Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Scott Walker, Governor
Laura Gutiérrez, Secretary

CONTROLLED SUBSTANCES BOARD
Room 121A, 1400 East Washington Avenue, Madison
Contact: Dan Williams (608) 266-2112
May 11, 2018

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

AGENDA

9:30 A.M.

(or immediately following the Controlled Substances Workgroup meeting)

OPEN SESSION - CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-3)

B. Approval of Minutes of March 9, 2018 (4-7)

C. Administrative Matters - Discussion and Consideration

1. Staff Updates
2. Board Members
   a. Yvonne Bellay – Dept. of Agriculture, Trade, and Consumer Protection Designee
   b. Alan Bloom – Pharmacologist
   c. Doug Englebert – Dept. of Health Services Designee
   d. Philip Trapskin – Pharmacy Examining Board Designee
   e. Subhadeep Barman – Psychiatrist
   f. Peter Kallio – Board of Nursing Designee
   g. Leonardo Huck – Dentistry Examining Board Designee
   h. Timothy Westlake – Medical Examining Board Designee

D. Legislation and Rule Matters – Discussion and Consideration (8-34)

1. Adopt CR 17-075 Relating to Scheduling Cyclopropyl
2. CSB 2.54 Relating to Scheduling Oral Dronabinol
3. CSB 2.58 Relating to Excluding Naldemedine
4. CSB 2.59 Relating to Scheduling Ortho-Fluorofentanyl
5. CSB 2.60 Relating to Scheduling FUB-AMB
6. CSB 5 Relating to Approval of Pharmacies and Physicians that May Dispense Cannabidiol
7. Law Enforcement Hearing to Receive Information on Drug Trends for Future Controlled Substances Scheduling (EO 228)
8. Federal Proposed Rule Relating to Controlled Substances Quotas
9. Update on Legislation and Pending and Possible Rulemaking Projects

E. Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration (35-48)

1. WI ePDMP Operations Update
    a. Staff Updates
    b. Recent and Upcoming Releases
    c. Status of Grants
    d. User Feedback
    e. EHR Integration Status
2. PDMP Quarterly Report Update
3. WI ePDMP Outreach Events
4. PDMP Referral Workgroup Update
5. Informational Items

F. Controlled Substances Board Annual Report – Discussion and Consideration (49)

G. Special Use Authorizations – Discussion and Consideration

H. Travel Requests, Speaking Engagements, and Public Relations Requests - Discussion and Consideration

I. Informational Item(s)

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

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

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

K. Special Use Authorizations – Discussion and Consideration

L. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

O. Public Comments

ADJOURNMENT

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

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 1400 East Washington Avenue, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
MARCH 9, 2018

PRESENT: Yvonne Bellay, Doug Englebert, Leonardo Huck *(arrived at 9:52 a.m.)*, Peter Kallio, Jason Smith, Philip Trapskin *(via GoToMeeting)*, Timothy Westlake *(via GoToMeeting; arrived at 10:32 a.m.)*

EXCUSED: Alan Bloom, Subhadeep Barman

STAFF: Dan Williams, Executive Director; Laura Smith, 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 was confirmed.

ADOPTION OF AGENDA

Amendments to the Agenda:

- *Correct the date of the minutes from February 21, 2017 to February 21, 2018.*

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

APPROVAL OF MINUTES

MOTION: Jason Smith moved, seconded by Peter Kallio, to approve the minutes of February 20, 2018 as published. Motion carried unanimously.

SPECIAL USE AUTHORIZATIONS

Request for Special Use Authorization

Jacob Danielson

MOTION: Jason Smith moved, seconded by Peter Kallio, to deny the request of Jacob Danielson for a Special Use Authorization. Motion carried unanimously.

Special Use Authorizations for Animal Shelters – Consideration of Education Regarding Application Process and Importance of Documentation

MOTION: Peter Kallio moved, seconded by Jason Smith, to authorize Yvonne Bellay to prepare and present educational materials relating to Special Use Authorizations for humane societies on behalf of the Board. Motion carried unanimously.

Expansion of the Special Use Authorization Liaison Delegation to Denials and Stipulations Under CSB 3.045

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

LEGISLATION AND RULE MATTERS

CSB 2.58 Relating to Excluding naldemine from Scheduling

MOTION: Peter Kallio moved, seconded by Yvonne Bellay, to approve the preliminary rule draft of CSB 2.58, relating to excluding naldemine from scheduling, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CSB 2.59 Relating to Scheduling ortho-fluorofentanyl

MOTION: Peter Kallio moved, seconded by Yvonne Bellay, to approve the preliminary rule draft of CSB 2.59, relating to scheduling ortho-fluorofentanyl, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CSB 2.60 Relating to Scheduling FUB-AMB

MOTION: Peter Kallio moved, seconded by Yvonne Bellay, to approve the preliminary rule draft of CSB 2.60, relating to scheduling FUB-MAB, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CSB 2.61 Relating to Scheduling MT-45

MOTION: Peter Kallio moved, seconded by Yvonne Bellay, to approve the Scope Statement revising CSB 2.61, relating to scheduling MT-45, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board moves to authorize the Chair to approve the scope for implementation no less than 10 days after publication. Motion carried unanimously.

CSB 2.62 Relating to Scheduling Para-chloroisobutyryl fentanyl

MOTION: Peter Kallio moved, seconded by Yvonne Bellay, to approve the Scope Statement revising CSB 2.62, relating to scheduling para-chloroisobutyryl fentanyl, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board moves to authorize the Chair to approve the scope for implementation no less than 10 days after publication. Motion carried unanimously.

Scheduling Law Enforcement Hearing to Receive Information on Drug Trends for Future Controlled Substances Scheduling (Executive Order 228)

MOTION: Peter Kallio moved, seconded by Jason Smith, to commit to holding a hearing at the Opioid Summit in Milwaukee in October 2018. Motion carried unanimously.

PRESCRIPTION DRUG MONITORING PROGRAM (PDMP) UPDATE

Discussion of Disclosures of PDMP Data to Relevant Boards Under CSB 4.15(5)

Report Requested at January 12, 2018 Meeting

MOTION: Leonardo Huck moved, seconded by Yvonne Bellay, to create a Work Group of Peter Kallio, Timothy Westlake, Doug Englebert, and Philip Trapskin to develop criteria for analyzing prescribing and dispensing practices that should be brought to the Board's attention. Motion carried unanimously.

MOTION: Peter Kallio moved, seconded by Yvonne Bellay, to request that the Department place an appearance by PDMP staff for the following Boards at their next meeting: Board of Nursing, Medical Examining Board, Dentistry Examining Board, Optometry Examining Board, Podiatry Affiliated Credentialing Board and Pharmacy Examining Board. Motion carried unanimously.

ANNUAL REPORT ON DISTRIBUTION AND ABUSE OF CONTROLLED SUBSTANCES, INCLUDING RECOMMENDATIONS FOR IMPROVING CONTROL AND PREVENTION OF THE DIVERSION OF CONTROLLED SUBSTANCES

MOTION: Tim Westlake moved, seconded by Peter Kallio, to authorize DSPS staff and the DOJ representative to the Controlled Substances Board to participate in Scientific Trends Open Network Exchange (STONE) phone conferences. Motion carried unanimously.

MOTION: Jason Smith moved, seconded by Peter Kallio, to request that DSPS staff prepare an initial draft of the 2017 Controlled Substances Board Annual Report to be presented at the May 11, 2018 meeting, which includes information and executive summaries from the PDMP quarterly reports, a listing of SUA's granted and substances scheduled, a summary of rulemaking activity, copies of press releases, a summary of outside engagement and outreach, board liaison reports, and a current listing of agency and law enforcement entities that provide reports and information to the board. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 11:05 a.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Sharon Henes **Administrative Rules Coordinator**	**20 April 2018** 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:	5) Attachments:	6) How should the item be titled on the agenda page?
11 May 2018	☐ Yes ☐ No	**Legislation and Rule Matters – Discussion and Consideration** **1. Adopt CR 17-075 Relating to Scheduling Cyclopropyl** **2. CSB 2.54 Relating to Scheduling Oral Dronabinol** **3. CSB 2.58 Relating to Excluding Naldemedine** **4. CSB 2.59 Relating to Scheduling ortho-fluorofentanyl** **5. CSB 2.60 Relating to Scheduling FUB-AMB** **6. CSB 5 Relating to Approval of Pharmacies and Physicians that May Dispense Cannabidiol** **7. Law Enforcement Hearing to Receive Information on Drug Trends for Future Controlled Substances Scheduling (EO 228)** **8. Federal Proposed Rule Relating to Controlled Substances Quotas** **9. Update on Legislation and Pending and Possible Rulemaking Projects**

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes (Fill out Board Appearance Request) ☐ No	

10) Describe the issue and action that should be addressed:

11) Authorization

Sharon Henes

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 PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE 17-075)

ORDER

An order of the Controlled Substances Board to create s. CSB 2.57 relating to scheduling cyclopropyl fentanyl.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:

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

The controlled substances board, by rule and without regard to the requirements of sub. (1m), may schedule a controlled substance analog as a substance in schedule I regardless of whether the substance is substantially similar to a controlled substance in schedule I or II, if the board finds that scheduling of the substance on an emergency basis is necessary to avoid an imminent hazard to the public safety and the substance is not included in any other schedule or no exemption or approval is in effect for the substance under 21 USC 355. Upon receipt of notice under s. 961.25, the board shall initiate scheduling of the controlled substance analog on an emergency basis under this subsection. The scheduling of a controlled substance analog under this subsection expires one year after the adoption of the scheduling rule. With respect to the finding of an imminent hazard to the public safety, the board shall consider whether the substance has been scheduled on a temporary basis under federal law or factors under sub. (1m) (d), (e) and (f), and may also consider clandestine importation, manufacture or distribution, and, if available, information concerning the other factors under sub. (1m). The board may not promulgate a rule under this subsection until it initiates a rule−making proceeding under subs. (1), (1m), (1r) and (2) with respect to the controlled substance analog. A rule promulgated under this subsection lapses upon the conclusion of the rule−making proceeding initiated under subs. (1), (1m), (1r) and (2) with respect to the substance. (s. 961.11 (4m), Stats.)

Related statute or rule: s. 961.14, Stats.

Plain language analysis:

This rule schedules cyclopropyl fentanyl as a Schedule I controlled substance.

Emr 1716 schedules cyclopropyl fentanyl as a Schedule I controlled substance by creating s. 961.14 (2) (fe), Stats. Act 60 renumbered s. 961.14 (2) (fe) to 961.14 (2) (nd) 10d., Stats.

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

Cyclopropyl fentanyl is not currently scheduled under the Controlled Substances Act. On November 21, 2017, the DEA published a notice of intent to schedule cyclopropyl fentanyl as a schedule I.

Comparison with rules in adjacent states:

Illinois: A review of the Illinois Controlled Substances Act does not indicate the scheduling of cyclopropyl fentanyl.

Iowa: A review of the Iowa Controlled Substances Act does not indicate the scheduling of cyclopropyl fentanyl.

Michigan: A review of the Michigan Controlled Substances Act does not indicate the scheduling of cyclopropyl fentanyl.

Minnesota: A review of the Minnesota Controlled Substances Act does not indicate the scheduling of cyclopropyl fentanyl.

Summary of factual data and analytical methodologies:

Based upon the Milwaukee Medical Examiner's request for emergency scheduling and the finding of an imminent hazard to the public safety, the Controlled Substances Board decided to schedule cyclopropyl fentanyl. In making the finding of imminent hazard to the public safety, the Board considered the following factors: the history and current pattern of abuse; the scope, duration and significance of abuse; and the risk to the public health.

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

The rule schedules a synthetic opiate as a Schedule I substance controlled substance which will not have any effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

TEXT OF RULE

SECTION 1. CSB 2.57 is created to read:

CSB 2.57 Scheduling of cyclopropyl fentanyl. Section 961.14 (2) (nd) 10d. is created to read: *961.14 (2) (nd) 10d. Cyclopropyl fentanyl* (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide).

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

(END OF TEXT OF RULE)

Dated _____

_____
Chair
Controlled Substances Board

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

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

Explanation of agency authority:

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

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

Related statute or rule: s. 961.14, Stats.

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

On March 23, 2017, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing Food and Drug Administration approved products of oral solutions containing dronabinol into Schedule II of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating Food and Drug Administration approved products of oral solutions containing dronabinol as a schedule II controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on May 12, 2017 to similarly treat Food and Drug Administration approved products of oral solutions containing dronabinol under chapter 961 effective May 15, 2017 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

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

Comparison with rules in adjacent states:

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

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

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

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

Summary of factual data and analytical methodologies:

The methodology was to schedule Food and Drug Administration approved products of oral solutions containing dronabinol to conform with the federal Controlled Substances Act.

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

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

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

TEXT OF RULE

SECTION 1. CSB 2.54 is created to read:

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

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

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

(END OF TEXT OF RULE)

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

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

Explanation of agency authority:

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

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

Related statute or rule: s. 961.16, Stats.

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

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

Plain language analysis:

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

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

Comparison with rules in adjacent states:

Illinois: Illinois has not excluded naldemedine from scheduling.

Iowa: Iowa has not excluded naldemedine from scheduling.

Michigan: Michigan has not excluded naldemedine from scheduling.

Minnesota: Minnesota has not excluded naldemedine from scheduling.

Summary of factual data and analytical methodologies:

The methodology was to exclude naldemedine from scheduling to conform with the federal Controlled Substances Act.

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

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by May 9, 2018 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.58 is created to read:

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

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

(END OF TEXT OF RULE)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
13 April 2018

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.58

4. Subject
Exclusion of naldemedine

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
20.165(1)(g)

7. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
The United States Department of Justice, Drug Enforcement Administration excluded naldemedine as a controlled substance effective September 29, 2017. The Wisconsin Controlled Substances Board took affirmative action on November 10, 2017 to similarly treat naldemedine effective November 20, 2017. The Board is currently promulgating a final rule.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule will not have an economic or fiscal impact on businesses, business sectors, public utility rate payers, local governmental units or the State's economy as a whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion.

16. Long Range Implications of Implementing the Rule
Naldemedine will be not treated be treated as a controlled substance

17. Compare With Approaches Being Used by Federal Government
The federal government has excluded naldemedine from controlled substance scheduling

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Our surrounding states have not excluded naldemedine from controlled substance scheduling.

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 261-2377

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

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
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ATTACHMENT A

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

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

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

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

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:

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

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

Related statute or rule: s. 961.14, Stats.

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

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

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating ortho-fluorofentanyl as a schedule I controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on November 30, 2017 to similarly treat ortho-fluorofentanyl under chapter 961 effective December 4, 2017 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.14 (2) (nd) 16m., Stats. which adds ortho-fluorofentanyl to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled ortho-fluorofentanyl.

Iowa: Iowa has not scheduled ortho-fluorofentanyl.

Michigan: Michigan has not scheduled ortho-fluorofentanyl.

Minnesota: Minnesota has not scheduled ortho-fluorofentanyl.

Summary of factual data and analytical methodologies:

The methodology was to schedule ortho-fluorofentanyl to conform with the federal Controlled Substances Act.

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

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by May 9, 2018 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.59 is created to read:

CSB 2.59 Addition of ortho-fluorofentanyl to schedule I. Section 961.14 (2) (nd)16m., Stats., is created to read:
961.14 (2) (nd) 16m. Ortho-fluorofentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide)

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

(END OF TEXT OF RULE)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
13 April 2018

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.59

4. Subject
Scheduling of ortho-fluorofentanyl

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
20.165(1)(g)

7. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
The United States Department of Justice, Drug Enforcement Administration scheduled ortho-fluorofentanyl as a schedule I controlled substance effective October 26, 2017. The Wisconsin Controlled Substances Board took affirmative action on November 30, 2017 to similarly treat ortho-fluorofentanyl as a schedule I controlled substance effective December 4, 2017. The Board is currently promulgating a final rule.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule will not have an economic or fiscal impact on businesses, business sectors, public utility rate payers, local governmental units or the State's economy as a whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion. In addition, it is in the best interest of Wisconsin citizens to schedule opiate drugs as controlled substances.

16. Long Range Implications of Implementing the Rule
Ortho-fluorofentanyl will be treated as a schedule I controlled substance.

17. Compare With Approaches Being Used by Federal Government
The federal government has scheduled ortho-fluorofentanyl as a schedule I controlled substance.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Our surrounding states have not scheduled ortho-fluorofentanyl.

19. Contact Name	20. Contact Phone Number
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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

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

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:

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

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

Related statute or rule: s. 961.14, Stats.

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

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

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating FUB-AMB as a schedule I controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on December 6, 2017 to similarly treat FUB-AMB under chapter 961 effective December 11, 2017 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.14 (4) (tb) 43., Stats. which adds FUB-AMB to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled FUB-AMB.

Iowa: Iowa has not scheduled FUB-AMB.

Michigan: Michigan has not scheduled FUB-AMB.

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

Summary of factual data and analytical methodologies:

The methodology was to schedule FUB-AMB to conform with the federal Controlled Substances Act.

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

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by May 9, 2018 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.60 is created to read:

CSB 2.60 Addition of FUB-AMB to schedule I. Section 961.14 (4) (tb) 43., Stats., is created to read:
961.14 (4) (tb) 43. methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, commonly known as FUB-AMB, MMB-FUBINACA or AMB-FUBINACA.

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

(END OF TEXT OF RULE)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
13 April 2018

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.60

4. Subject
Scheduling FUB-AMB

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
20.165(1)(g)

7. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
The United States Department of Justice, Drug Enforcement Administration scheduled FUB-AMB as a schedule I controlled substance effective November 3, 2017. The Wisconsin Controlled Substances Board took affirmative action on December 6, 2017 to similarly treat FUB-AMB as a schedule I controlled substance effective December 11, 2017. The Board is currently promulgating a final rule.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This rule will not have an economic or fiscal impact on businesses, business sectors, public utility rate payers, local governmental units or the State's economy as a whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion.

16. Long Range Implications of Implementing the Rule
FUB-AMB will be treated as a schedule I controlled substance.

17. Compare With Approaches Being Used by Federal Government
The federal government has scheduled FUB-AMB as a schedule I controlled substance.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Minnesota has scheduled FUB-AMB as a schedule I controlled substance. The other surrounding states have not.

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

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

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

Brad D. Schimel
Wisconsin Attorney General

P.O. Box 7857
Madison, WI 53707-7857

NEWS FOR IMMEDIATE RELEASE

May 4, 2017

AG Schimel Issues Guidance to Wisconsin Law Enforcement on CBD Oil and Industrial Hemp Production

MADISON, Wis. – Last week, the Wisconsin Department of Justice (DOJ) and Wisconsin Statewide Intelligence Center (WSIC) released an unclassified Analytical Note to advise law enforcement of the legal status of CBD in Wisconsin since law enforcement agencies have received many inquiries about the legality of cannabidiol (CBD) products, including CBD which is derived from hemp. Nothing in this Analytical Note prohibits farmers from cultivating industrial hemp and using it for other lawful purposes.

"Law enforcement has encountered examples of products claiming to be CBD oil that resulted in people getting hurt and sick," said Attorney General Schimel. "We have an obligation to protect public health and safety, and need to provide frontline law enforcement with the knowledge to enforce the law as it is written by the Wisconsin State Legislature and United States Congress."

As explained in the Analytical Note, the Wisconsin State Legislature has chosen to allow the possession and distribution of CBD in only very limited circumstances.

1. An individual may possess CBD only if he/she has a doctor's certification under Section 961.32 of the Wisconsin Statutes;
2. Only a physician or pharmacy may sell CBD if they have an FDA investigational drug permit and approval from the Wisconsin Controlled Substances Board, under Sections 961.34 and 961.38 of the Wisconsin Statutes;
3. The Legislature has only chosen to allow this type of possession and distribution if the CBD does not have a psychoactive effect.

John P. Koremenos, Jr., Communications Director (608) 266-1221

Any possession or distribution of CBD outside of these very limited exceptions is prohibited by law.

The authorization for the Wisconsin industrial hemp pilot program is defined under Wis. Stat. Sec 94.55(2)(a) as follows: "Subject to the provisions under this subsection, a person may plant, grow, cultivate, harvest, sample, test, process, transport, transfer, take possession of, sell, import and export industrial hemp in this state **to the greatest extent allowed under federal law**."

Except under very limited circumstances, the production of cannabidiol is illegal under Federal Law. Under 21 USC Section 802 (16) cannabidiol is a "derivative" of the cannabis plant and is therefore a controlled substance. Because cannabidiol is a controlled substance under Federal law, Section 94.55(2) forbids the processing of it under Wisconsin state law.

While the industrial hemp law allows a licensee to plant, grow, cultivate, harvest, sample, test, process, transport, transfer, take possession of, sell, import and export industrial hemp pursuant to the rules of the Wisconsin Department of Agriculture, Trade and Consumer Protection program, the Wisconsin State Legislature and Congress have not authorized the production and possession of CBD except as outlined above.

Farmers are not prohibited under state law for growing industrial hemp, even for the express purpose of producing CBD. The Wisconsin Legislature, however, has banned CBD possession, distribution, and production within the state, except in the limited circumstances outlined in the Analytical Note. Wisconsin law would not prevent farmers from shipping the hemp out of state.

The Wisconsin Attorney General is responsible for enforcing the laws as written by the Wisconsin State Legislature and signed into law by the Governor.

John P. Koremenos, Jr., Communications Director (608) 266-1221

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Andrea Magermans	04/30/2018 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:
Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
05/11/18	☒ Yes ☐ No	Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☒ Yes, by PDMP Staff ☐ No	

10) Describe the issue and action that should be addressed:

1. WI ePDMP Operations Update
    a. Staff Update
    b. Recent and Upcoming Releases
    c. Status of Grants
    d. User Feedback
    e. EHR Integration Status
2. PDMP Quarterly Report Update
3. WI ePDMP Outreach Events
4. PDMP Referral Workgroup Update
5. Informational Items

11) Authorization

Signature of person making this request — Date

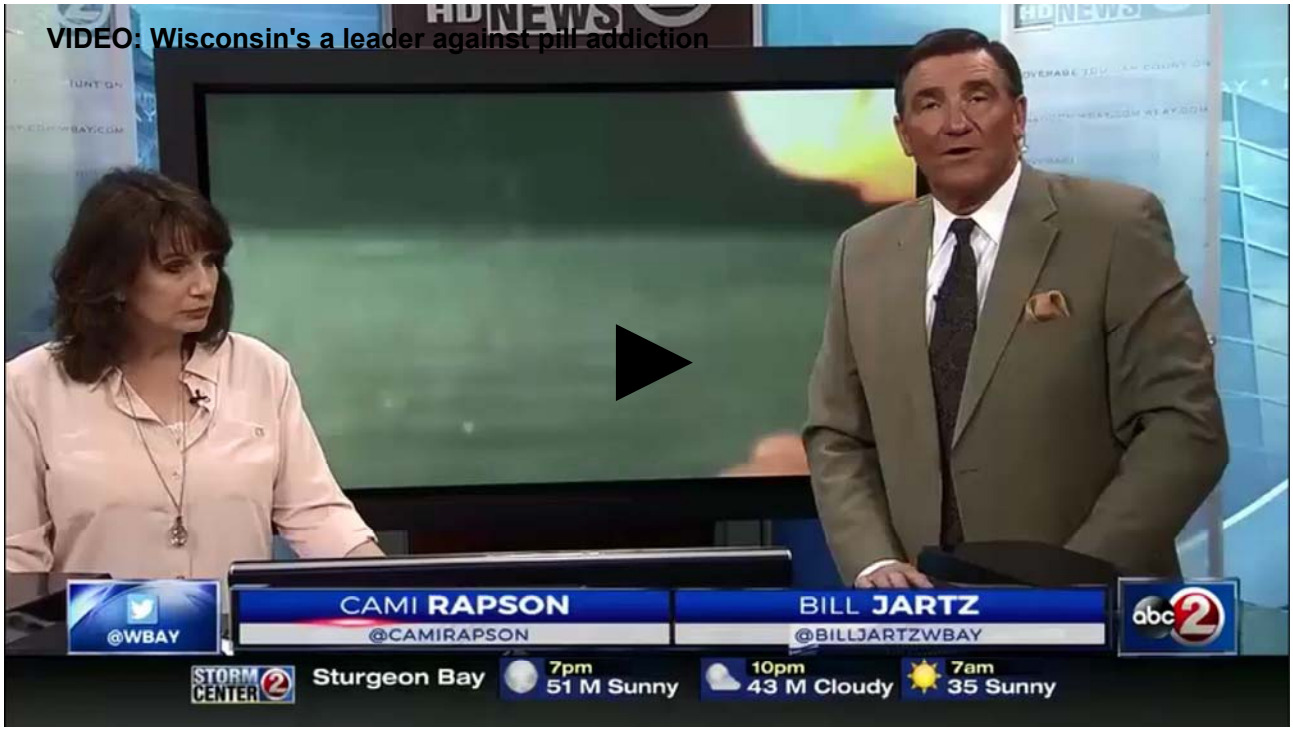
Andrea Magermans 4/30/18

Supervisor (if required) — Date

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — Date

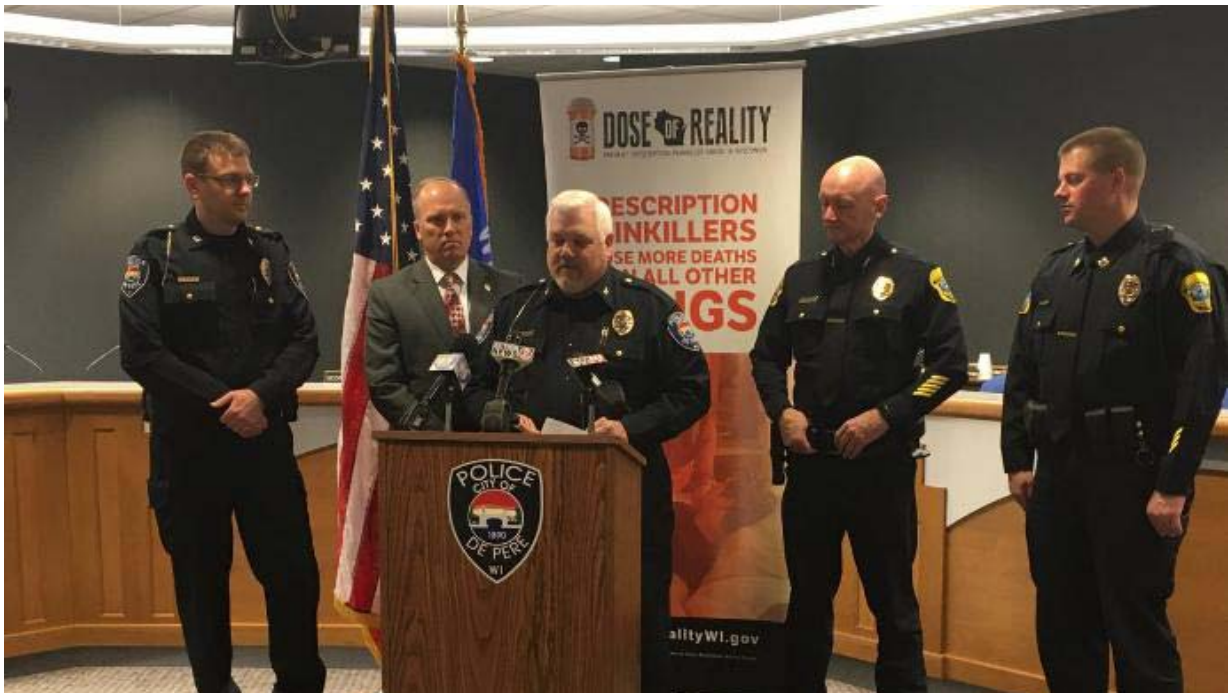
Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

AG: Wisconsin leading the way in battle against opioid addiction



By Sarah Thomsen | Posted: Tue 4:45 PM, Apr 24, 2018 | Updated: Tue 6:48 PM, Apr 24, 2018

BROWN COUNTY, Wis. (WBAY) - Wisconsin is becoming a national leader in the opioid addiction battle with officials testifying before Congress about local initiatives.



Wisconsin doctors, pharmacists, and law enforcement are working together to help reduce opioid addiction.

"We're not saying you don't ever give these out, because somebody breaks their leg or something like that," says Dr. Paul Pritchard, Prevea Health, VP and Chief Quality Officer. "They're going to be in pain. But we have to make sure it's reasonable."

In 2017, Wisconsin launched the Enhanced Prescription Drug Monitoring Program. It's a statewide database that doctors and pharmacists are required to check before giving opioids to patients.

The first year-long report from the Controlled Substances Board gives a snapshot of drug use.

In 2017, 42,000 Wisconsin doctors and pharmacists queried more than six million patients or prescriptions.

Click here to read the full report.

"I think in a lot of ways it's made us look at how we provide care sometimes," Pritchard says.

There is still a need for some people to take opioids. However, the report finds fewer are being prescribed.

Opioid prescriptions are down 20 percent from 2015.

"I've had a number of patients over the last couple years say, 'you know what, I don't want it. I hear the dangers. I know I can get addicted or my grand kids can get into it if it's not locked up. I don't want it,'" Pritchard says.

Wisconsin Attorney General Brad Schimel stopped in De Pere where he encouraged people to be part of the solution.

Schimel is anticipating a record collection for the semi-annual Drug Take Back event on Saturday, April 28.

"When people start abusing those painkillers, they did not get them directly from a doctor. They did not get them from a traditional street level drug dealer. They got them, over 70 percent of the time, from a family member or friend," Schimel says.

Schimel says the prescription database and new guidelines pushing addicts into treatment make Wisconsin the leader in the addiction battle.

Last fall, state officials testified before a U.S. Senate Committee and a Congressional Caucus highlighting the state's efforts.

"We're really all pulling together," Schimel says.

Again, residents can safely dispose of medication during the April 28 Drug Take Back in Wisconsin.

Click here to find a drug take back location near you.

> Local law enforcement and AG Brad Schimel urging people to participate in drug take back day Saturday to get rid of unwanted pills. @WBAY #OpioidEpidemic pic.twitter.com/dmiiT6djrm
>
> — Sarah Thomsen (@SThomsenWbay) April 24, 2018

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As Wisconsin opioid prescriptions decline, John Nygren looks ahead to next steps

By Jessie Opoien, the Capitol Times

As he evaluates the effects of five years of legislative work to fight opioid abuse in Wisconsin, Rep. John Nygren, R-Marinette, is careful not to claim victories.

"You don't take any victory laps when you've still got people dying," Nygren said in an interview.

But that doesn't mean he doesn't celebrate successes. Doctors are prescribing fewer opioids and data suggests that fewer patients are "doctor shopping" —going from one doctor to the next seeking prescriptions — than they were two years ago. Two new bipartisan bills aimed at curbing the epidemic are on their way to Gov. Scott Walker's desk.

From 2015 to 2017, the state saw a 20 percent overall decrease in opioid prescriptions, according to data from the state's Controlled Substances Board. Prescriptions for hydrocodone-acetaminophen decreased by 26 percent in the same time period, and benzodiazepine prescriptions went down by 13 percent. The average monthly "doctor shopping" alerts decreased by 47 percent.

Nygren credits those changes in large part to changes adopted by the state Legislature, including setting prescribing guidelines and implementing a Prescription Drug Monitoring Program.

Under state law passed as part of the Legislature's HOPE Agenda, doctors who prescribe certain prescription drugs are required to submit information to the PDMP within 24 hours. They are also required to check a patient's record when first prescribing a monitored prescription drug.

Law enforcement officers must also update the PDMP if they find someone misusing or breaking the law with scheduled drugs.

"The PDMP is probably the biggest prevention tool we have, because if you can reduce the number of people becoming addicted, then that’s the only way that you’re going to ever be able to get your arms around the current environment of people that are addicts," Nygren said. "If it keeps growing, there’s no way that you could ever address it."

Since 2013, 28 HOPE Agenda bills have been signed into law with overwhelming bipartisan support. Two more await the governor's signature after a Senate vote on Tuesday.

The Legislature has funded treatment alternatives and diversion programs, increased access to the overdose-countering drug naloxone, implemented a "Good Samaritan" law with limited immunity to encourage people to call 911 in the case of an overdose and funded regional treatment facilities in rural and underserved areas.

Wisconsin has earned national recognition for its efforts to combat the opioid epidemic, but the HOPE Agenda — spearheaded by Nygren, whose daughter continues to struggle with addiction — is far from complete.

With positive results still come setbacks. Opioid overdose deaths continue to rise, up 35 percent in Wisconsin from 2015 to 2016, the most recent year data is available. And emergency room visits for suspected opioid overdoses spiked 109 percent from 2016 to 2017 according to federal data released earlier this month.

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2018 Wisconsin Enhanced Prescription Drug Monitoring Program (WI ePDMP) User Survey

Usage

1. What is your profession?

2. Were you a user of the previous version of the WI PDMP (available prior to January 2017)?

- ◯ Yes
- ◯ No
- ◯ Unsure

3. Overall, how satisfied are you with the current functionality of the WI ePDMP?

Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied	N/A
◯	◯	◯	◯	◯	◯

4. What is your primary access route to the WI ePDMP?

- ◯ WI ePDMP website: logging in at https://pdmp.wi.gov/
- ◯ EHR: Integration within a health system EHR

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2018 Wisconsin Enhanced Prescription Drug Monitoring Program (WI ePDMP) User Survey

WI ePDMP via EHR

5. How often do you log in to the WI ePDMP outside of your EHR integration in order to access additional WI ePMDP features (such as dispensing data for other states, Delegate Management, your Prescriber Metrics Report, or your Patients Panel)?

- ◯ Daily
- ◯ 1 - 3 times per week
- ◯ 1 - 3 times per month
- ◯ Less than once a month
- ◯ I do not access the WI ePDMP outside of my EHR integration

2018 Wisconsin Enhanced Prescription Drug Monitoring Program (WI ePDMP) User Survey

Delegate Users

6. Do you have any delegates who are authorized to perform patient queries in the WI ePDMP on your behalf?

- ◯ Yes
- ◯ No

2018 Wisconsin Enhanced Prescription Drug Monitoring Program (WI ePDMP) User Survey

Delegate Users

7. Approximately what percentage of your WI ePDMP queries are conducted by your delegate(s)?

- ◯ More than 90%
- ◯ Between 50 and 90%
- ◯ Less than 50%

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2018 Wisconsin Enhanced Prescription Drug Monitoring Program (WI ePDMP) User Survey

Patient Searching in the WI ePDMP

8. On average, how many seconds does it normally take you or your delegate(s) to access a patient record?

- Less than 10 seconds
- Between 10 and 30 seconds
- Between 30 and 60 seconds
- More than 60 seconds

9. On average, how often do you or your delegate(s) use the WI ePDMP to obtain a patient report?

- Daily
- 1 - 3 times per week
- 1 - 3 times per month
- Less than once a month
- I do not obtain patient reports from the WI ePDMP

WISCONSIN | ePDMP

2018 Wisconsin Enhanced Prescription Drug Monitoring Program (WI ePDMP) User Survey

Using the WI ePDMP: The following questions will ask you about different features in the WI ePDMP.

10. User Account: Rate the following User Account functions in the WI ePDMP

	Very Easy	Easy	Neutral	Difficult	Very Difficult	N/A
Registering for WI ePDMP Access	○	○	○	○	○	○
Retrieving Your Username	○	○	○	○	○	○
Resetting Your Password	○	○	○	○	○	○
Creating Delegate Accounts	○	○	○	○	○	○
Managing Delegate Accounts	○	○	○	○	○	○
Accessing Patient Reports	○	○	○	○	○	○

11. Patient Report: Rate the following Patient Report features in the WI ePDMP

	Very helpful	Helpful	Neutral	Not very helpful	Not at all helpful	N/A
Overall Layout	○	○	○	○	○	○
Data Driven Alerts (multiple prescribers, MME dose, early fill)	○	○	○	○	○	○
Law Enforcement Alerts (fatal/non-fatal overdose, prescription theft, suspected controlled substance act violation)	○	○	○	○	○	○
Patient Demographic Information	○	○	○	○	○	○
Map of Patient's Prescription History	○	○	○	○	○	○
Chart of MME Calculation	○	○	○	○	○	○
Detail of Patient’s Prescription History	○	○	○	○	○	○
Printing/Exporting	○	○	○	○	○	○

12. Which of the following actions have you taken in the last 12 months as a result of using the information in WI ePDMP? (check all that apply)

- [ ] Spoken with a patient about controlled substance use
- [ ] Contacted a patient's prescribers or pharmacies
- [ ] Contacted law enforcement regarding an event detailed in law enforcement alert
- [ ] Confirmed that a patient was not misusing prescriptions
- [ ] Confirmed that a patient had other prescribers that patient had not previously disclosed
- [ ] Denied or modified a prescription for a patient
- [ ] Dismissed a patient from care
- [ ] Referred a patient to or recommended substance abuse treatment
- [ ] Referred a patient to or recommended pain management
- [ ] Referred a patient to or recommended behavioral health treatment services
- [ ] Other (please specify)

13. Which of the following WI ePDMP prescriber features have you used in the last 90 days?

- [ ] Patients Panel: summary of all patients you prescribed a controlled substance to in the last 100 days (including their average MME and number of WI ePDMP alerts)
- [ ] Prescriber Metrics Report: summary of your dispensing metrics for the last 100 days compared to others in your speciality
- [ ] Entered a Prescriber Led Alert: Overdose Event, Treatment Agreement Entered, or Treatment Agreement Violated
- [ ] None of the above
- [ ] Not Applicable (I am not a prescriber)

14. Please use the space below to provide any other comments, questions, or concern regarding the WI ePDMP.

2018 – WI ePDMP Outreach Calendar

	JANUARY	FEBRUARY	MARCH
1			Wisconsin Narcotics Officers Association
2			
3			
4			
5			
6			
7			
8		Pharmacy Society Legislative Day	
9			
10			
11			
12			
13			DSPS Secretary's Office PDMP Roundtables (Oshkosh/Green Bay)
14			
15			
16		Medical Society Council on Legislation	
17			
18			
19			
20			
21			
22			
23			
24			
25	Inter-Tribal Criminal Justice Council		
26			
27			
28			
29			
30			
31			

2018 – WI ePDMP Outreach Calendar

	April	May	June
1			SCAODA Meeting
2	National Rx Abuse and Heroin Summit		
3	National Rx Abuse and Heroin Summit		
4	National Rx Abuse and Heroin Summit		
5			
6			
7			NAMSDL PDMP Resource Group Meeting
8		DSPS Secretary's Office PDMP Roundtable (Manitowoc)	NAMSDL PDMP Resource Group Meeting
9			
10			
11			
12	DHS Opioid Forum		
13			
14			
15			
16			
17			
18		DSPS Secretary's Office Platteville Optimist Club	
19			
20			
21		1. CDC Grantee Meeting 2. WNA Jail Health Conference	
22		1. CDC Grantee Meeting 2. DSPS Secretary's Office PDMP Roundtable (Dodgeville)	Northwoods Coalition Annual Meeting
23			
24	DOJ DCI Narcotics Investigators School	DHS Bureau of Benefit Management Meeting	
25			
26	Janesville Mobilizing for Change Opioid Panel		
27			
28			
29			
30			
31			

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Dan Williams **Executive Director**	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:	5) Attachments:	6) How should the item be titled on the agenda page?
May 11, 2018	☒ Yes ☐ No	**CSB Annual report – Discussion and Consideration**

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☐ No	

10) Describe the issue and action that should be addressed:

MOTION: Jason Smith moved, seconded by Peter Kallio, to request that DSPS staff prepare an initial draft of the 2017 Controlled Substances Board Annual Report to be presented at the May 11, 2018 meeting, which includes information and executive summaries from the PDMP quarterly reports, a listing of SUA's granted and substances scheduled, a summary of rulemaking activity, copies of press releases, a summary of outside engagement and outreach, board liaison reports, and a current listing of agency and law enforcement entities that provide reports and information to the board. Motion carried unanimously.