenda

- 1) Monitoring Matters
- 2) Administrative Warnings
- 3) Review of Administrative Warning
- 4) Proposed Stipulations, Final Decisions and Orders
- 5) ALJ Proposed Final Decisions and Orders
- 6) Orders Fixing Costs/Matters Related to Costs
- 7) Petitions for Summary Suspension
- 8) Petitions for Re-hearings
- 9) Complaints
- 10) Credential Issues
- 11) Appearances from Requests Received or Renewed
- 12) Consulting with Legal Counsel

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

ADJOURNMENT

The next scheduled meeting is December 1, 2015.

**CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
August 14, 2015**

PRESENT: Yvonne Bellay, Doug Englebert, Franklin LaDien (*joined the meeting at 9:31am*), Gunnar Larson (*via GoToMeeting*), Patrick Mitchell, Timothy Westlake

EXCUSED: Alan Bloom, Jeffrey Miller, Wendy Pietz

STAFF: Chad Zadrazil – Managing Director; Gretchen Mrozinski – Board Legal Counsel; Nilajah Madison-Head - 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 five (5) members was confirmed.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES OF MARCH 24, 2015

Franklin LaDien joined the meeting 9:31am.

MOTION: Timothy Westlake moved, seconded by Yvonne Bellay, to adopt the minutes of March 24, 2015 as published. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Liaison Appointments

| 2015 LIAISON APPOINTMENTS | |
|----------------------------------|---------------------------|
| SUA Liaisons | Alan Bloom, Yvonne Bellay |
| SCAODA Liaison | Doug Englebert |
| Legislative Liaison | Doug Englebert |

BOARD BACKGROUND AND PDMP CHANGES

MOTION: Franklin LaDien moved, seconded by Timothy Westlake, to address quarterly compliance issue reports with the PDMP program, DSPS Staff is delegated the authority to send a letter to gain compliance, and if compliance is not gained the dispenser will be referred to the Controlled Substances Board. Motion carried unanimously.

LEGISLATION AND RULE MATTERS

CSB 2.39 Relating to Exclusion of Naloxegol

MOTION: Franklin LaDien moved, seconded by Timothy Westlake, to approve the preliminary rule draft of CSB2.39 relating to exclusion of Naloxegol for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Phar 18.04 Relating to Data Submission to PDMP

MOTION: Timothy Westlake moved, seconded by Franklin LaDien, to approve the preliminary rule draft of Phar 18.04 relating to data submission to PDMP for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Scope for Amending CSB 3 Relating to Special Use Authorization

MOTION: Gunnar Larson moved, seconded by Yvonne Bellay, to approve the Scope Statement on CSB 3 relating to Special Use Authorization 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.

Scope for Amending Phar 18 Relating to Operation of Prescription Drug Monitoring Program (Act 55)

MOTION: Yvonne Bellay moved, seconded by Franklin LaDien, to approve the Scope Statement on Phar 18 relating to operation of Prescription Drug Monitoring Program 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.

APPEARANCE – KRATOM (MITRAGYNINE) SCHEDULING

MOTION: Franklin LaDien moved, seconded by Timothy Westlake, to acknowledge and thank Jack Henningfield from Pinney Associates for his appearance before the Board. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Timothy Westlake, to acknowledge and thank Susan Ash from American Kratom Association for her appearance before the Board. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Timothy Westlake, to acknowledge and thank Kerry Biggs for her appearance before the Board. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Timothy Westlake, to acknowledge and thank Lance Dyer from the Dakota Dyer Foundation for his appearance before the Board. Motion carried unanimously.

MOTION: Timothy Westlake moved, seconded by Patrick Mitchell, to authorize DSPS Legal Counsel to research the options the Board may have regarding Wis. Stat § 961.14 (Kratom). Motion carried unanimously.

CLOSED SESSION

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay, to 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 investigation with administrative warning (ss.19.85(1)(b), Stats. and 440.205, 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.). Doug Englebert, Chair, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Yvonne Bellay-yes, Alan Bloom-yes; Doug Englebert-yes; Franklin LaDien-yes; Gunnar Larson-yes; Patrick Mitchell-yes. Motion carried unanimously.

The Board convened into Closed Session at 12:06 p.m.

RECONVENE TO OPEN SESSION

MOTION: Timothy Westlake moved, seconded by Franklin LaDien, to reconvene into open session. Motion carried unanimously.

The Board reconvened into Open Session at 12:10 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Patrick Mitchell moved, seconded by Franklin LaDien, to affirm all motions made in closed session. Motion carried unanimously.

CASE CLOSURE(S)

14 CSB 001 – Safe Harbor Humane Society

MOTION: Timothy Westlake moved, seconded by Yvonne Bellay, to close DLSC case number 14 CSB 001, against Safe Harbor Humane Society, for Prosecutorial Discretion (P2). Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 12:11 p.m.

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

AGENDA REQUEST FORM

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|--|---|--|--|-----------------------------|-----------------|---|------|--------------------------|------|--|--|------|--|
| 1) Name and Title of Person Submitting the Request: Nilajah Madison-Head, Bureau Assistant | | 2) Date When Request Submitted: 08/05/15 | | | | | | | | | | | |
| Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting | | | | | | | | | | | | | |
| 3) Name of Board, Committee, Council, Sections: Controlled Substances Board | | | | | | | | | | | | | |
| 4) Meeting Date: 10/06/15 | 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 | | | | | | | | | | | |
| 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: Board is to review Liaison appointments and make changes as necessary | | | | | | | | | | | | | |
| 11) Authorization <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; border-bottom: 1px solid black;"><i>Nilajah Madison-Head</i></td> <td style="width: 40%; border-bottom: 1px solid black; text-align: right;"><i>08/05/15</i></td> </tr> <tr> <td style="font-size: small;">Signature of person making this request</td> <td style="text-align: right; font-size: small;">Date</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Supervisor (if required)</td> <td style="border-bottom: 1px solid black; text-align: right;">Date</td> </tr> <tr> <td colspan="2" style="border-bottom: 1px solid black;">Executive Director signature (indicates approval to add post agenda deadline item to agenda)</td> </tr> <tr> <td colspan="2" style="border-bottom: 1px solid black;">Date</td> </tr> </table> | | | | <i>Nilajah Madison-Head</i> | <i>08/05/15</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 | |
| <i>Nilajah Madison-Head</i> | <i>08/05/15</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. | | | | | | | | | | | | | |

| 2015 LIAISON APPOINTMENTS | |
|----------------------------------|--|
| SUA Liaisons | Alan Bloom, Yvonne Bellay |
| SCAODA Liaison | Doug Englebert |
| Legislative Liaison | Doug Englebert (<i>Alternate:</i> Martin Koch) |

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

AGENDA REQUEST FORM

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|---|---|---|--|
| 1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator | | 2) Date When Request Submitted: 24 September 2015 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: 6 October 2015 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? Public Hearing on Clearinghouse Rule 15-070 relating to Submission of Data to Prescription Drug Monitoring Program Review and respond to Clearinghouse Report and Public Hearing comments | |
| 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: Hold Public Hearing at 9:30 a.m. Discuss any public hearing comments. Review, discuss and respond to any Clearinghouse comments. | | | |
| 11) Authorization | | | |
| <i>Sharon Henes</i> | | <i>6 October 2015</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
Department of Safety & Professional Services**

AGENDA REQUEST FORM

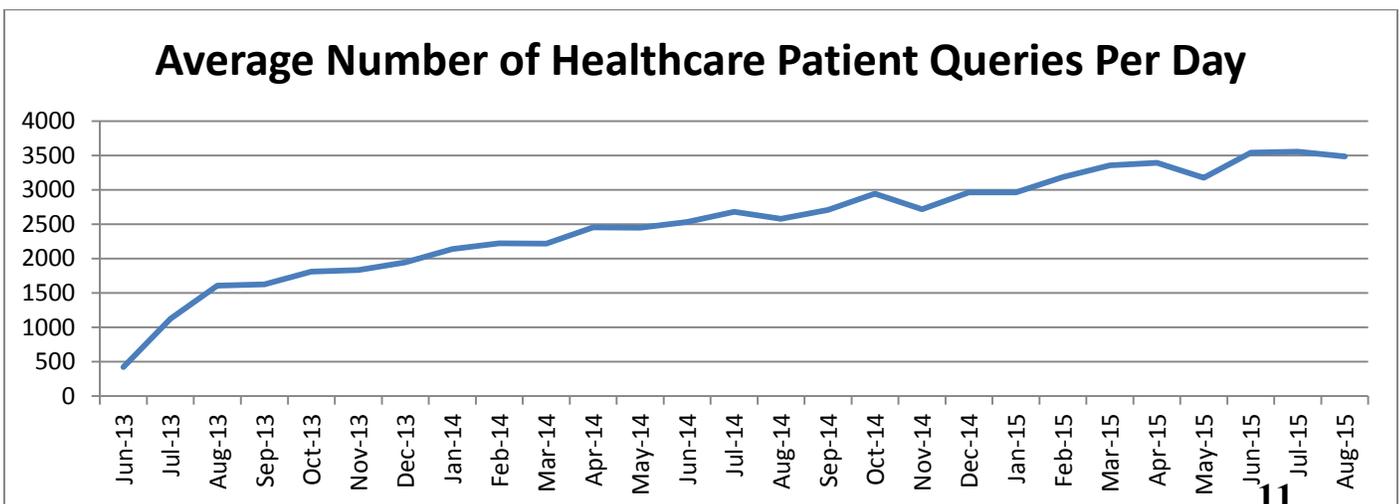
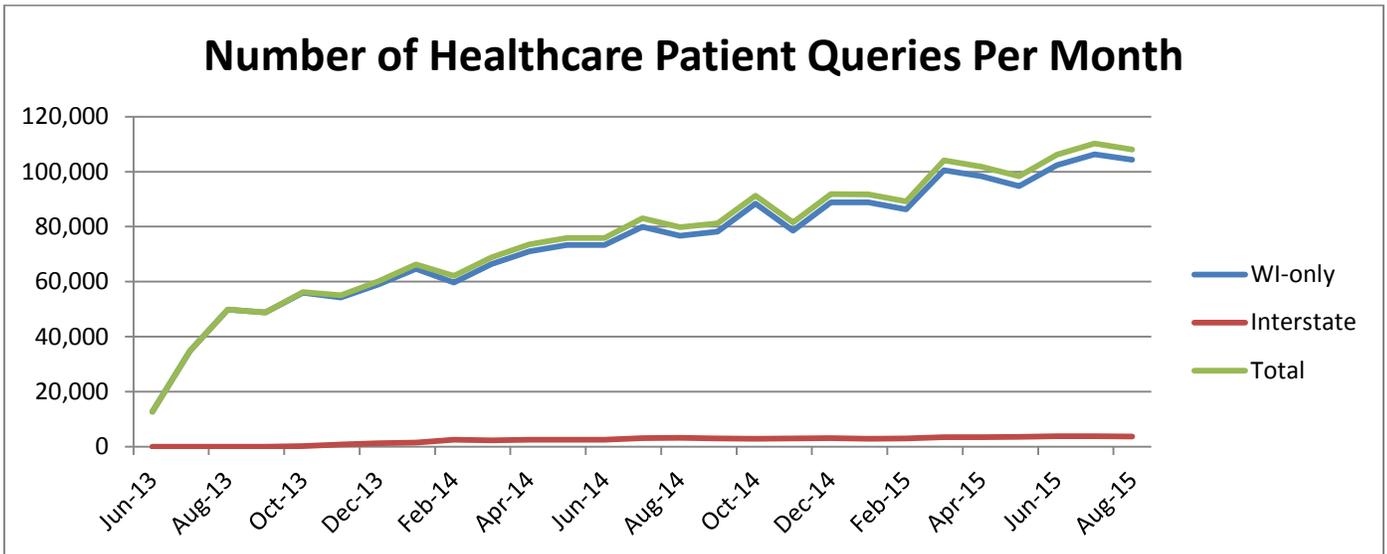
| | | | |
|---|---|--|--|
| 1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans | | 2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others | |
| 3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD | | | |
| 4) Meeting Date: 10/6/15 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? PDMP Operations Statistics - 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: For the Board's consideration, attached are statistics regarding the operations of the PDMP. | | | |



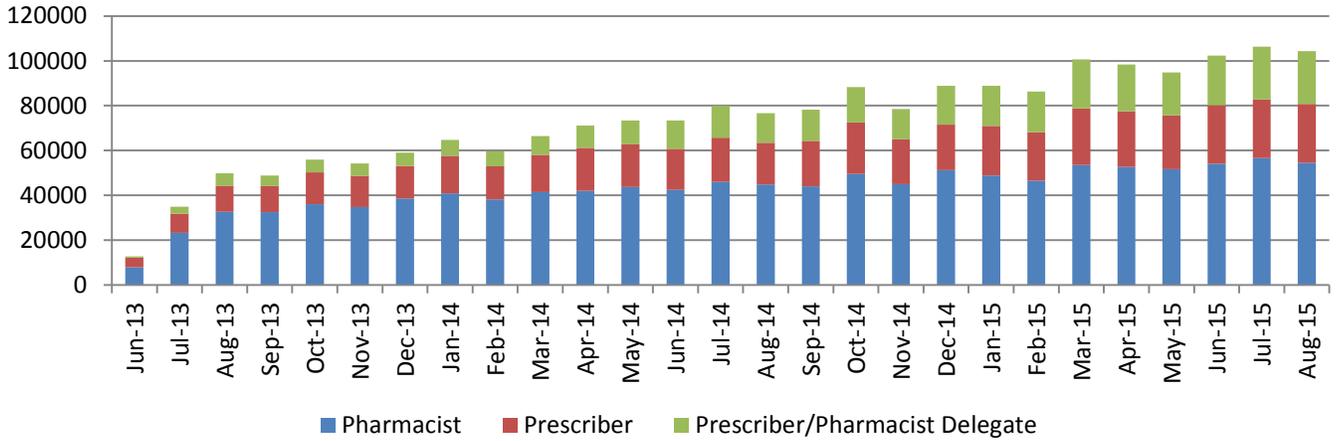
Operational Statistics of the WI PDMP

Compiled on September 30, 2015

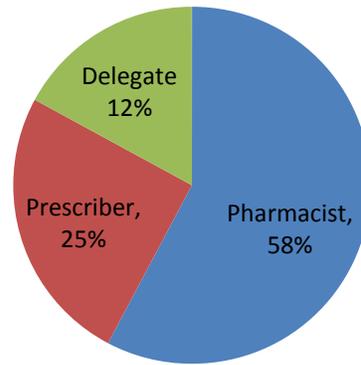
- Approximately 29.8 million R_x records in the database
- Approximately 1,800 dispensers actively submitting data
- Approximately 13,000 healthcare users have query accounts
- Healthcare users have created over 2 million recipient queries since June 1, 2013
 - In addition, healthcare users have created over 62,000 interstate queries since October 1, 2013
- Healthcare Users have initiated approximately 1,370 PDMP Alerts since July 1, 2013



Healthcare Patient Queries Performed by User Group

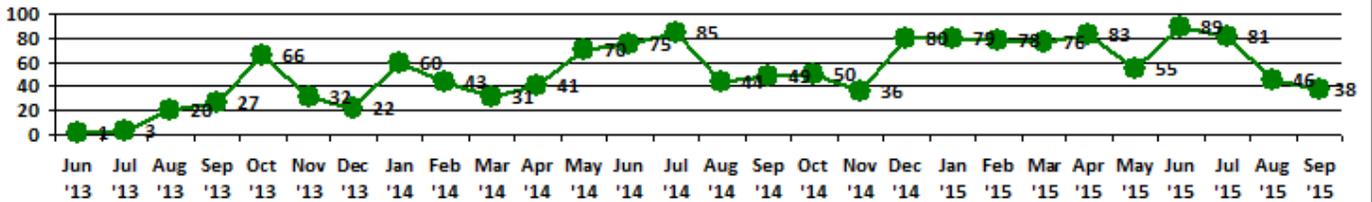


Healthcare Patient Queries Performed by User Group



- Approximately 160 law enforcement and government users with query accounts.
- Law enforcement and government requests:

Requests By Month



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

AGENDA REQUEST FORM

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|--|---|--|--|
| 1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans | | 2) Date When Request Submitted: 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: 10/6/15 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? PDMP Dispenser Compliance Audit- 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 about the results of the latest audit of pharmacies compliance with PDMP data submission requirements. Audit Results: 133 pharmacies licensed since last audit will receive "new pharmacy" letter 104 pharmacies will receive non-compliant letter | | | |



September 30, 2015

«Pharmacy_Name»
ATTN: MANAGING PHARMACIST
«Add_1»
«City», «State» «ZIP»

Dear Managing Pharmacist:

You are receiving this letter because a recent audit indicates that your pharmacy may not be collecting and submitting data to the Wisconsin Prescription Drug Monitoring Program (WI PDMP) as required by law. The Department of Safety and Professional Services' records indicate that your pharmacy, «Pharmacy_Name» (License #: «License_Number», DEA #: «DEA_Number») has never submitted data to the WI PDMP. Note that if your DEA # is listed as UNKNOWN, the Department does not have your DEA # on file, and that may be the reason your pharmacy appears non-compliant. If this is the case, please notify the Department of your DEA# as soon as possible.

As a recently-licensed pharmacy in Wisconsin, you may not be aware of the data collection and submission requirements of the WI PDMP. If your pharmacy dispenses monitored prescription drugs, Section CSB 4.06 of the Wisconsin Administrative Code requires you to compile and electronically submit data to the WI PDMP within 7 days of the dispensing. There are only two exceptions to the data collection and submission requirements. The first exception is for monitored prescription drugs that are directly administered to a patient, such as when a pharmacist at a hospital pharmacy prepares a monitored prescription drug and sends it to a unit for administration to an in-patient. The second exception is for the dispensing of less than 7-day supplies of non-narcotic schedule V substances. If your pharmacy has no dispensing transactions to report for a seven (7)-day reporting period, you must submit a zero report to the WI PDMP to account for the gap in data.

To avoid future non-compliance communications and possible disciplinary action against your license and the license of the pharmacy you manage, you must contact us and begin submitting data to the WI PDMP. This includes all data since the date on which your pharmacy became licensed in Wisconsin.

If your pharmacy does not dispense any monitored prescription drugs in Wisconsin, please notify the Department by applying for an Exemption from the Data Collection and Submission Requirements of the WI PDMP. The application for an exemption is enclosed.

Failure to submit data about all dispensing of monitored prescription drugs or zero reports to the PDMP in the future may result in disciplinary action against your license and the license of the pharmacy you manage. **Please send all applications and all communications regarding this notice to PDMP@wisconsin.gov.**

Sincerely,

Doug Englebert
Chairperson of the Controlled Substances Board



September 30, 2015

«Pharmacy_Name»
ATTN: MANAGING PHARMACIST
«Add_1»
«City», «State» «ZIP»

Dear Managing Pharmacist:

You are receiving this letter because a recent audit indicates that your pharmacy may not be collecting and submitting data to the Wisconsin Prescription Drug Monitoring Program as required by law. Based on the records of the Department of Safety and Professional Services, we found that your pharmacy, «Pharmacy_Name» (License #: «License_Number», DEA #: «DEA_Number») submitted data most recently on: «Data» and a zero report most recently on: «Zero». This means that your pharmacy may not be in compliance with the seven (7) day data reporting requirement of the WI PDMP. Note that if your DEA # is listed as UNKNOWN, the Department does not have your DEA # on file, and that may be the reason your pharmacy appears non-compliant. If this is the case, please notify the Department of your DEA# as soon as possible.

If your pharmacy has stopped dispensing monitored prescription drugs, or never has dispensed any monitored prescription drugs, please notify the Department by applying for an Exemption from the Data Collection and Submission Requirements of the WI PDMP. The application for an exemption is enclosed.

If your pharmacy dispenses monitored prescription drugs, Section CSB 4.06 of the Wisconsin Administrative Code requires it to compile and electronically submit data to the WI PDMP within 7 days of the dispensing. There are only two exceptions to the data collection and submission requirements. The first exception is for monitored prescription drugs that are directly administered to a patient, such as when a pharmacist at a hospital pharmacy prepares a monitored prescription drug and sends it to a unit for administration to an in-patient. The second exception is for the dispensing of less than 7-day supplies of non-narcotic schedule V substances.

To avoid possible disciplinary action against your pharmacy, your pharmacy must contact us and begin submitting data to the WI PDMP within 7 days of receiving this notice. This includes all data since the date on which your pharmacy stopped submitting data to the WI PDMP or since January 1, 2013, when the law requiring the submission of the data became effective. If your pharmacy has no dispensing transactions to report for a seven (7)-day reporting period, you must submit a zero report to the WI PDMP to account for the gap in data.

If your pharmacy is unable to become compliant within 7 days of receiving this notice, submit an application for an emergency waiver of the 7-day reporting requirement. The application for an emergency waiver is available on our website: http://dps.wi.gov/Documents/PDMP/Emergency_Waiver_Form.pdf.

Failure to become compliant within 7 days, or as otherwise agreed upon by the Department, and failure to submit data about all dispensing of monitored prescription drugs or zero reports to the PDMP in the future may result in disciplinary action against your license and the license of the pharmacy you manage. **Please send all applications and all communications regarding this notice to PDMP@wisconsin.gov.**

Sincerely,

Doug Englebort
Chairperson of the Controlled Substances Board

**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: 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: 10/6/15 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? PDMP Referral Process – 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 process the board may utilize to refer licensees to a regulatory board for PDMP investigations. | | | |

**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: 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: 8/14/15 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? Interstate PDMP Data– 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: For the Board’s consideration, attached is a letter from the MN Board of Pharmacy regarding data sharing with delegates. Also attached is information about the WI PDMP’s connection to the National Association of Boards of Pharmacy PMP InterConnect. | | | |

MINNESOTA BOARD OF PHARMACY



An Equal Opportunity Employer

2829 University Ave. SE., #530 • Minneapolis, MN 55414-3251 • Telephone: (651) 201-2825 • FAX: (651) 201-2837

MN RELAY SERVICE FOR HEARING/SPEECH IMPAIRED ONLY:

Metro and Non-Metro; 800-627-3529

E-Mail Address: Pharmacy.Board@state.mn.us

Web Site: www.pharmacy.state.mn.us

August 31, 2015

Mr. Dan Williams, Executive Director
Pharmacy Examining Board
Wisconsin Department of Safety and Professional Services
PO Box 8935
Madison, WI 53708-8935

Mr. Williams,

This letter is being sent requesting the Pharmacy Examining Board to reconsider permitting access to Wisconsin PMP data through PMP InterConnect for authorized MN prescription monitoring program (PMP) delegates. The Minnesota Board of Pharmacy feels strongly that prescriber and pharmacist delegates are an integral part in accessing data to combat the prescription drug abuse problem while increasing patient safety. Our shared border increases the potential that patients are traveling between our states to obtain controlled substances, therefore denying access to authorized delegates is a barrier to providing safe care to patients in both of our states.

Wisconsin and Minnesota have been exchanging data through PMP InterConnect for several months and our individual states allow for delegate access. We acknowledge the importance of the time constraints put on our prescribers and pharmacists and having delegate's access data on their behalf is highly valued. The privacy of patient data is of utmost importance, therefore in Minnesota our delegates are only authorized to access data when "linked" to a master account holder (prescriber or pharmacist), and the master account holder is responsible for all data that is accessed by the delegate. MN PMP master account holders are also able to link and unlink a delegate at any time and are required to do so when a delegate's leaves their employment. The PMP staff educates master account holders on how to audit their delegate access and highly encourage these audits are performed on a routine basis. The MN Board of Pharmacy believes this highly secure process for delegate access ensures the privacy of patient data.

The MN Board of Pharmacy greatly appreciates your consideration of opening delegate access between Minnesota and Wisconsin. If the Board is not the appropriate authority for this request please advise. We welcome any questions or comments you may have, please contact the PMP Program Manager Barbara Carter at 651-201-2833 or email barbara.a.carter@mn.state.us.

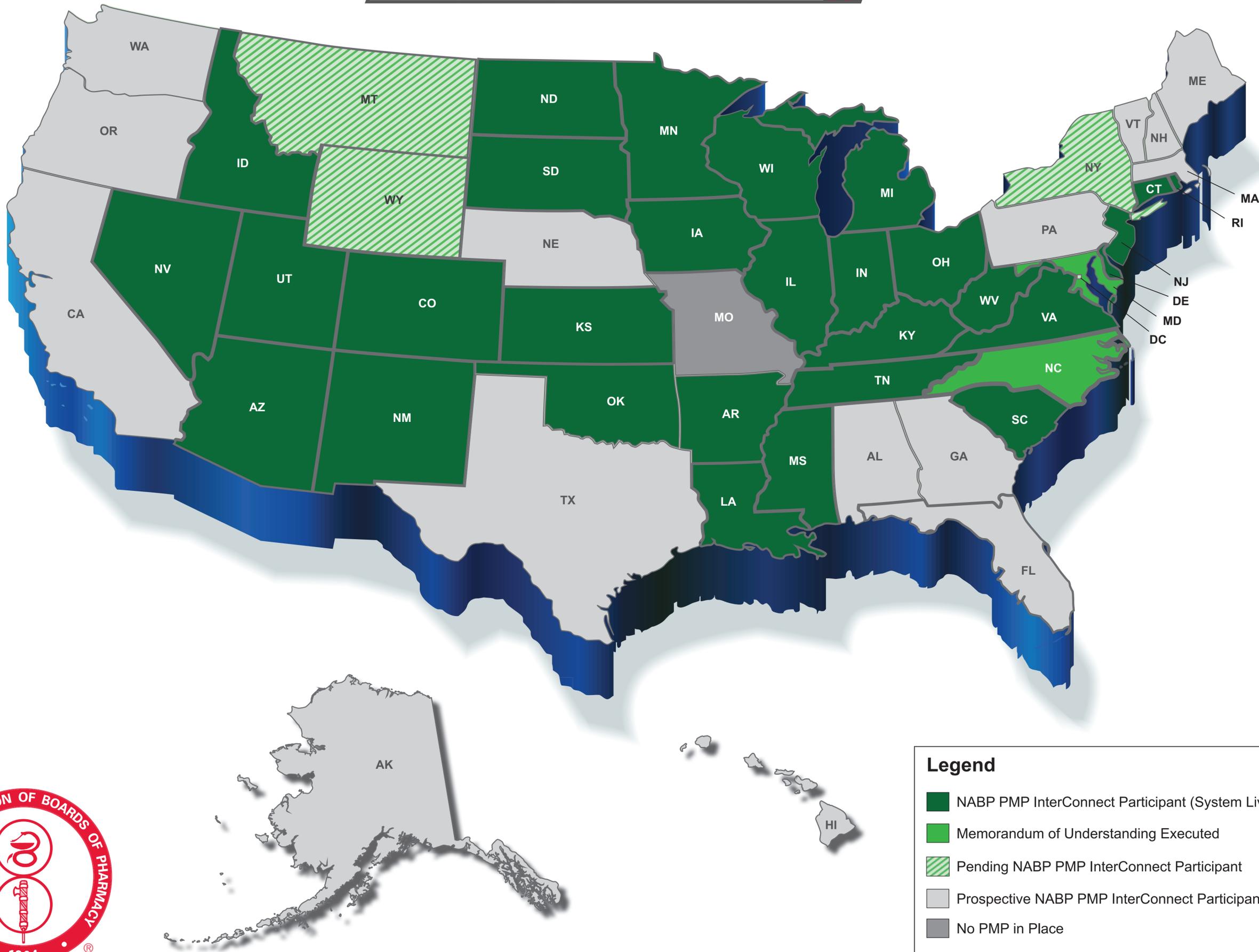
Sincerely,

A handwritten signature in black ink that reads "Cody Wiberg". The signature is written in a cursive style with a large initial "C".

Cody Wiberg, PharmD., M.S., RPh
Executive Director
Minnesota Board of Pharmacy

Cc: Chad Zadrazil, WI PMP Manager
Barbara Carter, MN PMP Manager

PMP INTERCONNECT®



Legend

- NABP PMP InterConnect Participant (System Live)
- Memorandum of Understanding Executed
- Pending NABP PMP InterConnect Participant
- Prospective NABP PMP InterConnect Participant
- No PMP in Place

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

AGENDA REQUEST FORM

| | | | |
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| 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 about the 2015 Harold Rogers PDMP Implementation and Enhancement Grant Award awarded to the Department of Safety and Professional Services. | | | |

From: PDMP Training and Technical Assistance Center
<info=pdmpassist.org@mail207.atl81.rsgsv.net> on behalf of PDMP Training and
Technical Assistance Center <info@pdmpassist.org>
Sent: 23 Sep 2015 11:20 AM
To: Zadrazil, Chad J - DSPS
Subject: 2015 BJA Harold Rogers PDMP Grant Awards Announcement



2015 BJA Harold Rogers PDMP Grant Awards Announcement

The U.S. Department of Justice (DOJ), Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA) announced the awards for the FY 2015 Harold Rogers Prescription Drug Monitoring Program grants. There were four (4) grant categories available: PDMP Implementation and Enhancement Grants (Category 1), PDMP Practitioner and Research Partnerships (Category 2), Data-Driven Multi-Disciplinary Approaches to Reducing Rx Abuse Grants (Category 3), and Tribal Prescription Drug Monitoring Program Data Sharing Grants (Category 4). The recipients for these grants are:

- **Category 1** – State of Ohio Board of Pharmacy, Florida Department of Health, Texas State Board of Pharmacy, New Hampshire Department of Justice, Wisconsin Department of Safety and Professional Services, New Jersey Department of Law and Public Safety, Nebraska Department of Health & Human Services, Nevada State Board of Pharmacy, Pennsylvania Department of Health, Montana Board of Crime Control, Oklahoma Bureau of Narcotics and Dangerous Drugs Control, and Kentucky Cabinet for Health and Family Services. View [AWARD](#).
- **Category 2** – Maryland Department of Health & Mental Hygiene, California

Department of Justice, Colorado Department of Regulatory Agencies, Rhode Island Department of Health, and Reno Police Department. View [AWARD](#).

- **Category 3** – Middle District Attorney’s Office Worcester County, MA, Colorado Department of Public Health and Environment. View [AWARD](#).
- **Category 4** – No grants awarded

You're receiving this message because you've subscribed to the PDMP TTAC mailing list

Our mailing address is:

PDMP Training and Technical Assistance Center
415 South Street, MS 035
Waltham, MA 02454



[Add us to your address book](#)

[unsubscribe from this list](#) | [update subscription preferences](#)

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

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| 10) Describe the issue and action that should be addressed: Discussion about the CDC Prescription Drug Overdose: Prevention for States Grant awarded to the Department of Health Services. | | | |

CDC funding helps states combat prescription drug overdose epidemic

Agency commits \$20 million to advance prevention on multiple fronts

Press Release

For Immediate Release: Friday, September 4, 2015

Contact: [Media Relations \(http://www.cdc.gov/media\)](http://www.cdc.gov/media)

(404) 639-3286

Today, the Centers for Disease Control and Prevention (CDC) announced the launch of *Prescription Drug Overdose: Prevention for States*, a new program to help states end the ongoing prescription drug overdose epidemic. The *Prevention for States* program, as part of the U.S. Department of Health and Human Services' Opioid Initiative, will make a strong investment in 16 states, giving them the resources and expertise they need to help prevent overdose deaths related to prescription opioids. The program builds upon the infrastructure of CDC's Prevention Boost and Core Violence and Injury Prevention programs.

Through a competitive application process, CDC selected 16 states to receive funds through the program: Arizona, California, Illinois, Kentucky, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, Vermont, and Wisconsin.

"The prescription drug overdose epidemic requires a multifaceted approach, and states are key partners in our efforts on the front lines to prevent overdose deaths," said Secretary Sylvia M. Burwell. "With this funding, states can improve their ability to track the problem, work with insurers to help providers make informed prescribing decisions, and take action to combat this epidemic."

In FY2015, CDC is committing \$20 million to launch this program in 16 states. Over the next four years, CDC plans to give the states annual awards between \$750,000 and \$1 million each year, subject to the availability of funds, to advance prevention, including in these areas:

- Enhancing prescription drug monitoring programs (PDMPs).
- Putting prevention into action in communities nationwide and encouraging education of providers and patients about the risk of prescription drug overdose.
- Working with health systems, insurers, and professional providers to help them make informed decisions about prescribing pain medication.
- Responding to new and emerging drug overdose issues through innovative projects, including

developing new surveillance systems or communications campaigns.

States can also use the funding to:

- Better understand and respond to the increase in heroin overdose deaths.
- Investigate the connection between prescription opioid abuse and heroin use.

The President's Budget for 2016 includes a request from Secretary Burwell for the resources needed to expand CDC's state efforts to all 50 states and launch a national program that will focus on prevention and prescription drug overdose surveillance.

A national epidemic

Since 1999, overdose deaths involving prescription opioids have quadrupled in the U.S. More than 16,000 people died from prescription opioid overdoses in 2013. Heroin deaths have also been on the rise, with more than 8,000 overdose deaths involving heroin in 2013—a nearly three-fold increase since 2010.

The amount of opioids prescribed and sold in the United States has increased four-fold since 1999, but there has not been an overall change in the amount of pain that Americans report.

“The prescription drug overdose epidemic is tragic and costly, but can be reversed,” said CDC Director Tom Frieden, MD, MPH. “Because we can protect people from becoming addicted to opioids, we must take fast action now, with real-time tracking programs, safer prescribing practices, and rapid response. Reversing this epidemic will require programs in all 50 states.”

CDC works with states, communities, and prescribers to prevent opioid misuse and overdose by tracking and monitoring the epidemic and helping states scale up effective programs. CDC also improves patient safety by equipping health care providers with data, tools, and guidance so they can make informed treatment decisions. Learn more at www.cdc.gov/DrugOverdose (<http://www.cdc.gov/DrugOverdose>).

Secretary Burwell has made addressing opioid abuse, dependence, and overdose a priority and work is underway within HHS on this important issue. [The evidence-informed initiative](http://www.hhs.gov/news/press/2015pres/03/20150326a.html) (<http://www.hhs.gov/news/press/2015pres/03/20150326a.html>) focuses on three promising areas: informing opioid prescribing practices, increasing the use of naloxone—a drug that reverses symptoms of a drug overdose—and using medication-assisted treatment to move people out of opioid addiction. Learn more about HHS activities at: [Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths](http://aspe.hhs.gov/pdf-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths) (<http://aspe.hhs.gov/pdf-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths>). The Obama Administration is also committed to tackling the prescription drug and heroin epidemic, proposing [significant investments](https://www.whitehouse.gov/ondcp/news-releases/2016-budget-opioid-resources) (<https://www.whitehouse.gov/ondcp/news-releases/2016-budget-opioid-resources>) to intensify efforts to reduce opioid misuse and abuse.

###

[U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES](http://www.hhs.gov/) (<http://www.hhs.gov/>)

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

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

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| 10) Describe the issue and action that should be addressed: Discussion about the development of the Wisconsin Enhanced Prescription Drug Monitoring Program (WIE-PDMP). The board may consider identifying a member to represent the board on the Executive Committee that will be involved in the project. | | | |

WI E-PDMP Grants and High-Level Deliverables Schedule
9/23/15

Sources of Funding for the Public Health Portal (PHP):

2014 Harold Rogers PDMP Enhancement Grant

- \$229,375
- 10/1/14 through 3/31/16 (requesting extension until 3/31/17)
- Quarterly Performance Measurement Reports
- Semi-Annual Programmatic Progress Reports

Sources of Funding for Enhanced Prescription Drug Monitoring Program (E-PDMP):

2015 CDC PDO Grant (via DHS)

- \$440,015
- 9/1/15 through 8/31/16 (with three possible additional years through 2019)
- Reporting schedule currently unknown

2015 Harold Rogers PDMP Enhancement Grant

- \$500,000 (Currently \$132,000 remaining balance for project)
- 10/1/15 through 9/30/17
- Quarterly Performance Measurement Reports
- Semi-Annual Programmatic Progress Reports

Strategic Prevention Framework Partnerships for Success II Supplemental (SEOW) Grant (via DHS)

- \$30,243
- To be used by 9/29/16

Deliverable Schedule:

September 30, 2016:

- PDMP Submitters Notified of E-PDMP

January 1, 2017:

- E-PDMP Dispenser Portal goes live
- E-PDMP Administrator Site goes live

January 15, 2017

- E-PDMP Healthcare Query Site(s) go live

March 31, 2017

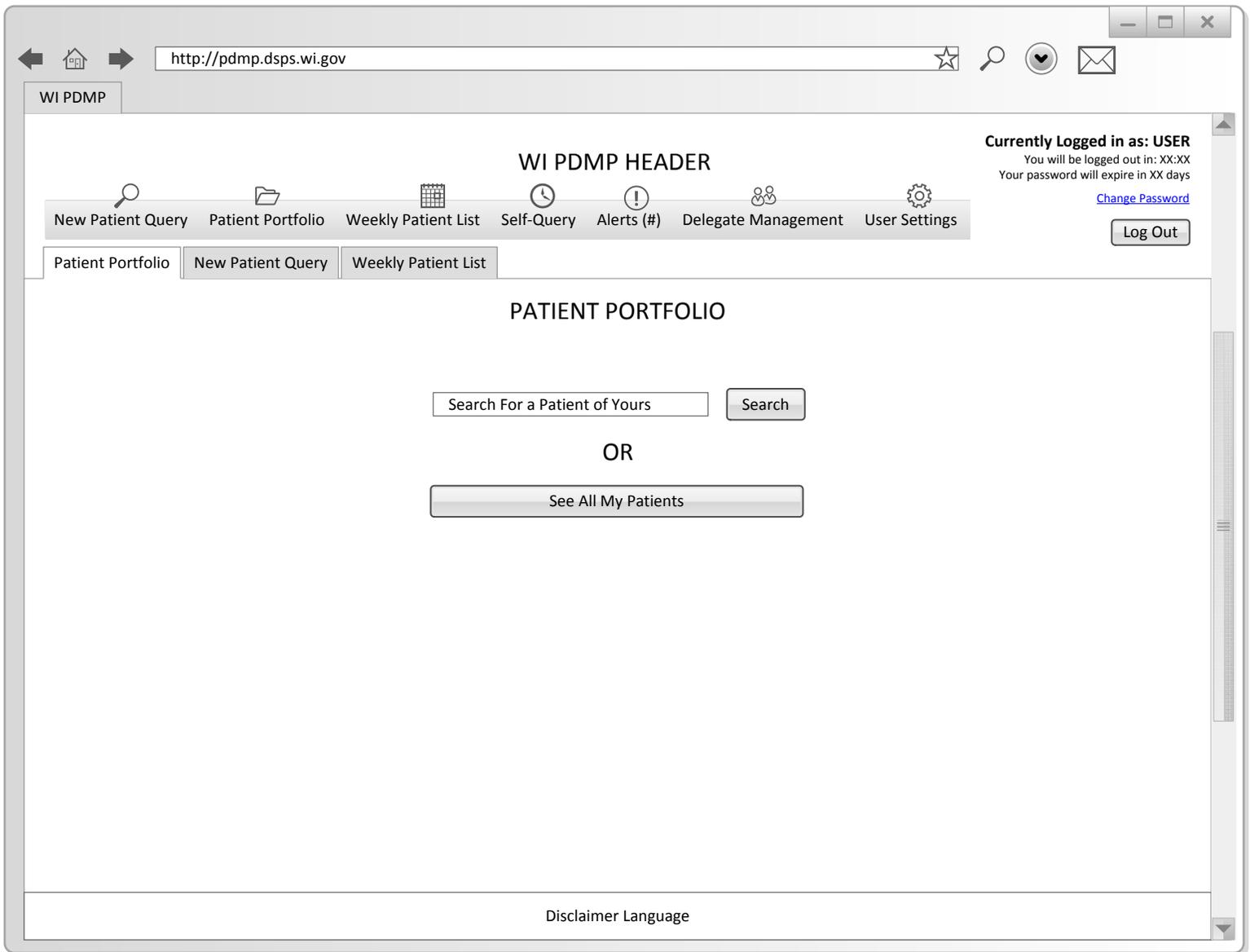
- PHP goes live

April 30, 2017

- E-PDMP Law Enforcement and Government Query Site(s) go live

July 1, 2017

- E-PDMP interface to WI Crime Alert Network goes live



Purpose: This is one of two possible landing pages the prescriber users (and their delegates, if enabled in the prescriber's user preferences) can select (the other being the New Patient Query). It enables users to search for a patient in their patient portfolio or see their entire patient portfolio.

Icons Introduced on this Page:

- None

Header Information:

- Header standard on all pages and includes PDMP Logo, menu ribbon, and user/session information
- Username easily readable
- Countdown timer indicating when the session will timeout
- Countdown in days to password expiration
- Link to change password
- Button to log out

Footer Information:

- Footer on all pages explaining the confidentiality of the website

Key Features:

- Sends user to Patient Portfolio listing of all patients matching search criteria, either one patient or all patients.

WI PDMP HEADER

Currently Logged in as: USER
You will be logged out in: XX:XX
Your password will expire in XX days
[Change Password](#)
[Log Out](#)

New Patient Query Patient Portfolio Weekly Patient List Self-Query Alerts (#) Delegate Management User Settings

Patient Portfolio New Patient Query Weekly Patient List

PATIENT PORTFOLIO

Search For a Patient of Yours
Search

| Name | DOB | Date of Last Prescription | Number Visited in Past Year | | Avg Daily MME | | Number of Alerts in the Past Year | | | | | Add to Weekly Patient List? |
|----------------------------|---------------------|---------------------------|-----------------------------|------------|---------------|---------------|-----------------------------------|---------|--------|--------|-------|-----------------------------|
| | | | Prescribers | Dispensers | Past 30 Days | Past 120 Days | Behavior | Lock-in | Pain K | Report | Theft | |
| Patient 1 | DOB | | 5 | | 45.4 | 113.2 | 0 | 0 | 1 | 3 | | <input type="checkbox"/> |
| Patient 2 | DOB | | 4 | | | | | | | | | <input type="checkbox"/> |
| Patient 3 | DOB | | 0 | | | | | | | | | <input type="checkbox"/> |
| Patient 4 | DOB | | | | | | | | | | | <input type="checkbox"/> |
| Patient 5 | DOB | | | | | | | | | | | <input type="checkbox"/> |
| Patient 6 | DOB | | | | | | | | | | | <input type="checkbox"/> |
| Patient 7 | DOB | | | | | | | | | | | <input type="checkbox"/> |
| Patient 8 | DOB | | | | | | | | | | | <input type="checkbox"/> |
| Patient 9 | DOB | | | | | | | | | | | <input type="checkbox"/> |
| Patient 10 | DOB | | | | | | | | | | | <input type="checkbox"/> |

Disclaimer Language

Purpose: This page displays a snapshot chart of all patients in whose WI PDMP Patient Report the prescriber user (and delegates, if enabled) is listed. This page is not available to non-prescriber users or the delegates of non-prescriber users.

Icons Introduced on this Page:

- Funnel: Filter based on user-entered criteria
- A-Z: Sort based on user-chosen criteria
- Map: Map of locations
- Save: Save Patient Portfolio as pdf
- Printer: Print Patient Portfolio

Key Features:

- Patients automatically removed from Patient Portfolio if not prescribed to by the prescriber user in the past year
- Search by name for a patient in the Patient Portfolio
- Clicking on the name of any patient in the Patient Portfolio brings up that patient’s WI PDMP Patient Report using the query criteria chosen in user preferences
- Color-coded information based on user chosen criteria for number visiting in past year columns, daily average MME columns, and alert columns
- 1-click access to an inventory of all alerts issued about the patient(s) in past year from alert data in the table
- 1-click, with confirmation pop-up, to add a patient to the Weekly Patient List

WI PDMP

http://pdmp.dps.wi.gov

WI PDMP HEADER

Currently Logged in as: USER
You will be logged out in: XX:XX
Your password will expire in XX days
[Change Password](#)
[Log Out](#)

New Patient Query Patient Portfolio Weekly Patient List Self-Query Alerts (#) Delegate Management User Settings

Patient Portfolio New Patient Query Weekly Patient List

NEW PATIENT QUERY

Patient Information:

First Name

Last Name

Suffix

DOB

ZIP Code

States to Query:

Wisconsin Other State Other State Other State

Illinois Other State Other State Other State

Minnesota Other State Other State Other State

Michigan Other State Other State Other State

Iowa Other State Other State Other State

Add Patient to Weekly Patient List?

[Disclaimer Language](#)

Purpose: This is one of two possible landing pages the prescriber user can select (the other being the Patient Portfolio search screen). This is the landing page for all non-prescriber users. It enables users to enter search criteria for a specific patient.

Icons Introduced on this Page:

- None

Key Features:

- Sends user to WI PDMP Patient Report of patient(s) matching search criteria
- Queries the past year of data only
- User may add a patient to his or her Weekly Patient List

http://pdmp.dsps.wi.gov

WI PDMP HEADER

Currently Logged in as: USER
You will be logged out in: XX:XX
Your password will expire in XX days
[Change Password](#)
[Log Out](#)

New Patient Query Patient Portfolio Weekly Patient List Self-Query Alerts (#) Delegate Management User Settings

Patient Portfolio New Patient Query Weekly Patient List

WEEKLY PATIENT LIST
XX/XX/XXXX – XX/XX/XXXX

Search For a Patient
Search

| Name | DOB | Date of Last Prescription | Number Visited in Past Year | | Avg Daily MME | | Number of Alerts in the Past Year | | | | Remove from Weekly Patient List? |
|----------------------------|---------------------|---------------------------|-----------------------------|------------|---------------|---------------|-----------------------------------|---------|--------|--------------|----------------------------------|
| | | | Prescribers | Dispensers | Past 30 Days | Past 120 Days | Behavior | Lock-in | Pain K | Theft Report | |
| Patient 1 | DOB | XX/XX/XXXX | 5 | | 45.4 | 113.2 | 0 | 0 | 1 | 3 | <input type="checkbox"/> |
| Patient 2 | DOB | | 4 | | | | | | | | <input type="checkbox"/> |
| Patient 3 | DOB | | 0 | | | | | | | | <input type="checkbox"/> |
| Patient 4 | DOB | | | | | | | | | | <input type="checkbox"/> |
| Patient 5 | DOB | | | | | | | | | | <input type="checkbox"/> |
| Patient 6 | DOB | | | | | | | | | | <input type="checkbox"/> |
| Patient 7 | DOB | | | | | | | | | | <input type="checkbox"/> |
| Patient 8 | DOB | | | | | | | | | | <input type="checkbox"/> |
| Patient 9 | DOB | | | | | | | | | | <input type="checkbox"/> |
| Patient 10 | DOB | | | | | | | | | | <input type="checkbox"/> |

Disclaimer Language

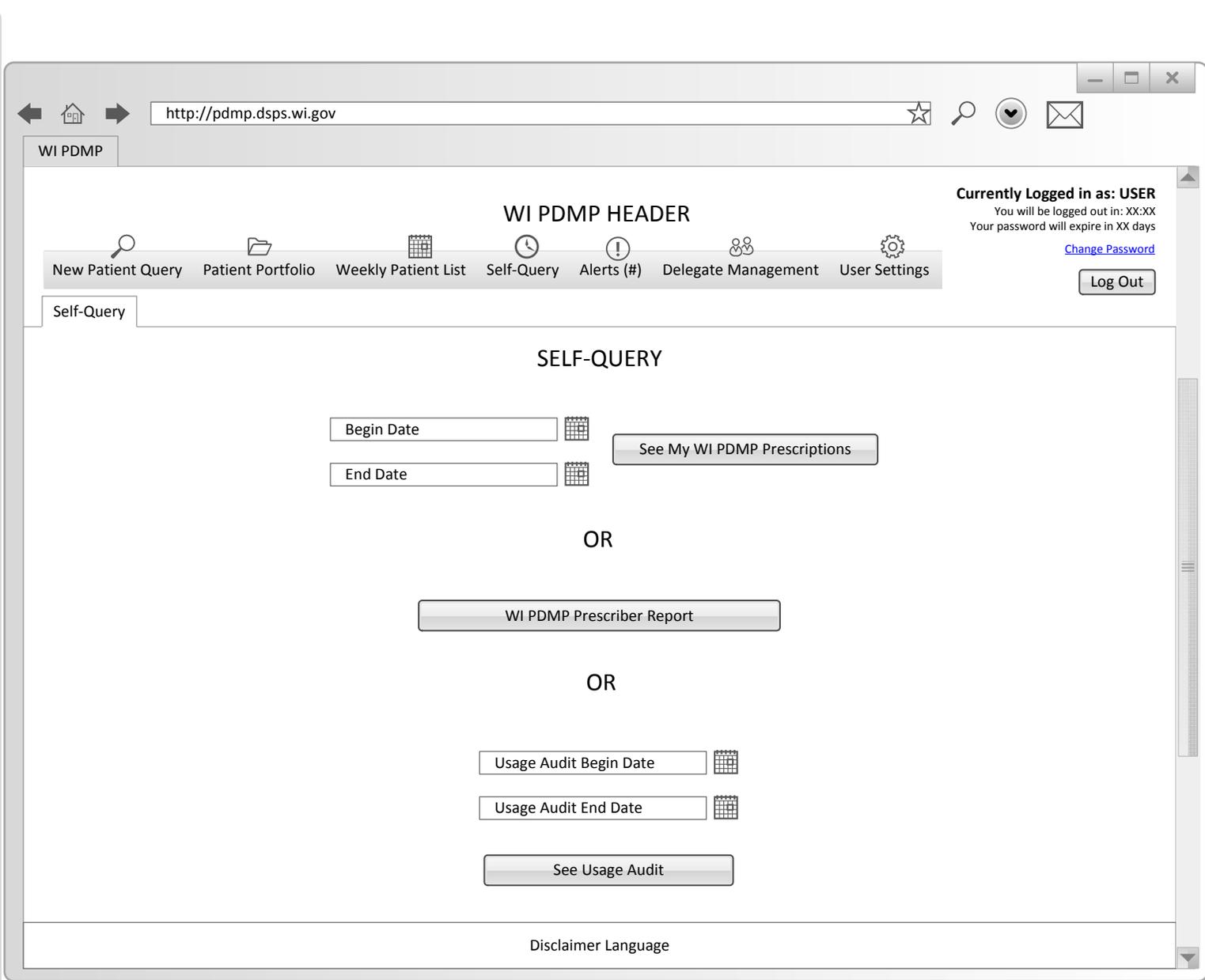
Purpose: This page displays a snapshot chart of patients with upcoming appointments and chosen by the prescriber user and any of his or her delegates, either individually or via a CSV file (CSV to include: name, DOB, appointment date). This page is not available to non-prescriber users or the delegates of non-prescriber users.

Unique Icons:

- X: Clear Weekly Patient List
- Paperclip: Upload weekly patient list file (CSV?)

Key Features:

- Upload a bulk CSV file with names, DOBs, and appointment date for patients to be included in Weekly Patient List
- Patients listed in order of appointment date, which shall be a column on the left side of the table (not shown)
- Patients automatically removed from weekly patient list 7 days after the appointment date
- Search by name for a patient in the Weekly Patient List
- Clicking on the name of any patient in the Weekly Patient List brings up that patient’s WI PDMP Patient Report using the query criteria chosen in user preferences
- Color-coded information based on administrator-changeable criteria for number visiting in past year columns, daily average MME columns, and alert columns
- 1-click, with confirmation pop-up, to remove a patient from the Weekly Patient List



Purpose: This page enables users to obtain an audit trail of their WI PDMP usage and prescriber users (not delegates or pharmacists) to obtain a list of all prescriptions in the database attributed to them or a WI PDMP Prescriber Report.

Key Features:

- Date chooser for prescription list and audit trail
- Audit trail shall include audit for all delegates, with the ability to separate audit trail by each user

Potential Future Enhancement to keep in mind:

- Clinic managers and medical director access to this page for all prescribers in his or her clinic.

http://pdmp.dps.wi.gov

WI PDMP

WI PDMP HEADER

Currently Logged in as: USER
You will be logged out in: XX:XX
Your password will expire in XX days
[Change Password](#)
[Log Out](#)

New Patient Query Patient Portfolio Weekly Patient List Self-Query Alerts (#) Delegate Management User Settings

Prescriber Report Audit Trail

WI PDMP PRESCRIBER REPORT

You prescribe more controlled substances that the following percentages of your peers:

The average daily MME for your patients in the WI PDMP for the following 6 months:

| Category | Percentage |
|-----------|------------|
| State | 27% |
| County | 36% |
| Specialty | 36% |

Number of Patients Exceeding 100 Daily MME

Month

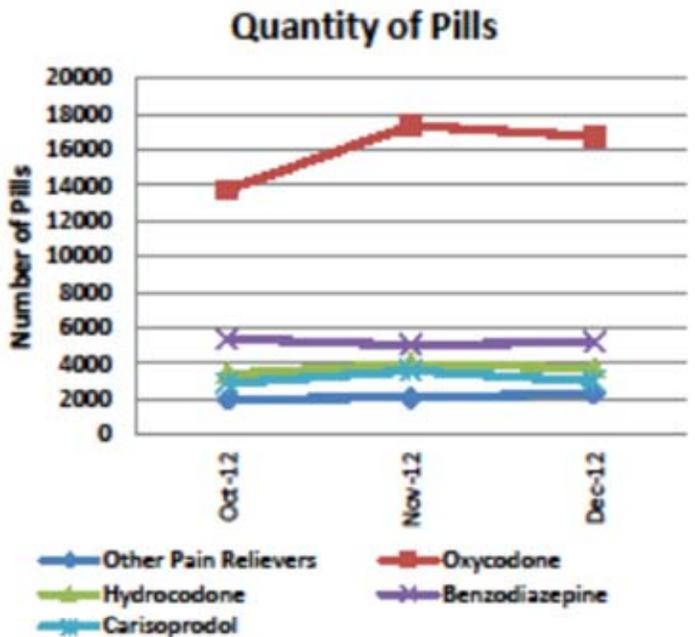
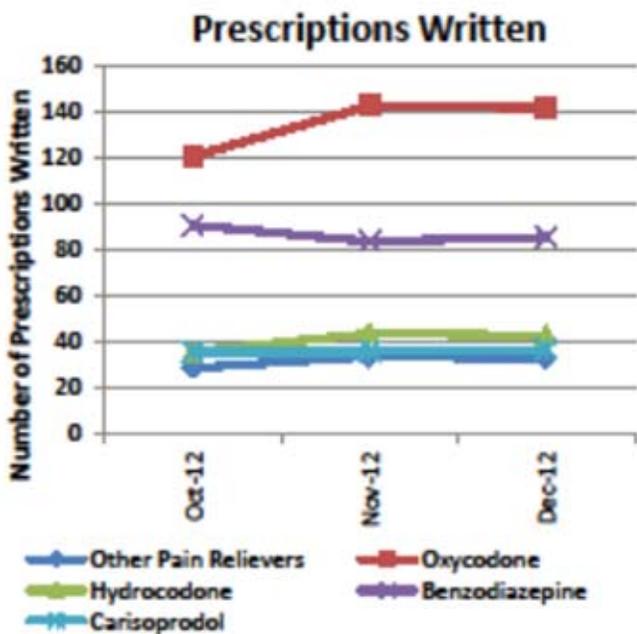
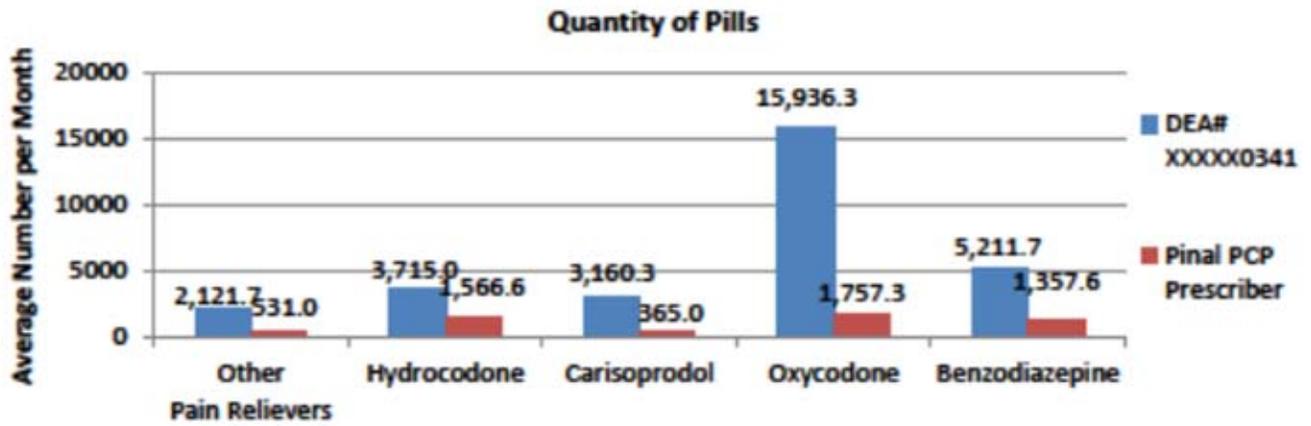
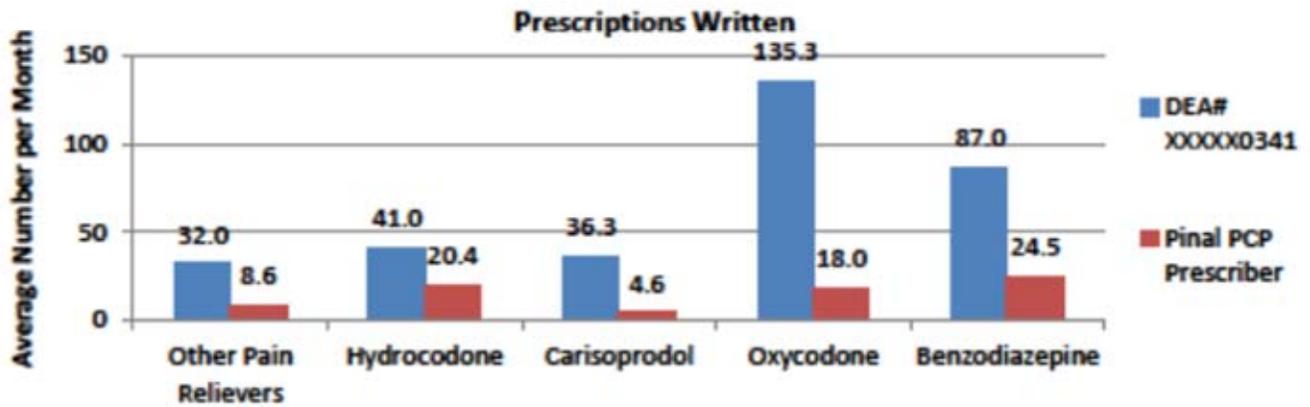
Disclaimer Language

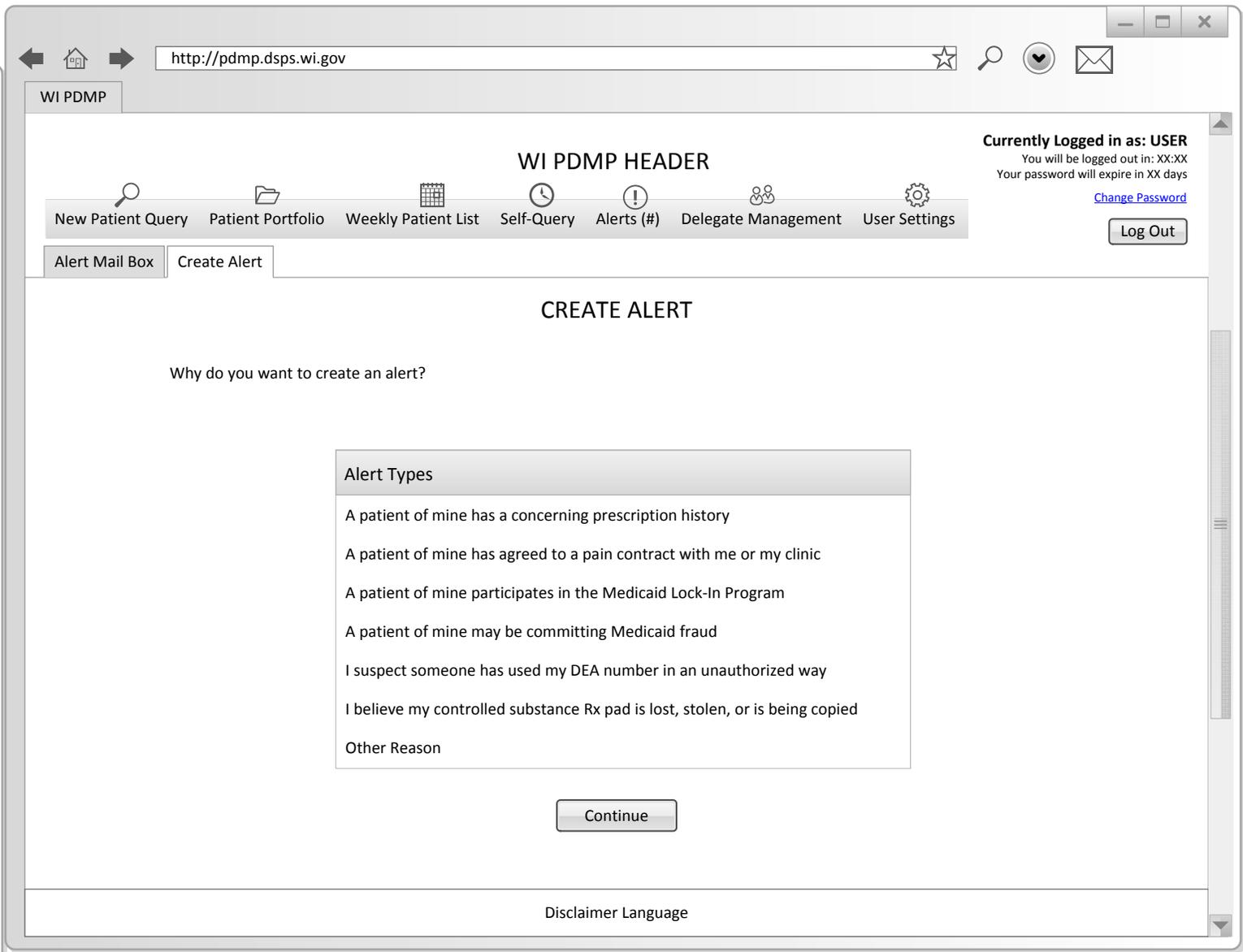
Purpose: This page displays information about the prescriber users' prescribing practices in comparison to other prescribers in the WI PDMP.

Key Features:

- Real-time dynamic display of data specific to the prescriber (or data refreshed at a specific interval)
- Tooltips provide more detail about the data in each widget
- Clicking on a widget will bring up information specific to the widget (for example, clicking on the widget about patients meeting a criteria, clicking the widget will bring up a list of patients meeting the criteria)
- Patients exceeding MME chosen in user preferences chart

OTHER WI PDMP PRESCRIBER REPORT ELEMENTS





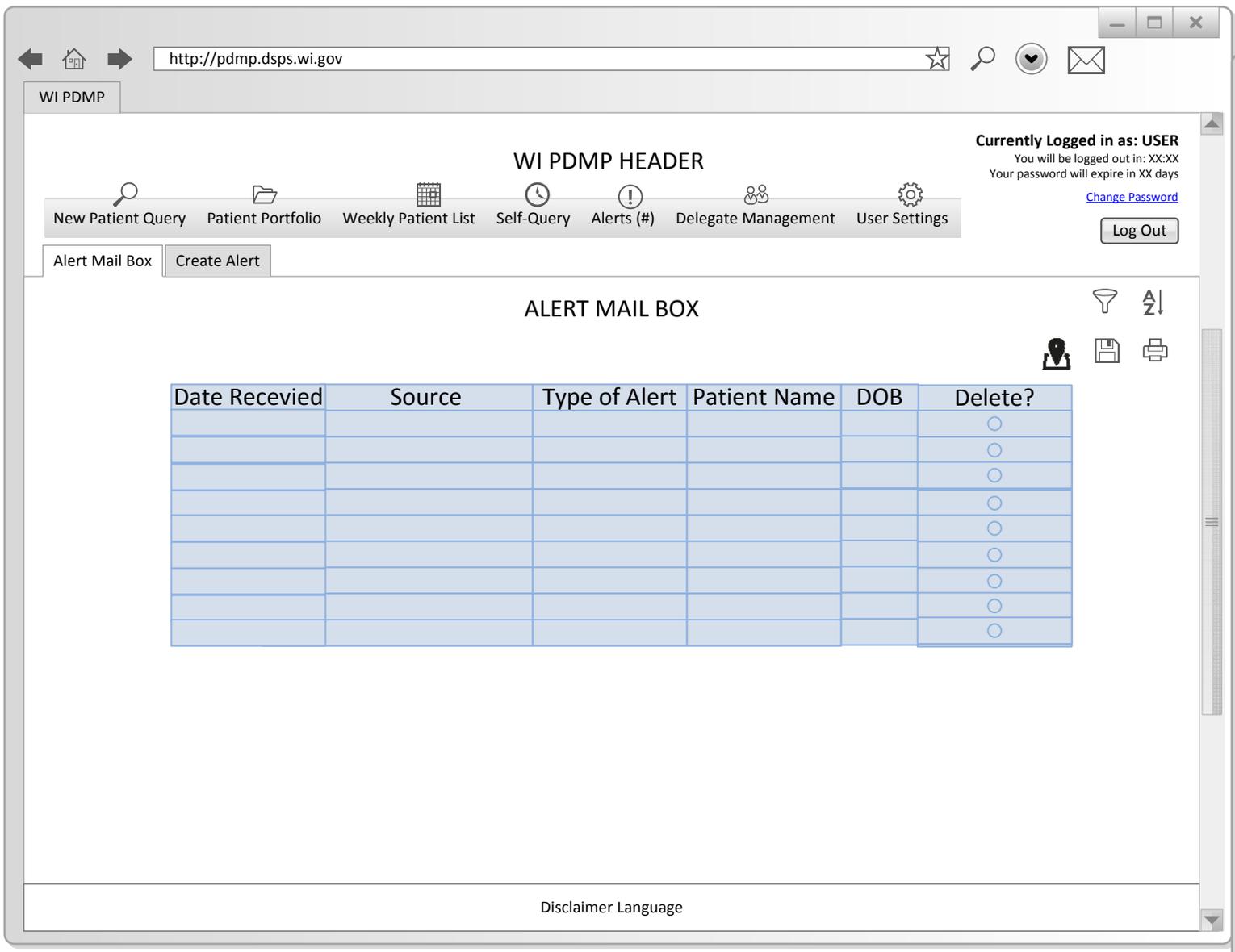
Purpose: This page enables healthcare users to create an alert or notice to send to other WI PDMP healthcare users.

Key Features:

- Efficient process to create an alert and send it to other healthcare users

Potential Future Enhancement to keep in mind:

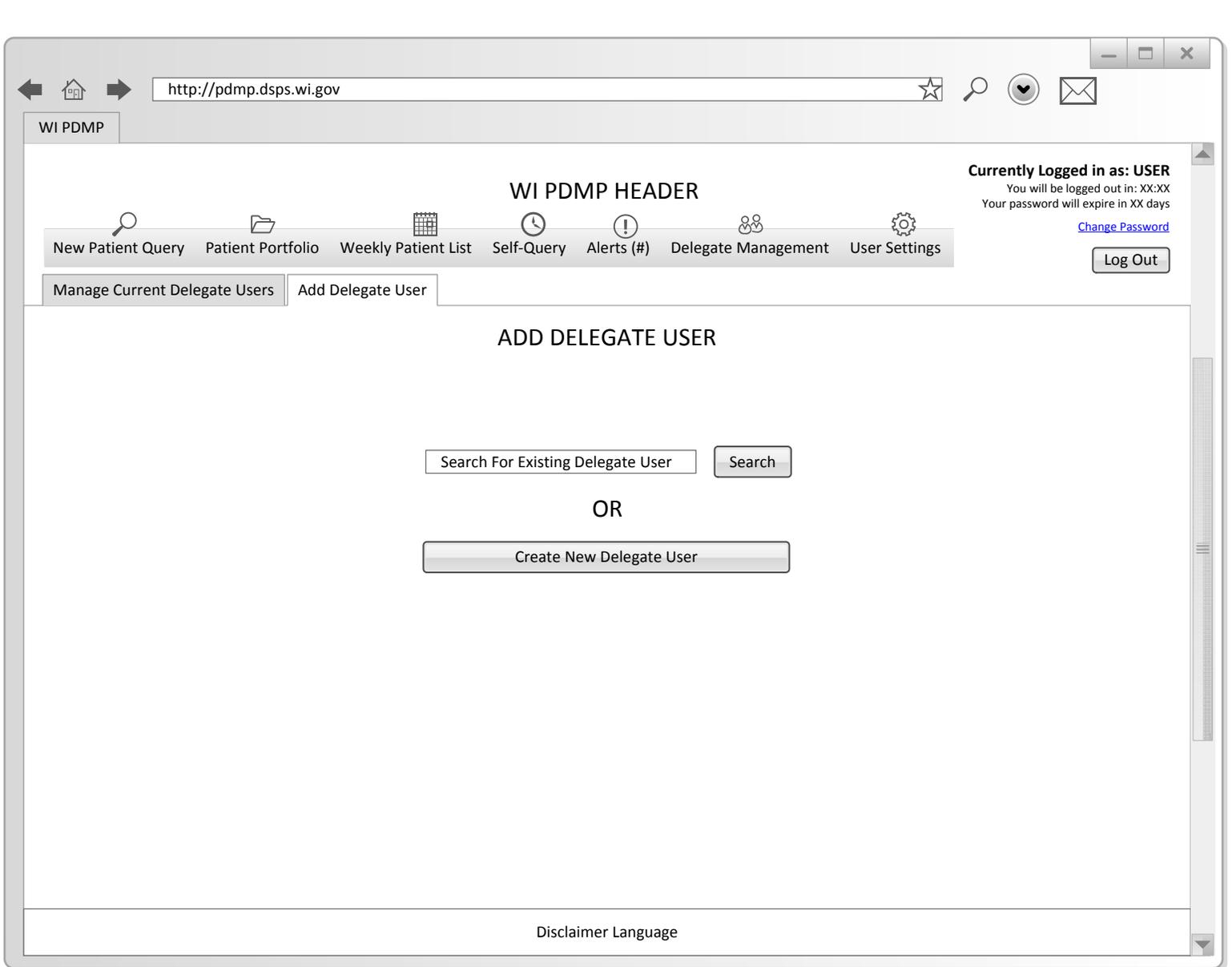
- Law enforcement users being able to create and send alerts to healthcare users via a similar page or the Wisconsin Crime Alert Network



Purpose: This page is a user's mailbox for WI PDMP alerts and notices.

Key Features:

- Basic mailbox functionality, similar to a any mail client
- Highlighting a row brings up the text of the alert
- Clicking on a patient name in the text of the alert brings up the patient report



Purpose: This page is designed to easily allow master account users to find and approve or create new delegate accounts.

Key Features:

- Find existing delegate users by name or clinic
- Create a new delegate user in the master account holder's page (notice sent to delegate to approve the account)

WI PDMP

WI PDMP HEADER

Currently Logged in as: **USER**
 You will be logged out in: XX:XX
 Your password will expire in XX days
[Change Password](#)
 Log Out

New Patient Query Patient Portfolio Weekly Patient List Self-Query Alerts (#) Delegate Management User Settings

Manage Current Delegate Users Add Delegate User

MANAGE CURRENT DELEGATE USERS

You have 0 pending delegate user requests.

| User Name | Date of Last Query | Number of Queries in Past 30 Days | Other Master Accounts | Activate? | Remove Delegate? |
|----------------------------|--------------------|-----------------------------------|-----------------------|-----------|-----------------------|
| Delegate 1 | | | | | <input type="radio"/> |
| | | | | | <input type="radio"/> |
| | | | | | <input type="radio"/> |
| | | | | | <input type="radio"/> |
| | | | | | <input type="radio"/> |
| | | | | | <input type="radio"/> |
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| | | | | | <input type="radio"/> |
| | | | | | <input type="radio"/> |
| | | | | | <input type="radio"/> |

Disclaimer Language

Purpose: This page enables master account users to manage the delegate accounts associated with his or her account.

Key Features:

- Easily disassociate delegates from the master account
- Display of basic information regarding each delegates use of the WI PDMP
- 1-click access to a delegates audit trail by clicking on the number of queries in past 30 days data in the table

**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: 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: 10/6/15 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? WI E-PDMP Development – 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 about the development of the Wisconsin Enhanced Prescription Drug Monitoring Program (WI E-PDMP). The board may consider identifying a member to represent the board on the Executive Committee that will be involved in the project. | | | |

WI E-PDMP Grants and High-Level Deliverables Schedule
9/23/15

Sources of Funding for the Public Health Portal (PHP):

2014 Harold Rogers PDMP Enhancement Grant

- \$229,375
- 10/1/14 through 3/31/16 (requesting extension until 3/31/17)
- Quarterly Performance Measurement Reports
- Semi-Annual Programmatic Progress Reports

Sources of Funding for Enhanced Prescription Drug Monitoring Program (E-PDMP):

2015 CDC PDO Grant (via DHS)

- \$440,015
- 9/1/15 through 8/31/16 (with three possible additional years through 2019)
- Reporting schedule currently unknown

2015 Harold Rogers PDMP Enhancement Grant

- \$500,000 (Currently \$132,000 remaining balance for project)
- 10/1/15 through 9/30/17
- Quarterly Performance Measurement Reports
- Semi-Annual Programmatic Progress Reports

Strategic Prevention Framework Partnerships for Success II Supplemental (SEOW) Grant (via DHS)

- \$30,243
- To be used by 9/29/16

Deliverable Schedule:

September 30, 2016:

- PDMP Submitters Notified of E-PDMP

January 1, 2017:

- E-PDMP Dispenser Portal goes live
- E-PDMP Administrator Site goes live

January 15, 2017

- E-PDMP Healthcare Query Site(s) go live

March 31, 2017

- PHP goes live

April 30, 2017

- E-PDMP Law Enforcement and Government Query Site(s) go live

July 1, 2017

- E-PDMP interface to WI Crime Alert Network goes live

**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: 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: 10/6/15 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? HOPE Draft Bills – 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 about four new HOPE draft bills under consideration: <ol style="list-style-type: none"> 1) PDMP Changes 2) PDMP Law Enforcement Requirements 3) Methadone Clinics 4) Pain Clinics | | | |



2015 ASSEMBLY BILL 364

September 25, 2015 - Introduced by Representatives NYGREN, PETRYK, NOVAK, TAUCHEN, SWEARINGEN, SPIROS, JAGLER, A. OTT, RIPP, KOLSTE, KERKMAN, SCHRAA, OHNSTAD, HORLACHER, SINICKI, MURTHA, EDMING, LOUDENBECK, VANDERMEER, GENRICH, MEYERS, ALLEN, BARCA, PETERSEN, KUGLITSCH, KNODL, MURSAU, MACCO, SANFELIPPO, BORN, SKOWRONSKI, J. OTT and SUBECK, cosponsored by Senators HARSDORF, GUDEx, COWLES, MARKLEIN, OLSEN, PETROWSKI, HANSEN and DARLING. Referred to Committee on Health.

1 **AN ACT** *to renumber and amend* 961.385 (1) (a); *to amend* 961.385 (1) (aj),
2 961.385 (2) (a) (intro.), 961.385 (2) (c), 961.385 (2) (h) and 961.385 (3) (b); and
3 **to create** 961.385 (1) (a) 1. to 3., 961.385 (1) (ab), 961.385 (1) (ad), 961.385 (1)
4 (ae), 961.385 (1) (af), 961.385 (2) (cm) 1., 961.385 (2) (cm) 2., 961.385 (2) (cm) 3.
5 a. and b., 961.385 (2) (cm) 4. and 961.385 (2) (cs) of the statutes; **relating to:**
6 reporting, disclosure, and practitioner review requirements under the
7 prescription drug monitoring program; providing an exemption from
8 emergency rule procedures; and granting rule-making authority.

Analysis by the Legislative Reference Bureau

This bill makes a number of changes to the Prescription Drug Monitoring Program (PDMP) administered by the Controlled Substances Board (board).

Under the bill, a pharmacy or practitioner generating a record under the PDMP when a monitored prescription drug is dispensed is required to submit the record to the board no later than 11:59 p.m. of the next business day after the monitored prescription drug is dispensed. Currently, there is no specific time frame required for the submission to the board of a record generated under the PDMP.

Under current law, the rules promulgated by the board implementing the PDMP must specify the persons to whom a record may be disclosed and the

ASSEMBLY BILL 364

circumstances under which the disclosure may occur, including disclosure to relevant state boards and agencies, relevant agencies of other states, and relevant law enforcement agencies under circumstances indicating suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner, or patient. The bill adds disclosure to relevant prosecutorial units, and the bill specifies that disclosure of a record generated under the PDMP is authorized under the following additional circumstances:

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

2. The state board or agency, agency of another state, law enforcement agency, or prosecutorial unit makes a written request for the record and is monitoring the patient as part of a drug court.

The bill further permits disclosure to a practitioner, pharmacist, registered nurse, or substance abuse counselor who is treating or rendering assistance to the patient for whom the record was generated and under other specific circumstances.

Finally, the bill authorizes disclosure of a record generated under the PDMP to a person who medically coordinates, directs, or supervises, or establishes standard operating procedures for, a practitioner, pharmacist, registered nurse, or substance abuse counselor to whom records may otherwise be disclosed, if the person is evaluating the job performance of the practitioner, pharmacist, registered nurse, or substance abuse counselor, or is performing quality assessment and improvement activities, including outcomes evaluation or development of clinical guidelines, and if the disclosure is limited to only those records about the practitioner, pharmacist, registered nurse, or substance abuse counselor.

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

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

1 **SECTION 1.** 961.385 (1) (a) of the statutes, as created by 2015 Wisconsin Act 55,
2 is renumbered 961.385 (1) (a) (intro.) and amended to read:

3 961.385 (1) (a) (intro.) “Administer” ~~has the meaning given in s. 450.01 (1).~~
4 means the direct application of a monitored prescription drug, whether by injection,
5 ingestion, or any other means, to the body of a patient by any of the following:

6 **SECTION 2.** 961.385 (1) (a) 1. to 3. of the statutes are created to read:

ASSEMBLY BILL 364

1 961.385 (1) (a) 1. A practitioner or his or her agent.

2 2. A patient at the direction of a practitioner.

3 3. A pharmacist.

4 **SECTION 3.** 961.385 (1) (ab) of the statutes is created to read:

5 961.385 (1) (ab) “Agent” means an authorized person who acts on behalf of or
6 at the direction of another person.

7 **SECTION 4.** 961.385 (1) (ad) of the statutes is created to read:

8 961.385 (1) (ad) “Business day” means any day on which the offices of the
9 department of safety and professional services are open.

10 **SECTION 5.** 961.385 (1) (ae) of the statutes is created to read:

11 961.385 (1) (ae) “Deliver” or “delivery” means the actual, constructive, or
12 attempted transfer of a monitored prescription drug from one person to another.

13 **SECTION 6.** 961.385 (1) (af) of the statutes is created to read:

14 961.385 (1) (af) “Dispense” means to deliver a monitored prescription drug
15 pursuant to the lawful prescription order of a practitioner, including the
16 compounding, packaging, or labeling necessary to prepare the monitored
17 prescription drug for delivery.

18 **SECTION 7.** 961.385 (1) (aj) of the statutes, as created by 2015 Wisconsin Act
19 55, is amended to read:

20 961.385 (1) (aj) “Patient” means an individual or animal for whom a monitored
21 prescription drug is prescribed or to whom a monitored prescription drug is
22 dispensed or administered.

23 **SECTION 8.** 961.385 (2) (a) (intro.) of the statutes, as affected by 2015 Wisconsin
24 Act 55, is amended to read:

ASSEMBLY BILL 364**SECTION 8**

1 961.385 (2) (a) (intro.) Require a pharmacy or a practitioner to generate a
2 record documenting each dispensing of a monitored prescription drug at the
3 pharmacy or, if the monitored prescription drug is not dispensed at a pharmacy, by
4 the practitioner and to submit the record to the board no later than 11:59 p.m. of the
5 next business day after the monitored prescription drug is dispensed, except that the
6 program may not require the generation of a record in any of the following
7 circumstances:

8 **SECTION 9.** 961.385 (2) (c) of the statutes, as affected by 2015 Wisconsin Act 55,
9 is amended to read:

10 961.385 (2) (c) Specify the persons to whom a record may be disclosed and the
11 circumstances under which the disclosure may occur. The Except as otherwise
12 provided under this section, the rule promulgated under this paragraph shall comply
13 with s. 146.82, except that the rule shall permit.

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

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

20 c. The circumstances ~~indicating~~ indicate suspicious or critically dangerous
21 conduct or practices of a pharmacy, pharmacist, practitioner, or patient. The board
22 shall define what constitutes suspicious or critically dangerous conduct or practices
23 for purposes of the rule promulgated under this paragraph this subd. 3. c.

24 **SECTION 10.** 961.385 (2) (cm) 1. of the statutes is created to read:

ASSEMBLY BILL 364

1 961.385 (2) (cm) 1. A practitioner, pharmacist, registered nurse licensed under
2 s. 441.06, or substance abuse counselor, as defined in s. 440.88 (1) (b) if any of the
3 following is applicable:

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

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

9 **SECTION 11.** 961.385 (2) (cm) 2. of the statutes is created to read:

10 961.385 (2) (cm) 2. A person who medically coordinates, directs, or supervises,
11 or establishes standard operating procedures for, a practitioner, pharmacist,
12 registered nurse, or substance abuse counselor to whom records may be disclosed
13 under subd. 1., if the person is evaluating the job performance of the practitioner,
14 pharmacist, registered nurse, or substance abuse counselor, or is performing quality
15 assessment and improvement activities, including outcomes evaluation or
16 development of clinical guidelines, and if the disclosure is limited to only those
17 records about the practitioner, pharmacist, registered nurse, or substance abuse
18 counselor the person medically coordinates, directs, or supervises, or for whom the
19 person establishes standard operating procedures.

20 **SECTION 12.** 961.385 (2) (cm) 3. a. and b. of the statutes are created to read:

21 961.385 (2) (cm) 3. a. The state board or agency, agency of another state, law
22 enforcement agency, or prosecutorial unit makes a written request for the record and
23 is engaged in an active and specific investigation or prosecution of a violation of any
24 state or federal law involving a monitored prescription drug, and the record being
25 requested is reasonably related to that investigation or prosecution.

ASSEMBLY BILL 364**SECTION 12**

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

4 **SECTION 13.** 961.385 (2) (cm) 4. of the statutes is created to read:

5 961.385 (2) (cm) 4. An agent of a practitioner or pharmacist if disclosure to the
6 practitioner or pharmacist is authorized subject to subd. 1.

7 **SECTION 14.** 961.385 (2) (cs) of the statutes is created to read:

8 961.385 (2) (cs) Require a practitioner to review a patient's records under the
9 program before the practitioner issues a prescription order for the patient.

10 **SECTION 15.** 961.385 (2) (h) of the statutes, as affected by 2015 Wisconsin Act
11 55, is amended to read:

12 961.385 (2) (h) Ensure that the program complies with s. 146.82, except as
13 otherwise provided in this section, and 45 CFR part 164, subpart E.

14 **SECTION 16.** 961.385 (3) (b) of the statutes, as affected by 2015 Wisconsin Act
15 55, is amended to read:

16 961.385 (3) (b) Nothing in this section may be construed to require a pharmacy,
17 or pharmacist, or practitioner to obtain, before ~~prescribing or~~ dispensing a monitored
18 prescription drug to a patient, information about the patient that has been collected
19 pursuant to the program established under sub. (2).

20 **SECTION 17. Nonstatutory provisions.**

21 (1) EMERGENCY RULES. The controlled substances board may promulgate
22 emergency rules under section 227.24 of the statutes implementing section 961.385
23 of the statutes, as amended by this act. Notwithstanding section 227.24 (1) (c) and
24 (2) of the statutes, emergency rules promulgated under this subsection remain in
25 effect until January 1, 2018, or the date on which permanent rules take effect,

ASSEMBLY BILL 364

1 whichever is sooner. Notwithstanding section 227.24 (1) (a) and (3) of the statutes,
2 the board is not required to provide evidence that promulgating a rule under this
3 subsection as an emergency rule is necessary for the preservation of the public peace,
4 health, safety, or welfare and is not required to provide a finding of emergency for a
5 rule promulgated under this subsection.

6 **SECTION 18. Effective date.**

7 (1) This act takes effect on January 1, 2017.

8 **(END)**



2015 ASSEMBLY BILL 365

September 25, 2015 - Introduced by Representatives NYGREN, KOLSTE, KITCHENS, VANDERMEER, PETRYK, NOVAK, TAUCHEN, SWEARINGEN, SPIROS, JAGLER, A. OTT, RIPP, KERKMAN, SCHRAA, HORLACHER, MURTHA, EDMING, LOUDENBECK, ALLEN, PETERSEN, KUGLITSCH, KNODL, BALLWEG, TITTL, MURSAU, SANFELIPPO, BORN, SKOWRONSKI, MACCO, J. OTT, JACQUE, JOHNSON, CONSIDINE, JORGENSEN, GOYKE, OHNSTAD, SINICKI, GENRICH, MEYERS, SPREITZER, BARCA, SUBECK, C. TAYLOR and POPE, cosponsored by Senators HARSDORF, GUDEx, COWLES, OLSEN, PETROWSKI, WANGGAARD, HANSEN and DARLING. Referred to Committee on Health.

1 **AN ACT** *to create* 961.37 and 961.385 (2) (i) of the statutes; **relating to:** duty of
2 law enforcement officers to report to the Prescription Drug Monitoring Program
3 controlled-substance violations, opioid-related drug overdoses or deaths, and
4 reports of stolen prescription drugs.

Analysis by the Legislative Reference Bureau

Under this bill, if a law enforcement officer encounters a suspected controlled-substance violation involving certain prescription drugs or an opioid-related drug overdose or death, or a law enforcement officer receives a report of a stolen controlled-substance prescription, the officer must report to his or her law enforcement agency the name and birth date of any individual involved in the suspected violation, overdose, or death or from whom the prescription was stolen; the prescribing practitioner; the prescription number; and the name of the prescription drug. The law enforcement agency must then provide that information, as well as notice of the suspected violation, overdose or death, or theft to the Prescription Drug Monitoring Program. The program may disclose information provided by the law enforcement agency to persons such as relevant practitioners and pharmacists.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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

ASSEMBLY BILL 365**SECTION 1**

1 **SECTION 1.** 961.37 of the statutes is created to read:

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

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

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

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

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

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

16 1. The individual who is suspected of violating this chapter.

17 2. The individual who experienced an opioid-related drug overdose.

18 3. The individual who died as a result of using a narcotic drug.

19 4. The individual who filed the report of a stolen controlled-substance
20 prescription.

21 5. The individual for whom a prescription drug related to an event under subd.
22 1., 2., 3., or 4. was prescribed.

23 (b) The name of the prescribing practitioner, the prescription number, and the
24 name of the drug as it appears on the prescription order or prescription medicine
25 container if a prescription medicine container was in the vicinity of the suspected

ASSEMBLY BILL 365

1 violation, drug overdose, or death or if a controlled-substance prescription was
2 reported stolen.

3 **(3)** (a) The law enforcement agency receiving the report under sub. (2) shall,
4 except as provided under par. (b), submit notice of the suspected violation of this
5 chapter, the opioid-related drug overdose, the death as a result of using a narcotic
6 drug, or the report of a stolen controlled-substance prescription, and the information
7 reported under sub. (2) to the prescription drug monitoring program.

8 (b) If a law enforcement agency determines that submitting any information
9 under par. (a) would interfere with an active criminal investigation, the law
10 enforcement agency may postpone the action until the investigation concludes.

11 **SECTION 2.** 961.385 (2) (i) of the statutes is created to read:

12 961.385 **(2)** (i) Disclose information submitted to the program by a law
13 enforcement agency under s. 961.37 (3) (a) to relevant practitioners, pharmacists,
14 and others to whom the board may make disclosures under par. (c).

15 **(END)**



2015 ASSEMBLY BILL 366

September 25, 2015 - Introduced by Representatives NYGREN, PETRYK, NOVAK, TAUCHEN, SWEARINGEN, SPIROS, JAGLER, A. OTT, RIPP, KOLSTE, KERKMAN, GOYKE, SCHRAA, HORLACHER, MURTHA, EDMING, VANDERMEER, ALLEN, E. BROOKS, KUGLITSCH, MURSAU, MACCO, SANFELIPPO, BORN, SKOWRONSKI, J. OTT, OHNSTAD, SINICKI, LOUDENBECK, GENRICH, MEYERS, SPREITZER, BARCA, PETERSEN, SUBECK and BILLINGS, cosponsored by Senators DARLING, GUDEx, HARSDORF, MARKLEIN, OLSEN, PETROWSKI and COWLES. Referred to Committee on Health.

1 **AN ACT** *to repeal* subchapter IV (title) of chapter 50 [precedes 50.90]; *to amend*
2 20.435 (6) (jm), 50.56 (3), 146.40 (1) (bo), 146.81 (1) (L) and 146.997 (1) (d) 18.;
3 and *to create* subchapter V (title) of chapter 50 [precedes 50.60], 50.60, 50.65
4 and subchapter VI (title) of chapter 50 [precedes 50.90] of the statutes; **relating**
5 **to:** pain clinic certification and requirements, granting rule-making authority,
6 and providing a penalty.

Analysis by the Legislative Reference Bureau

This bill requires certification of a pain clinic in order for it to operate. A pain clinic must submit an application to the Department of Health Services (DHS), which is required to issue the certificate of operation if the pain clinic meets the requirements specified in the bill, has paid any required application fee, and meets any requirements established by DHS. Each pain clinic location is certified separately regardless of whether the clinic is operated under the same business name, ownership, or management as another pain clinic. The bill requires a pain clinic to have a medical director who is a physician that practices in Wisconsin and requires a pain clinic to report annually to DHS certain information specified in the bill. The bill also requires a physician or other health care provider at a pain clinic authorized to prescribe pain medication to review for treatment purposes an individual's records on the prescription drug monitoring database for use of other pain medications.

ASSEMBLY BILL 366

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

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

1 **SECTION 1.** 20.435 (6) (jm) of the statutes is amended to read:

2 20.435 (6) (jm) *Licensing and support services.* The amounts in the schedule
3 for the purposes specified in ss. 48.685 (2) (am) and (b) 1., (3) (a), (am), (b), and (bm),
4 and (5) (a), 49.45 (47), 50.02 (2), 50.025, 50.065 (2) (am) and (b) 1., (3) (a) and (b), and
5 (5), 50.13, 50.135, 50.36 (2), 50.49 (2) (b), 50.495, 50.52 (2) (a), 50.57, 50.981, and
6 146.40 (4r) (b) and (er), and subch. ~~IV~~ VI of ch. 50 and to conduct health facilities plan
7 and rule development activities, for accrediting nursing homes, convalescent homes,
8 and homes for the aged, to conduct capital construction and remodeling plan reviews
9 under ss. 50.02 (2) (b) and 50.36 (2), and for the costs of inspecting, licensing or
10 certifying, and approving facilities, issuing permits, and providing technical
11 assistance, that are not specified under any other paragraph in this subsection. All
12 moneys received under ss. 48.685 (8), 49.45 (42) (c), 49.45 (47) (c), 50.02 (2), 50.025,
13 50.065 (8), 50.13, 50.36 (2), 50.49 (2) (b), 50.495, 50.52 (2) (a), 50.57, 50.93 (1) (c), and
14 50.981, all moneys received from fees for the costs of inspecting, licensing or
15 certifying, and approving facilities, issuing permits, and providing technical
16 assistance, that are not specified under any other paragraph in this subsection, and
17 all moneys received under s. 50.135 (2) shall be credited to this appropriation
18 account.

19 **SECTION 2.** 50.56 (3) of the statutes is amended to read:

20 50.56 (3) Notwithstanding sub. (2), insofar as a conflict exists between this
21 subchapter, or the rules promulgated under this subchapter, and subch. I, II or IV

ASSEMBLY BILL 366

1 VI, or the rules promulgated under subch. I, II or IV VI, the provisions of this
2 subchapter and the rules promulgated under this subchapter control.

3 **SECTION 3.** Subchapter V (title) of chapter 50 [precedes 50.60] of the statutes
4 is created to read:

CHAPTER 50**SUBCHAPTER V****CLINICS**

8 **SECTION 4.** 50.60 of the statutes is created to read:

9 **50.60 Definitions; clinics.** In this subchapter: (1) “Advanced practice nurse
10 prescriber” means an individual certified under s. 441.16 (2).

11 (2) “Health care provider” has the meaning given in s. 146.81 (1) (a) to (hp).

12 (3) “Pain clinic” means any of the following:

13 (a) A privately owned facility at which a physician, advanced practice nurse
14 prescriber, physician assistant, or other health care provider with prescribing
15 privileges, who prescribes controlled substances, provides pain management
16 services to patients, a majority of whom are prescribed opioids or opiates,
17 benzodiazepines, barbiturates, or carisoprodol, and provides prescriptions for more
18 than 90 days in a 12-month period.

19 (b) Any privately owned facility or office that advertises or otherwise holds
20 itself out as providing pain management services and that has one or more employees
21 or contractors who prescribe a controlled substance for pain management.

22 (4) “Physician assistant” has the meaning given in s. 448.01 (6).

23 **SECTION 5.** 50.65 of the statutes is created to read:

24 **50.65 Pain clinics.** (1) CERTIFICATION REQUIRED. (a) No pain clinic may
25 operate unless it holds a certificate to operate issued by the department.

ASSEMBLY BILL 366**SECTION 5**

1 (b) A pain clinic shall submit to the department an application, on a form
2 prescribed by the department, for a certificate. Each pain clinic location is certified
3 separately regardless of whether the clinic is operated under the same business
4 name, ownership, or management as another pain clinic. The department may
5 charge an applicant a fee for applying for a certificate.

6 (c) A certified pain clinic that undergoes a change of majority ownership shall
7 submit a new application for a certificate.

8 (d) A pain clinic shall have a medical director who is a physician that practices
9 in this state. In the event that the medical director no longer meets the requirements
10 of holding the position of medical director, the pain clinic shall notify the department
11 within 10 business days of the identity of a physician who meets the requirements
12 of medical director and who acts as medical director at that pain clinic. Failure to
13 notify the department of an acting medical director within 10 days of the departure
14 of the previous medical director may be a basis for the department to suspend the
15 pain clinic's certification.

16 (e) The department shall issue a certificate of operation to a pain clinic if the
17 department finds that the pain clinic meets the requirements of this section, has paid
18 any application fee required by the department, and meets any requirements
19 established by the department.

20 **(2) PENALTY FOR VIOLATION.** (a) If the department finds that a pain clinic which
21 was issued a certificate under this section no longer meets any requirement of this
22 section or rules promulgated under this section or of requirements established by the
23 department, the department may do any of the following:

24 1. Suspend the certificate of the pain clinic until the department determines
25 that the pain clinic demonstrates compliance.

ASSEMBLY BILL 366

- 1 2. Revoke the certificate of the pain clinic.
- 2 3. Impose a forfeiture of up to \$1,000 per day for each day of continued violation.
- 3 (b) A pain clinic subject to a penalty under par. (a) is entitled to an appeal and
- 4 a hearing under ch. 227.
- 5 **(3) REPORTING.** (a) Annually, a pain clinic shall report to the department all
- 6 of the following:
- 7 1. The ratio of pain clinic staff to the number of individuals receiving pain
- 8 treatment.
- 9 2. The number of individuals receiving pain treatment who are also receiving
- 10 behavioral health services.
- 11 3. The pain clinic staff's plan for tapering individuals off of pain medications,
- 12 if applicable.
- 13 4. The average mileage that individuals receiving pain treatment in the pain
- 14 clinic are traveling to receive treatment in that clinic.
- 15 (b) The pain clinic shall ensure that the information under par. (a) is provided
- 16 in a manner that does not permit the identification of an individual who is receiving
- 17 pain medication from the pain clinic.
- 18 **(4) PRESCRIPTION MONITORING.** Before prescribing a pain medication, a
- 19 physician or other health care provider at a pain clinic who is authorized to prescribe
- 20 pain medication shall review for treatment purposes an individual's records on the
- 21 prescription drug monitoring database for use of other pain medications.
- 22 **(5) APPLICABILITY.** This section does not apply to any of the following:
- 23 (a) A medical or dental school, nursing school, physician assistant training
- 24 program, or outpatient clinic associated with any of the schools or training programs
- 25 specified in this paragraph.

ASSEMBLY BILL 366**SECTION 5**

1 (b) A hospital, as defined in s. 50.33 (2).

2 (c) Hospice, as defined in s. 50.90 (1).

3 (d) A nursing home, as defined in s. 50.01 (3).

4 **(6) RULES.** The department may promulgate rules it determines are necessary
5 to implement this section.

6 **SECTION 6.** Subchapter VI (title) of chapter 50 [precedes 50.90] of the statutes
7 is created to read:

8 **CHAPTER 50**

9 **SUBCHAPTER VI**

10 **HOSPICES**

11 **SECTION 7.** Subchapter IV (title) of chapter 50 [precedes 50.90] of the statutes
12 is repealed.

13 **SECTION 8.** 146.40 (1) (bo) of the statutes is amended to read:

14 146.40 (1) (bo) "Hospice" means a hospice that is licensed under subch. ~~IV~~ VI
15 of ch. 50.

16 **SECTION 9.** 146.81 (1) (L) of the statutes is amended to read:

17 146.81 (1) (L) A hospice licensed under subch. ~~IV~~ VI of ch. 50.

18 **SECTION 10.** 146.997 (1) (d) 18. of the statutes is amended to read:

19 146.997 (1) (d) 18. A hospice licensed under subch. ~~IV~~ VI of ch. 50.

20 **SECTION 11. Nonstatutory provisions.**

21 (1) Notwithstanding section 50.65 (1) (a) of the statutes, a pain clinic, as defined
22 in section 50.60 (3) of the statutes, that is operating on the effective date of this
23 subsection may continue to operate without the certificate required under section
24 50.65 (1) (a) of the statutes if the pain clinic submits an application for a certificate

ASSEMBLY BILL 366

1 under section 50.65 (1) of the statutes within 30 days after the date the department
2 of health services publishes the certificate application form on its Internet site.

3 (END)



2015 ASSEMBLY BILL 367

September 25, 2015 - Introduced by Representatives NYGREN, PETRYK, NOVAK, TAUCHEN, SWEARINGEN, SPIROS, JAGLER, A. OTT, RIPP, KERKMAN, SCHRAA, HORLACHER, MURTHA, EDMING, LOUDENBECK, VANDERMEER, ALLEN, PETERSEN, KUGLITSCH, KNODL, TITTL, MURSAU, MACCO, SANFELIPPO, BORN, SKOWRONSKI, QUINN, J. OTT, KOLSTE, GOYKE, OHNSTAD, SINICKI, GENRICH, MEYERS, SPREITZER, BARCA, SUBECK, BILLINGS and BROSTOFF, cosponsored by Senators DARLING, GUDEX, HARS DORF, MARKLEIN, OLSEN, PETROWSKI, COWLES and BEWLEY. Referred to Committee on Health.

1 **AN ACT to create** 51.4223 of the statutes; **relating to:** reporting by treatment
2 programs using methadone and requiring review of prescription drug
3 monitoring database.

Analysis by the Legislative Reference Bureau

This bill requires treatment programs that treat addiction using methadone to report annually to the Department of Health Services (DHS) the information specified in the bill. The bill requires that the treatment program ensure that the information reported to DHS is provided in a manner that does not permit the identification of an individual who is receiving methadone treatment from the program. The bill also requires that before prescribing methadone, a physician or other health care provider authorized to prescribe methadone must review for treatment purposes an individual's records on the prescription drug monitoring database for other methadone or pain medication use.

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

4 **SECTION 1.** 51.4223 of the statutes is created to read:

**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: 24 September 2015 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: 6 October 2015 | 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 15-007 Relating to Rescheduling Hydrocodone Combination Products 2. Adopt CR 15-008 Relating to Scheduling Tramadol 3. Adopt CR 15-009 Relating to Scheduling Suvorexant 4. Clearinghouse Report for CR 15-068 Relating to Exclusion of Naloxegol 5. Federal Exclusion of ioflupane 6. Draft amending CSB 3 Relating to Special Use Authorization 7. Proposals for amending CSB 4 Relating to Prescription Drug Monitoring Program operation 8. Update on Pending Legislation and 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>24 September 2015</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 15-007)

ORDER

An order of the Controlled Substances Board to create CSB 2.37 relating to rescheduling hydrocodone combination products.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.18, Stats.

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

Explanation of agency authority:

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).

Related statute or rule: N/A

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating hydrocodone combination products as a schedule II instead of schedule III under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on October 7, 2014 to similarly treat hydrocodone combination products under chapter 961 effective November 1, 2014 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule repeals sections 961.18(5)(c) and (d) which reschedules hydrocodone combination products from a schedule III to a schedule II.

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

On August 22, 2014, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register rescheduling hydrocodone combination products from a schedule III to a schedule II of the federal Controlled Substances Act. The scheduling action was effective October 6, 2014.

Comparison with rules in adjacent states:

Illinois: Illinois has not rescheduled hydrocodone combination products.

Iowa: Iowa is in the process of promulgating an administrative rule to amend the Iowa statutes to reschedule hydrocodone combination products from schedule III to schedule II.

Michigan: Michigan has not rescheduled hydrocodone combination products.

Minnesota: Minnesota has not rescheduled hydrocodone combination products.

Summary of factual data and analytical methodologies:

The methodology was to reschedule hydrocodone combination products 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:

None.

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 Eric.Esser@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 8935, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.37 is created to read:

CSB 2.37 Rescheduling of hydrocodone combination products. Section 961.18(5)(c) and (d), Stats. are repealed.

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 15-008)

ORDER

An order of the Controlled Substances Board to create CSB 2.36 relating to scheduling tramadol as a schedule IV controlled substance.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

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

Explanation of agency authority:

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).

Related statute or rule: N/A

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

On July 2, 2014, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing tramadol into schedule IV of the federal Controlled Substances Act. The scheduling action was effective August 18, 2014.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating tramadol as a schedule IV under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on August 14, 2014 to similarly treat tramadol under chapter 961 effective September 1, 2014 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.20(4)(e), Stats. which adds tramadol to schedule IV.

Comparison with rules in adjacent states:

Illinois: Illinois scheduled tramadol as a schedule IV controlled substance.

Iowa: Iowa is in the process of promulgating an administrative rule to amend the Iowa statutes to schedule tramadol as a schedule IV controlled substance.

Michigan: Michigan has not scheduled tramadol.

Minnesota: Minnesota has not scheduled tramadol.

Summary of factual data and analytical methodologies:

The methodology was to schedule Tramadol 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:

None.

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 Eric.Esser@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 8935, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.36 is created to read:

CSB 2.36 Addition of tramadol to schedule IV. Section 961.20(4)(e), Stats., is created to read: *Section 961.20(4)(e) Tramadol, including any of its isomers and salts of isomers.*

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 15-009)

ORDER

An order of the Controlled Substances Board to create CSB 2.38 relating to scheduling suvorexant as a schedule IV controlled substance.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

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

Explanation of agency authority:

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).

Related statute or rule: N/A

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

On August 28, 2014, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing Suvorexant into schedule IV of the federal Controlled Substances Act. The scheduling action was effective September 29, 2014.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating Suvorexant as a schedule IV under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on October 8, 2014 to similarly treat Suvorexant under chapter 961 effective November 1, 2014 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.20(2)(mr), Stats. which adds Suvorexant to schedule IV.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled Suvorexant.

Iowa: Iowa is in the process of promulgating an administrative rule to amend the Iowa statutes to schedule Suvorexant as a schedule IV controlled substance.

Michigan: Michigan has not scheduled Suvorexant.

Minnesota: Minnesota has not scheduled Suvorexant.

Summary of factual data and analytical methodologies:

The methodology was to schedule Suvorexant 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:

None.

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 Eric.Esser@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 8935, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 2.38 is created to read:

suvorexant to schedule IV. Section 961.20(2)(mr), Stats., is created to read:

Section 961.20(2)(mr) Suvorexant.

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

not contain adequate or appropriate safety standards for this design feature. Maintaining a structured assessment to determine potential installation issues mitigates the concern that the addition of a full authority engine controller does not produce a failure condition not previously considered.

Applicability

The special conditions are applicable to the KC-100. Should Korea Aerospace Industries, Ltd., apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would also apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the KC-100. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, notice and opportunity for prior public comment hereon are unnecessary and the FAA finds good cause, in accordance with 5 U.S. Code §§ 553(b)(3)(B) and 553(d)(3), making these special conditions effective upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113 and 44701; 14 CFR 21.16 and 21.17; and 14 CFR 11.38 and 11.19.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Korea Aerospace Industries, Ltd., Model KC-100 airplanes.

1. Electronic Engine Control

a. For electronic engine control system installations, it must be established that no single failure or malfunction or probable combinations of failures of Electronic Engine Control (EEC) system components will have an effect on the system, as installed in the airplane, that causes the Loss of Thrust Control (LOT)/Loss of Power Control (LOPC) probability of the system to exceed those allowed in part 33 certification.

b. EEC system installations must be evaluated for environmental and atmospheric conditions, including lightning. The EEC system lightning and high intensity radiated frequency effects that result during a LOTC/LOPC should be considered catastrophic.

c. The components of the installation must be constructed, arranged, and installed so as to ensure their continued safe operation between normal inspections or overhauls.

d. Functions incorporated into any EEC that make it part of any equipment, system or installation having functions beyond that of basic engine control, and may also introduce system failures and malfunctions, are not exempt from § 23.1309 and must be shown to meet part 23 levels of safety as derived from § 23.1309. Part 33 certification data, if applicable, may be used to show compliance with any part 23 requirements. If part 33 data is to be used to substantiate compliance with part 23 requirements, then the part 23 applicant must be able to provide this data for their showing of compliance.

Note: The term “probable” in the context of “probable combination of failures” does not have the same meaning as in AC 23.13091D. The term “probable” in “probable combination of failures” means “foreseeable,” or not “extremely improbable,” as referenced in AC 23.1309-1D.

Issued in Kansas City, Missouri on August 28, 2015.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-22872 Filed 9-10-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-415F]

Schedules of Controlled Substances: Removal of [123]ioflupane From Schedule II of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration removes [123]ioflupane from the schedules of the Controlled Substances Act. This action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after an opportunity for a hearing through formal rulemaking. Prior to the effective date of this rule, [123]ioflupane was, by definition, a schedule II controlled substance because it is derived from cocaine via ecgonine, both of which are schedule II controlled substances. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle [123]ioflupane.

DATES: *Effective Date:* September 11, 2015.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801-971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(2), the Attorney General may, by rule, “remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.” The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA, 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion, (2) at the request of the Secretary of the Department of Health and Human Services (HHS),¹ or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated at the request of the Assistant Secretary for Health of the HHS, and is supported by, inter alia, a recommendation from the Assistant Secretary of the HHS and an evaluation of all relevant data by the DEA. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle or propose to handle [¹²³I]ioflupane.

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

Background

[¹²³I]ioflupane is, by definition, a schedule II controlled substance because it is derived from cocaine, a schedule II substance, via ecgonine (a schedule II substance). See 21 U.S.C. 812(c), Schedule II, (a)(4). [¹²³I]ioflupane is the active pharmaceutical ingredient (API) in the drug product DaTscan and it is a new molecular entity. The Food and Drug Administration (FDA) approved the New Drug Application (NDA) for DaTscan on January 14, 2011, for the indication of visualizing striatal DATs in the brains of adult patients with suspected Parkinsonian syndromes (PS).

DEA and HHS Eight Factor Analyses

Pursuant to 21 U.S.C. 811(b), (c), and (f), the HHS recommended to the DEA on November 2, 2010, that FDA-approved products containing [¹²³I]ioflupane be removed from schedule II of the CSA. The HHS provided to DEA a scientific and medical evaluation document entitled “Basis for the Recommendation to Remove FDA Approved Products Containing [¹²³I]ioflupane from Schedule II of the Controlled Substances Act (CSA).” Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of FDA-approved products containing [¹²³I]ioflupane, along with the HHS's recommendation to remove FDA-approved products containing [¹²³I]ioflupane from the schedules of the CSA. The HHS later clarified to DEA that its November 2, 2010, recommendation also supports the decontrol of the substance [¹²³I]ioflupane.²

In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, and all other relevant data. The DEA and HHS collaborated further regarding the available information. In a letter dated February 2, 2015, the HHS provided detailed responses to specific inquiries from the DEA (submitted by letter dated September 16, 2014). Upon further review of all of the available information, the DEA completed its own eight-factor review document on FDA-approved diagnostic products containing [¹²³I]ioflupane (currently, only DaTscan) pursuant to 21 U.S.C. 811(c).

The FDA-approved diagnostic product, DaTscan, was used as the basis for the scientific and medical evaluation of FDA-approved products containing [¹²³I]ioflupane for both the HHS and

² Letter from Karen B. DeSalvo, Acting Assistant Secretary for Health, HHS to John J. Riley, Acting Deputy Administrator, DEA (Aug. 19, 2015).

DEA eight-factor analysis. Both the DEA and HHS analyses and other relevant documents are available in their entirety in the public docket of this rule (Docket Number DEA-415F) at <http://www.regulations.gov> under “Supporting and Related Material.”

Determination To Decontrol [¹²³I]ioflupane

After a review of the available data, including the scientific and medical evaluation and recommendation, the Administrator of the DEA published in the **Federal Register** a notice of proposed rulemaking (NPRM) entitled “Schedules of Controlled Substances: Removal of [¹²³I]ioflupane from Schedule II of the Controlled Substances Act” which proposed removal of [¹²³I]ioflupane from the schedules of the CSA. 80 FR 31521, June 3, 2015. The proposed rule provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations by July 6, 2015.

No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before July 6, 2015.

Comments Received

The DEA received nine comments on the proposed rule to decontrol [¹²³I]ioflupane. All commenters supported the decontrol of [¹²³I]ioflupane.

Commenters in support of decontrolling [¹²³I]ioflupane included an international medical society for neurology; an association of industry members that manufacture radiopharmaceuticals; a professional organization representing radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists; an advocacy group for the Parkinson's community; a trade association representing medical imaging, radiotherapy and radiopharmaceutical manufacturers; the sponsor of the drug product containing [¹²³I]ioflupane; a physician; a health services company; and a private citizen, all of whom expressed support for the DEA's proposal to decontrol [¹²³I]ioflupane. Some commenters also stated that the proposal would improve patient access to an important diagnostic pharmaceutical and reduce the burden on providers and nuclear pharmacies.

The DEA appreciates the comments in support of this rulemaking.

Effective Date of the Rule

Generally, DEA scheduling actions are effective 30 days from the date of

publication of the final rule in the **Federal Register**. 21 CFR 1308.45; see also 5 U.S.C. 553(d). In this instance, and in accordance with 21 CFR 1308.45, the DEA finds that the conditions of public health or safety necessitate an earlier effective date, *i.e.*, the date of publication in the **Federal Register**. An earlier effective date would allow specialized members of the healthcare community to readily utilize this substance as a component of an important diagnostic tool, DaTscan. DaTscan, which contains [¹²³I]ioflupane, is used in differentiating essential tremors from tremors due to PS, (idiopathic Parkinson's disease, multiple system atrophy, and progressive supranuclear palsy), and can help healthcare professionals provide more accurate diagnoses. This earlier effective date will allow patients to receive, without delay, important diagnostic testing that is critical to their health and treatment. These findings, coupled with the fact that this is an action for decontrol, indicate that conditions of public health necessitate an immediate effective date upon publication in the **Federal Register**.

The DEA also notes that its decision to make this rule effective upon publication aligns with the exceptions to the 30-day effective date requirement of the Administrative Procedure Act (APA). One of the APA's exceptions to the 30-day effective date is for a substantive rule granting or recognizing an exemption or which relieves a restriction. 5 U.S.C. 553(d)(3).

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation and clarification from the HHS, and based on the DEA's consideration of its own eight-factor analysis, the Administrator finds that these facts and all relevant data demonstrate that [¹²³I]ioflupane does not meet the requirements for inclusion in any schedule, and will be removed from control under the CSA.

Regulatory Analyses

Executive Orders 12866 and 15363

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of

Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. This rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this rule is to remove [¹²³I]ioflupane from the list of schedules of the CSA. This action removes regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of [¹²³I]ioflupane. Accordingly, it has the potential for some economic impact in the form of cost savings.

This rule will affect all persons who handle, or propose to handle, [¹²³I]ioflupane. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the distribution and administration rates of radiopharmaceutical substances, the DEA is unable to determine the number of entities and small entities which might handle [¹²³I]ioflupane. In other instances where a controlled pharmaceutical drug is removed from the schedules of the CSA, the DEA is

able to quantify the estimated number of affected entities and small entities because the handling of the drug is expected to be limited to DEA registrants even after removal from the schedules. In such instances, the DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities. However, [¹²³I]ioflupane is expected to be handled by persons who hold DEA registrations regardless of whether this rule is promulgated (*e.g.*, hospital radiopharmacies) and by persons who are not currently registered with the DEA to handle controlled substances (*e.g.*, diagnostic clinics and imaging centers that do not routinely handle controlled substances). The DEA does not have a reliable basis to estimate the number of non-registrants who plan to handle [¹²³I]ioflupane.

Although the DEA does not have a reliable basis to estimate the number of affected entities and quantify the economic impact of this final rule, a qualitative analysis indicates that this rule is likely to result in some cost savings for the healthcare industry. The affected entities will continue to meet existing Federal and/or state requirements applicable to those who handle radiopharmaceutical substances, including licensure, security, recordkeeping, and reporting requirements, which in many cases are more stringent than the DEA's requirements. However, the DEA believes cost savings will be realized from the removal of the administrative, civil, and criminal sanctions for those entities handling or proposing to handle [¹²³I]ioflupane, in the form of saved DEA registration fees, and the elimination of additional physical security, recordkeeping, and reporting requirements.

Because of these facts, this rule will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, that this action would not result in any federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year" Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act

This action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: An annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and Recordkeeping Requirements.

For the reasons set out above, 21 CFR part 1308 is amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. In § 1308.12, revise paragraph (b)(4) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these

substances, except that the substances shall not include:

- (i) Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine; or
- (ii) [¹²³I]ioflupane.

* * * * *

Dated: September 4, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015–22919 Filed 9–10–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket No. USCG–2015–0512]

RIN 1625–AA00

Safety Zone; Mad Dog Truss Spar, Green Canyon 782, Outer Continental Shelf on the Gulf of Mexico

AGENCY: Coast Guard, DHS.

ACTION: Interim rule and request for comments.

SUMMARY: The Coast Guard published in the *Federal Register* on July 29, 2005, a final rule establishing a safety zone around the Mad Dog Truss Spar. The coordinates for the location of the Mad Dog Truss Spar were published incorrectly as 27°11'18" N., 91°05'12" W. This interim rule corrects the coordinates to reflect the actual location of the Mad Dog Truss Spar as 27°11'18.124" N., 90°16'7.363" W., therefore correctly publishing the area covered by the safety zone around the Mad Dog Truss Spar system, located in Green Canyon Block 782 on the Outer Continental Shelf (OCS) in the Gulf of Mexico.

DATES: This interim rule is effective September 11, 2015. Comments and related material must be received by the Coast Guard on or before October 13, 2015.

ADDRESSES: You may submit comments identified by docket number USCG–2015–0512 using any one of the following methods:

- (1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.
- (2) *Fax:* 202–493–2251.
- (3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries

accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments. To avoid duplication, please use only one of these four methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this interim rule, call or email Mr. Rusty Wright, U.S. Coast Guard, District Eight Waterways Management Branch; telephone 504–671–2138, rusty.h.wright@uscg.mil. If you have questions on viewing or submitting material to the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

| | |
|------|-------------------------------------|
| CFR | Code of Federal Regulations |
| DHS | Department of Homeland Security |
| EEZ | Exclusive Economic Zone |
| FR | Federal Register |
| IMO | International Maritime Organization |
| OCS | Outer Continental Shelf |
| USCG | United States Coast Guard |

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at <http://www.regulations.gov>, or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

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.

CSB 3.04 (6) (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)

Chapter CSB 4

PRESCRIPTION DRUG MONITORING PROGRAM

| | | | |
|----------|--|----------|---|
| CSB 4.01 | Authority and scope. | CSB 4.08 | Exemptions from compiling and submitting dispensing data. |
| CSB 4.02 | Definitions. | CSB 4.09 | Direct access to PDMP information. |
| CSB 4.03 | Drugs that have a substantial potential for abuse. | CSB 4.10 | Requests for review. |
| CSB 4.04 | Compilation of dispensing data. | CSB 4.11 | Methods of obtaining PDMP information. |
| CSB 4.05 | Electronic submission of dispensing data. | CSB 4.12 | Use of PDMP information by the board and department. |
| CSB 4.06 | Frequency of submissions. | CSB 4.13 | Confidentiality of PDMP information. |
| CSB 4.07 | Correction of dispensing data. | CSB 4.14 | Exchange of PDMP information. |

Note: Chapter Phar 18 was renumbered chapter CSB 4 under s. 13.92 (4) (b) 1., Stats., Register September 2015 No. 717.

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

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.

CSB 4.02 Definitions. As used in this chapter:

(1) “Access” means to have the ability to view PDMP information through an account established with the board.

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

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

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

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

(4) “Board” has the meaning given in s. 450.01 (2), Stats.

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

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

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

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

(7) “Dispense” has the meaning given in s. 450.01 (7), Stats.

(8) “Dispenser” means all of the following:

(a) A pharmacy.

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

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

(9) “Dispenser delegate” means any of the following:

(a) A managing pharmacist of a pharmacy.

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

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

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

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

(11r) “Managing pharmacist” has the meaning given in s. Phar 1.02 (6).

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

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

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

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

(13) “Patient” has the meaning given in s. 450.01 (14), Stats.

(14) “Person authorized by the patient” means person authorized by the patient in s. 146.81 (5), Stats., and includes persons with delegated authority under s. 48.979, Stats.

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

(15) “PDMP information” means any of the following:

(a) The data compiled and stored by the board from dispensing data submitted to it by dispensers.

(b) The information created by the board to satisfy the requirements in s. CSB 4.12.

(15g) “Pharmacist” has the meaning given in s. 961.385 (1) (aL), Stats.

(15r) “Pharmacist delegate” means an agent of a pharmacist to whom the pharmacist has delegated the task of accessing PDMP information.

(16) “Pharmacy” means any place of practice licensed by the board under ss. 450.06 or 450.065, 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.

(18) “Practitioner delegate” means an agent or employee of a practitioner to whom the practitioner has delegated the task of accessing PDMP information.

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

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

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

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

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (5) (b) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13-065: cr. (3m), (13e), am. (16), (17), r. (22) Register February 2014 No. 698, eff. 3-1-14; (13e) renum. to (14e) under s. 13.92 (4) (b) 1., Stats., Register February 2014 No. 698; correction in (17) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14-003: am. (8) (a), renum. (9) to (9) (intro.) and am., cr. (9) (a), (b), (11g), (11r), am. (15) (intro.), cr. (15g), (15r), am. (17) Register August 2014 No. 704, eff. 9-1-14; correction in (3), (9) (b), (10), (12) (a) 1., 2., (15) (b), (15g), (17), (20) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.

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

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

(2) A controlled substance identified in schedule IV or V in subch. II of ch. 961, Stats., as amended by ch. CSB 2.

(3) Tramadol.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13-065: am. (intro.) Register February 2014 No. 698, eff. 3-1-14; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; **correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.**

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

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

(b) "Dispenser identifier" means the DEA registration number or when the DEA registration number is not available, the NPI number.

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

(d) "NPI number" means national provider identifier number, the registration number issued to a dispenser or practitioner by the national provider identifier registry.

(e) "Practitioner identifier" means the DEA registration number or when the DEA registration number is not available, the NPI number.

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

- (a) The dispenser's full name.
- (b) The dispenser identifier, if available.
- (c) The date dispensed.
- (d) The prescription number.
- (e) The NDC number or the name and strength of the monitored prescription drug.
- (f) The quantity dispensed.
- (g) The estimated number of days of drug therapy.
- (ge) The classification code for payment type.
- (gm) The number of refills authorized by the prescriber.
- (gs) The refill number of the prescription.
- (h) The practitioner's full name.
- (i) The practitioner identifier, if available.
- (j) The date prescribed.
- (L) The patient's full name or if the patient is an animal, the animal's name and the owner's last name.
- (m) The patient's address, or if the patient is an animal, patient's owner's address, including street address, city, state, and ZIP code.
- (n) The patient's date of birth, or if the patient is an animal, patient's owner's date of birth.
- (o) The patient's gender.

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

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (1) (b), (e), (3) (b), (d), (i), (k) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (title), renum. (2) to (2) (intro.) and am., cr. (2) (ge), (gm), (gs), renum. (3) (a) to (g) and (h) to (j) to (2) (a) to (g) and (h) to (j), r. (3) (k), renum. (3) (L) to (o) to (2) (L) to (o) and am. (L) to (n), am. (4) Register August 2014 No. 704, eff. 9-1-14; correction in (2) (intro.) made under s. 35.17, Stats., and in (4) made under s. 13.92 (4) (b) 7., Stats., Register August 2014 No. 704; **correction in (2) (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.**

CSB 4.05 Electronic submission of dispensing data. (1) Unless exempt under s. CSB 4.08, a dispenser shall electronically submit dispensing data through an account with the board.

Note: The application to create an account may be completed online at www.dps.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.

(2) The dispensing data shall be submitted to the board in compliance with the data standards in the version and release of ASAP implementation guide for prescription monitoring programs identified by the board or other electronic format identified by the board.

Note: The guide for dispensers which specifies the data standards in the version and release of the ASAP implementation guide for prescription monitoring programs identified by the board and other electronic formats identified by the board may be obtained online at www.dps.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.

(3) If a dispenser is not able to create an account or submit dispensing data as required by subs. (1) and (2), the board may grant a waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser agrees to begin filing dispensing data on a paper form identified by the board for each monitored prescription drug dispensed.

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

Note: The application for a waiver may be obtained online at www.dps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

(4) A dispenser and dispenser delegate, if applicable, who fail to create an account with the board and submit dispensing data as required by subs. (1) and (2) or be granted a waiver under sub. (3) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (2) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (1), (4) Register August 2014 No. 704, eff. 9-1-14; **correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.**

CSB 4.06 Frequency of submissions. (1) A dispenser shall submit dispensing data to the board within 7 days of dispensing a monitored prescription drug.

(2) If a dispenser does not dispense a monitored prescription drug for 7 days, the dispenser shall submit a zero report to the board for each 7-day period during 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 a monitored prescription drug as required by sub. (1), 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 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.

Note: The application for an emergency waiver may be obtained online at www.dps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

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

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

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

CSB 4.07 Correction of dispensing data. If a dispenser discovers omissions or inaccuracies in previously submitted dispensing data or other PDMP information, the dispenser shall submit correct information within 7 days.

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

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. Register August 2014 No. 704, eff. 9–1–14.

CSB 4.08 Exemptions from compiling and submitting dispensing data. (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew his or her license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

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

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

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

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

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

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. (1) (a), cr. (3) Register August 2014 No. 704, eff. 9–1–14.

CSB 4.09 Direct access to PDMP information.

(1) Pharmacists, pharmacist delegates, practitioners, and practitioner delegates may access PDMP information 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.

(2) To obtain access to PDMP information, pharmacists, pharmacist delegates, practitioners, and practitioner delegates shall do one of the following:

(a) Create an account with the board on a form provided by the board.

(b) Create an account with a prescription monitoring program operated by a relevant agency in another jurisdiction with whom the board exchanges PDMP information 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 PDMP information 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 PDMP information or that is connected to and lawfully obtains data from the state–designated entity under ch. 153, Stats.

Note: The application to create an account may be completed online at www.dsp.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

(3) The board may deny, suspend, revoke or otherwise restrict or limit a pharmacist's, pharmacist delegate's, practitioner's, or practitioner delegate's direct access to PDMP information for any of the following reasons:

(a) The pharmacist, pharmacist delegate, practitioner, or practitioner delegate uses PDMP information 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 pharmacist, pharmacist delegate, practitioner, or practitioner delegate is no longer licensed in this state or another state and recognized by this state as a person authorized to prescribe or dispense monitored prescription drugs.

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

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

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

(f) The pharmacist, pharmacist delegate, practitioner, or practitioner delegate 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 PDMP information.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. (1), renum. (2) to (2) (intro.) and am., cr. (2) (a) to (d), am. (3) Register August 2014 No. 704, eff. 9–1–14; **corrections in (1), (2) (b), (3) (a) Register September 2015 No. 717.**

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

(a) The denial of a waiver requested pursuant to s. CSB 4.05 (3).

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

(c) The denial, suspension, revocation or other restriction or limitation imposed on the dispenser's, dispenser delegate's, practitioner's, or practitioner delegate's account pursuant to s. CSB 4.09 (3).

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

(a) The dispenser's, dispenser delegate's, practitioner's, or practitioner delegate's name and address, including street address, city, state and ZIP code.

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

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

(4) No discovery is permitted.

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

(6) The board shall provide the pharmacist, pharmacist delegate, practitioner, or practitioner delegate 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, pharmacist delegate, practitioner, or practitioner delegate fails to appear for a review, or withdraws the request for a review, the board may note the failure to appear in the minutes and affirm its original decision without further action.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; correction in (1) (b) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14–003: am. (1) (intro.), (2) (intro.), (b), (3), (6), (7) Register August 2014 No. 704,

eff. 9-1-14; correction in (1) (a) to (c) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.

CSB 4.11 Methods of obtaining PDMP information.

(1) The board shall disclose PDMP information 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.

(b) Makes a request for the PDMP information on a form provided by the board.

(2) The board shall disclose PDMP information about a patient to a person authorized by the patient if the person authorized by the patient does all of the following:

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

(b) Provides proof sufficient to the board of the authorization or delegation from the patient.

(c) Makes a request for the PDMP information on a form provided by the board.

(5) The board shall disclose the minimum amount of PDMP information necessary 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.

(b) Provides proof sufficient to the board that the federal or state governmental agency is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(6) The board shall disclose the minimum amount of PDMP information necessary 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.

(b) Provides proof sufficient to the board that the department is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(7) The board shall disclose the minimum amount of PDMP information necessary 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.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 21., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(8) The board shall disclose the minimum amount of PDMP information necessary 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.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 18., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(9) The board may disclose de-identified PDMP information which does not and cannot be reasonably used to identify any patient upon written request.

(10) The board shall disclose the minimum amount of PDMP information 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 if the designated staff does all of the following:

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

(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 the law enforcement agency is entitled to the information under s. 146.82 (2) (a) 11., Stats.

(c) Makes a request for PDMP information through its account with the board.

Note: The application to create an account and form to request PDMP information may be completed online at www.dsp.wi.gov or obtained at no charge from the Department of Safety and Professional Services 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

History: CR 12-009; cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: r. (3), (4), am. (6) (intro.), renum. (9) (intro.) to (9) and am., r. (9) (a) to (c) Register August 2014 No. 704, eff. 9-1-14; correction in (5) (intro.), (6) (intro.), (7) (intro.), (8) (intro.), (10) (intro.) Register September 2015 No. 717.

CSB 4.12 Use of PDMP information by the board and department. **(1)** The board shall develop and maintain a PDMP database to store PDMP information.

(2) The PDMP database shall store PDMP information in an encrypted format.

(3) The board shall maintain a log of persons to whom the board grants access to PDMP information.

(4) The board shall maintain a log of information submitted by each dispenser.

(4g) The board shall maintain a log of information accessed by each pharmacist, pharmacist delegate, practitioner, and practitioner delegate.

(4r) The board shall maintain a log of information disclosed, including the name of the person to whom the information was disclosed.

(5) The board shall maintain a log of requests for PDMP information.

(6) Board and department 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 necessary for all of the following purposes:

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

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

(c) Evaluating and responding to legitimate requests for PDMP information.

(d) Other legally authorized purposes.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (4), cr. (4g), (4r) Register August 2014 No. 704, eff. 9-1-14; **correction in (6) (b) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.**

CSB 4.13 Confidentiality of PDMP information.

(1) The PDMP information maintained by the board, department or a vendor contracting with the department which is submitted to, maintained, or stored as a part of the program is not subject to inspection or copying under s. 19.35, Stats.

(2) A person who discloses PDMP information 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 the licensing 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.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; **correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.**

CSB 4.14 Exchange of PDMP information. (1)

The board may exchange PDMP information with a prescription

monitoring program operated by a relevant agency in another state or jurisdiction if the prescription monitoring program satisfies all of the following conditions:

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

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

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

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

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

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

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

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

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

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (1) (intro.) Register August 2014 No. 704, eff. 9-1-14.

**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: 8/21/15 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: 10/6/15 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? Kratom (Mitragynine) Scheduling - 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: Update from Board Counsel and supplemental information. | | | |

**A Follow-Up Statement by the Botanical Legal Defense Re.
Kratom Hearing of August 14 before the Controlled Substances Board**

Kratom is a safe natural herbal supplement made from the leaves of the *Mitragyna speciosa* tree. The smooth 100-percent-natural leaves, related to coffee, have provided safe and effective relief for hundreds of years as a natural analgesic, muscle relaxer, anti-inflammatory, and antioxidant. Kratom has also made a dramatic difference to those who suffer debilitating anxiety and PTSD. And, millions worldwide have successfully used it to overcome addiction to “hard” drugs that truly are dangerous and illicit.

But, in recent years, Kratom has been widely misrepresented as dangerous and without medical value. These disturbing labels overlook the fact that valuable remedies and dietary supplements derived from Kratom benefit lives. Kratom, in fact, is not a drug at all, nor is it a “bad” drug: It is a plant derivative no more dangerous than a cup of coffee.

Some have lumped Kratom into the same category as really bad drugs known as “synthetics,” “research chemicals” and “designer drugs.” These synthetics are labeled “not for human consumption” to mask their intended purpose and avoid Food and Drug Administration (FDA) regulatory oversight of the manufacturing process.

We at the Botanical Legal Defense (BLD) believe that if a product is not packaged and marketed in compliance with all federal and state laws, consumers should not buy it -- Period. A simple check: is there an address and phone number of the company on the packaging? If not move on. We also will go as far to say that Kratom should not be sold in any other form than as a dietary supplement. Further, despite what a witness before your hearing stated, No One has

died from ingesting pure Kratom. Public records show that the cases he cited ALL include ingestion of other or additional dangerous substances or drugs.

Irrespective of the clear differences between Kratom as a dietary supplement and these synthetic products and other prescription drugs, efforts are underway to prohibit Kratom. Anything can be abused. But to claim that people can be “hooked” on Kratom and therefore it should be banned is just not true. It simply isn’t powerful enough. Further, Kratom has had a positive effect on those fighting and coming off of addictions to powerful opiates like heroin.

In addition, pharmaceutical drugs are one of the leading causes of death in this country, killing one American every 19 minutes. Prescription opiate painkillers account for more than 475,000 emergency room visits annually. Over the counter pain relievers send over 56,000 people to the emergency room each year with liver-related complications.

To ban Kratom on a pharmacological basis is just plain misguided. Please focus instead on those substances, synthetics and readily available prescribed drugs, that really do damage. Banning a beneficial, 100 percent natural botanical that is no more addictive than coffee or life threatening doesn’t make sense.

Thank you.

Kratom Comments and Observations

by Ryan F. Estevez, MD, PhD, MPH

- As psychiatrist and psychopharmacologist who has worked for years in emergency rooms, community health centers, and prisons, I am well versed in both “good” drugs that help people on a daily basis, and “bad” drugs that are epidemically abused and create a tremendous burden on society.
- Kratom is not one of these “bad” drugs (I have yet to admit anyone for kratom-addiction) and efforts to ban it are misguided and wasteful. In fact, there is emerging evidence that kratom can be helpful in alleviating symptoms of opioid withdrawal.
- I have been troubled by an increase in news reports and misinformation that has been disseminated about the “dangerous” and “addictive drug” kratom. Even worse is the subsequent careless and knee-jerk response by many legislators and policy makers to ban kratom. Unbeknownst to most, kratom comes from a tropical tree, indigenous to Southeast Asia, and has been used for more than 200 years by local inhabitants to treat a variety of maladies including diarrhea, depression, anxiety, lethargy, cough, chronic pain, and opioid withdrawal.
- Grieving parents, well intentioned policy makers, and opportunist politicians often seize on opportunities to assign blame and then offer a “quick fix” to infinitely complicated tragedies that result from public health problems. The proposal of an absolute ban of kratom perfectly illustrates what can happen when hype trumps science, as this plant has been benefiting millions of people for decades of time.
- I believe much of the negative publicity surrounding kratom to be the result of being incorrectly lumped in with synthetically derived mind-altering substances such as “spice” and bath-salts, substances that deserve their reputations for being dangerous and harmful. Unlike kratom, these new and lab created substances have not been available and used by humans for centuries, have no medicinal value, have clear health risks, and provide no future promise for future research and health benefits.
- Our collective response to any potentially beneficial plant or substance should be to learn more about it and empower government and private institutions to research and study, not ban it! We should not be hoodwinked into mistaking a ban for actual beneficial policy, or conned into believing eliminating kratom would alleviate or even address drug-related issues so impactful to millions of American families.

Ryan F. Estevez, MD, PhD, MPH is the Founder of the Tampa Bay Neurobehavior Institute and the Medical Director at Turning Point of Tampa, Inc. He holds Board Certifications in General, Forensic and Geriatric Psychiatry, Addiction Medicine and Psychosomatic Medicine. Dr. Estevez has no financial ties to Kratom, nor would he benefit financially from Kratom remaining legal or being banned.

**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: 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: 10/6/15 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? NGA Policy Academy Review - 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: For the Board's consideration, attached is the executive summary of recommendations developed during the State's participation in the National Governors Association Policy Academy on Reducing Prescription Drug Abuse. | | | |

Wisconsin Executive Summary

Mission Statement

To reduce prescription drug misuse, abuse, and diversion through a patient/family centered, data-driven, collaborative, multi-disciplinary approach that ensures adequate access for those with medical need.

Core Area #1: Public policy initiatives

Goal #1: Identify strategies to ensure adequate supply of naloxone

- Identify best practices in other states
- Determine most viable options to implement in Wisconsin
- Work with Governor and Legislature to implement the policy

Goal #2: Expand “good Samaritan” immunity to overdose patients

- Work with Governor and Legislature to implement the policy

Goal #3: Communicate with state and federal legislators regarding prescription drug-related legislation

- Monitor state and federal proposals regarding the following topics:
 - Targeted mandatory use of PDMPs
 - Mandatory continuing education requirements for prescribers of controlled substances
 - Pain as the fifth vital sign and requirements to use the pain scale

Core Area #2: Strategic criminal enforcement

Goal #1: Conduct training on the identification and investigation of cases related to prescription drug abuse

- Work with the U.S. Attorney’s Office, the Drug Enforcement Administration and others to develop and conduct six prescription drug abuse trainings around Wisconsin

Goal #2: Increase law enforcement awareness and use of the PDMP

- Work with DSPS to offer PDMP training to law enforcement officers around Wisconsin

Goal #3: Interface the PDMP with the Crime Alert Network

- Work with the Department of Safety and Professional Services to develop a communications interface between the PDMP and Crime Alert Network

Core Area #3: PDMP and public health data

Goal #1: Create a PDMP oversight body with a wide-ranging perspective

- Work with the Governor and Legislature to transfer oversight of the PDMP to the Wisconsin Controlled Substances Board
- Change the membership of the Controlled Substances Board to include a physician, nurse, and dentist in addition to representatives from the Department of Justice and Department of Health Services

Goal #2: Improve the usability and efficiency of the PDMP

- Continue projects to integrate PDMP data into electronic medical records software
- Improve the PDMP web portal to decrease the number of pages and clicks required to obtain data
- Improve the PDMP web portal to give prescribers data that compares their prescribing practices to similarly situated prescribers
- Work with the Governor and Legislature to decrease the reporting interval from 7-days to 24-hours
- Work with the Board overseeing the PDMP to expand access to non-prescribing health professionals such as NPs, medical directors, and support staff
- Improve the PDMP alert features to create more persistent “notes” on patient reports and include more types of alerts

Goal #3: Improve the availability of PDMP data for public health purposes

- Continue to create the PDMP Public Health Portal
- Work with the Department of Health Services to improve PDMP data quality
- Integrate PDMP data into existing public health data sources

Core Area #4: Substance abuse treatment

Goal #1: Establish non-methadone Opioid Treatment Programs

- Establish three opioid treatment programs in rural, underserved and high need areas of the state with associated funding to provide outpatient care, stabilization services, detoxification services and medication-assisted treatment services

Goal #2: Promote treatment best practices

- Establish at least two statewide training events for substance abuse counselors and clinicians regarding delivery of evidence-based treatment practices for individuals seeking treatment for opioid dependence
- Establish at least two statewide training events for physicians and allied health professionals to recruit more physicians to offer buprenorphine management services for individuals who are opioid dependent

Goal #3: Assure access to treatment on demand

- Work with State leadership and members of the Legislature to examine the current substance abuse treatment system and develop recommendations for greater funding flexibility to assure access to treatment on demand
- Expand regional service models through the Mental Health and Substance Abuse Regional Pilot Project

Core Area #5: Public education campaign

Goal #1: Develop a multi-faceted campaign about prescription drug safety

- Work with the Department of Health Services, Department of Justice, private stakeholders, and an advertising agency to create a statewide multimedia campaign about prescription drug safety that includes direct-to-consumer marketing and prescriber education components
- Launch campaign with press releases and spokespersons
- Develop criteria to monitor the effectiveness of the campaign over time

CSB Goals

- CSB 2 – proactive scheduling (Ongoing)
- Maintain and seek-out general communications and educational efforts (Ongoing)
- Website review (Ongoing)
- SUA Review Process Update
- Electronic SUA Form
- Prescription Drug Abuse Efforts – PDMP/NGA/Legislation

**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: 10/6/15 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? HOPE- PDMP Article - Informational Only | |
| 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: Attached is an article about the draft HOPE bills. | | | |

Bill targeting opiate abuse requires doctors to check database

By [Patrick Marley](#) of the Journal Sentinel
Sept. 8, 2015

Madison— A key lawmaker rolled out legislation Tuesday that would require doctors to check a statewide database before prescribing narcotics and other addictive drugs — a move aimed at slowing the abuse of opiates and heroin.

Rep. John Nygren (R-Marinette) also announced bills requiring doctors to be notified if prescriptions they write are found at the scene of a drug crime or overdose. Other legislation would require pain clinics and methadone clinics to register with the state so officials could gather more information about them.

"We want to snuff out the illegitimate use of these drugs," said Nygren, who described his plans in an interview and at a Capitol news conference.

Nygren, the co-chairman of the budget-writing Joint Finance Committee, in 2013 publicly took on the issue of fighting heroin and prescription drugs [in response to his daughter Cassie's battle with addiction](#).

Since then, he has led the charge on [changes to state law](#) getting a drug that counteracts heroin overdoses into the hands of more first responders; requiring people to show identification when picking up opiate prescriptions; granting immunity from prosecution to those who seek help responding to an overdose; and expanding treatment.

Drafts of his latest proposals will be released this week, he said. The past and current initiative is known as the HOPE agenda, which stands for heroin, opiate prevention and education.

Nygren stressed the need to address prescription drug abuse because it often leads to heroin addiction.

Since September 2014, the state has had a prescription drug monitoring program that catalogs prescriptions for narcotics and other addictive drugs. Pharmacies are required to enter prescriptions within seven days.

About 14% of doctors are registered with the database, Nygren said. That means the information isn't being used the way it should be, he said.

"If the information isn't completely accurate, if it's not all there, what's the point?" he said.

One of his bills would require doctors to check the database whenever they write a prescription or refill for drugs that have a potential for abuse. The requirement will help medical professionals identify instances when addicts are cycling through doctors to get prescriptions.

While doctors would be required to use the database, there would be no penalty if they failed to do so.

Sixteen other states require doctors to register with similar databases, according to Nygren's office. Three of those states — Kentucky, New York and Tennessee — mandate that doctors check the database before issuing prescriptions.

Prescriptions would have to be entered into the database within 24 hours under the bill.

Also, the database would see updates in 2017 that would allow doctors to run reports that would show how often they're writing prescriptions for such drugs compared to others. Nygren said he did not know what those upgrades would cost.

Another piece of legislation would have authorities notify doctors if their prescriptions were found at the scene of a drug crime or overdose.

Two other bills would require pain clinics and methadone clinics to register with the state Department of Health Services. That would help the state identify any problems, Nygren said. They would need to provide their caseloads, level of prescribing, staffing ratios and the like.

At his news conference, Nygren had the backing of GOP Attorney General Brad Schimel, Assembly Speaker Robin Vos (R-Rochester) and others — a sign that the proposals will be on a fast track. Nygren's past efforts under the HOPE agenda won unanimous support.

Nygren said the bills could be on the floor of the Assembly as early as October.

Find this article at:

<http://www.jsonline.com/news/statepolitics/bill-targeting-opiate-abuse-requires-doctors-to-check-database-b99572755z1-325753201.html>

Check the box to include the list of links referenced in the article.

**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: 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: 10/6/15 | 5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 6) How should the item be titled on the agenda page? CVS Naloxone Article – Informational Only | |
| 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: | | | |

CVS stocks overdose-antidote drug in 12 more states

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By Jackie Wattles @jacki



CVS said Thursday it's making an anti-opiate overdose drug available without a prescription in 12 more states.

Deaths in America caused by accidental overdoses to prescription medications have [quadrupled](#) since 1999. CVS wants to do something about that.

The company said Thursday it's putting an opioid antidote on its shelves in 12 states. The drug, Naloxone, reverses opioid overdoses and is already available without a prescription at CVS's in Rhode Island and Massachusetts.

The following states will now have access as well: Arkansas, California, Minnesota, Mississippi, Montana, New Jersey, North Dakota, Pennsylvania, South Carolina, Tennessee, Utah and Wisconsin.

Opioids include heroin and legal prescription pain medications such as oxycodone (Vicodin), which are addictive and commonly abused.

"Over 44,000 people die from accidental drug overdoses every year in the United States," CVS vice president Tom Davis said in a statement Thursday. "By providing access to this medication in our pharmacies without a prescription in more states, we can help save lives."

He added that the company is looking into ways to make Naloxone available in even more states. Company spokesperson Michael DeAngelis said states must set up programs allowing the medication to be dispensed without a prescription, which "is typically done through a state's department of health or board of pharmacy."

Naloxone has been carried for years by emergency response teams and police departments, and

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can be administered via a shot or nasally.

The antidote expansion is one of several unique initiatives by the retailer. Last year CVS [said it would stop selling cigarettes](#). It also works with the Partnership for Drug-Free Kids to provide a unit to police departments where the community can safely dispose of drugs.

Related: CVS banned tobacco. Now its sales are hurting

Related: Here are all the drugs CVS is dropping, including Viagra

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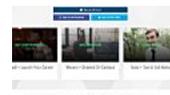


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