Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Tony Evers, Governor
Dawn B. Crim, Secretary

CONTROLLED SUBSTANCES BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison
Contact: Christian Albouras (608) 266-2112
January 10, 2020

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 REFERRAL CRITERIA WORK GROUP MEETING

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-3)

B. Approval of Minutes
1. November 15, 2019 **(4-5)**

C. 9:30 A.M. PUBLIC HEARING: Clearinghouse Rule 19-156 Relating Operation of Prescription Drug Monitoring (6-12)
1. Review and Respond to Clearinghouse Report and Public Hearing Comments

D. 9:30 A.M. PUBLIC HEARING: Clearinghouse Rule 19-157 Relating Special Use Authorizations (6, 13-22)
1. Review and Respond to Clearinghouse Report and Public Hearing Comments

E. 9:30 A.M. PRELIMINARY PUBLIC HEARING ON SCOPE STATEMENT: SS 108-19 Relating to Scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 (23-25)

F. 9:30 A.M. PRELIMINARY PUBLIC HEARING ON SCOPE STATEMENT: SS 111-19 Relating to Designating Gabapentin as a Monitored Drug (23, 26-27)

G. Administrative Matters - Discussion and Consideration
1. Department, Staff and Board Updates
2. Annual Policy Review
3. Election of Officers **(28-29)**
4. Appointment of Liaisons and Alternates **(28-29)**
5. Delegation of Authorities **(28, 30-31)**
6. 2020 Meeting Dates **(32)**
7. Board Members
   a. Doug Englebert – DHS Designated Member
   b. Alan Bloom – Pharmacologist

c. Yvonne Bellay – DATCP Designated Member
d. Subhadeep Barman – Psychiatrist
e. Leonardo Huck – Dentistry Examining Board Representative
f. Peter Kallio – Board of Nursing Representative
g. Sandy Koresch – Attorney General Designated Member
h. John Weitekamp – Pharmacy Examining Board Representative
i. Timothy Westlake – Medical Examining Board Representative

H. Prescription Drug Monitoring Program (PDMP) Update – Discussion and Consideration (33-)

1. WI e PDMP Operations
   a. Recent and Upcoming Releases **(34-35)**
   b. Interstate Data Sharing
      1. PMPi and RxCheck Active
      2. WI Currently Sharing Data with 24 State PDMPs
      3. New States: ID, NC
      4. Pending States: AL
      5. States Through RxCheck Available from Within EHR SSO: WA, UT
2. EHR Integration Status **(36)**
   a. 17 Health Systems Currently Live with EHR SSO (Approximately 50% of Monthly Patient Queries
   b. VHA Integration Pilot Through Appriss Gateway **(37-43)**
3. WI ePDMP Outreach Calendar **(44-45)**
4. Dispenser Compliance Audit **(46)**

I. Report and Action Resulting from the Referral Criteria Work Group Meeting

1. Review of Sample Prescriber Monitoring Reports

J. Board Member Reports

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

K. Liaison Reports

1. State Council on Alcohol and Other Drug Abuse (SCAODA) Liaison – Subhadeep Barman

L. Special Use Authorizations (SUA) – Discussion and Consideration

M. Administrative Rule Matters – Discussion and Consideration

1. Pending and Possible Rulemaking Projects

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

1. Introductions, Announcements, and Recognition
2. Administrative Matters
3. Election of Officers
4. Appointment of Liaisons and Alternates
5. Delegation of Authorities
6. Informational Items
7. Division of Legal Services and Compliance (DLSC) Matters
8. Education and Examination Matters

9. Credentialing Matters
10. Practice Matters
11. Legislative and Policy Matters
12. Administrative Rule Matters
13. Liaison Reports
14. Appearances from Requests Received or Renewed
15. Speaking Engagements, Travel, or Public Relations Requests, and Reports
16. Consulting with Legal Counsel

O. 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 individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

P. Deliberation on SUA Applications

1. Monica Gardner **(47-91)**

Q. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: MARCH 13, 2020

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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 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
NOVEMBER 15, 2019

PRESENT: Subhadeep Barman, Yvonne Bellay, Alan Bloom *(arrived at 9:42 a.m.)*, Doug Englebert, Leonardo Huck, Sandy Koresch, John Weitekamp, Timothy Westlake *(via Skype/excused at 11:08 a.m.)*

EXCUSED: Peter Kallio

STAFF: Christian Albouras, Executive Director; Jameson Whitney, Board Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Kimberly Wood, Program Assistant Supervisor-Advanced; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 9:41 a.m. A quorum was confirmed with seven (7) board members present.

ADOPTION OF AGENDA

Amendments to the Agenda

- Correction: Open Session - CORRECT item "D. Administrative Rule Matters; 3. Scope for CSB 2.70 Relating to Scheduling 5F-BDMB-PINACA, …" as follows:
  - "5F-~~B~~**BE**DMB-PINACA"

MOTION: Yvonne Bellay moved, seconded by Leonardo Huck, to adopt the Agenda as amended. Motion carried unanimously.

(Alan Bloom arrived at 9:42 a.m.)

APPROVAL OF MINUTES

Amendments to the Minutes:

- Correct all instances of "John Weitecamp" to "John Weitekamp"

MOTION: John Weitekamp moved, seconded by Yvonne Bellay, to approve the Minutes of September 13, 2019 as amended. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

CSB 3 Relating to Special Use Authorizations

MOTION: Yvonne Bellay moved, seconded by Alan Bloom, to authorize the Legislative Liaison, in consultation with Board Legal Counsel and Dr. Bellay, to express to the appropriate legislative authorities, the Board's concerns regarding limitations on SUAs specifically as pertains to Humane Societies and the practice of euthanasia. Motion carried unanimously.

MOTION: Alan Bloom moved, seconded by Yvonne Bellay, to authorize the Chairperson to approve the preliminary rule draft of CSB 3, relating to Special Use Authorizations, for posting of economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Scope for CSB 2.69 Relating to Scheduling Noroxymorphone

MOTION: Sandy Koresch moved, seconded by John Weitekamp, to approve the Scope Statement revising CSB 2.69, relating to listing noroxymorphone, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. Motion carried unanimously.

(Timothy Westlake was excused at 11:08 a.m.)

Scope for CSB 2.70 Relating to 4F-MDMB-BINACA and MMB-FUBICA

MOTION: Alan Bloom moved, seconded by Subhadeep Barman, to request DSPS staff draft a Scope Statement creating CSB 2.70, relating to scheduling MDMB-BINACA and MMB-FUBICA. Motion carried unanimously.

CSB 2.66 Relating to Scheduling 5F-EDMB-PINACA, 5f-MDMB-PICA, FUB-AKB-48, 5F-CUMYL-PINACA and FUB-144

MOTION: Sandy Koresch moved, seconded by Leonardo Huck, to approve the preliminary rule draft of CSB 2.66, relating to Scheduling 5F-EDMB-PINACA, 5f-MDMB-PICA, FUB-AKB-48, 5F-CUMYL-PINACA and FUB-144, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CSB 4 Relating to Operation of Prescription Drug Monitoring Programs

MOTION: Leonardo Huck moved, seconded by John Weitekamp, to authorize the Chairperson to approve the preliminary rule draft of CSB 4, relating to operation of the prescription drug monitoring program, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 12:07 p.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	18 December 2019 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
10 January 2020	☐ Yes ☐ No	Public Hearing on Clearinghouse Rule 19-156 relating Operation of Prescription Drug Monitoring Program a. Review and Respond to Clearinghouse Report and Public Hearing comments Public Hearing on Clearinghouse Rule 19-157 relating Special Use Authorizations a. Review and Respond to Clearinghouse Report and Public Hearing comments

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:

Hold Public Hearings at 9:30 a.m.

Discuss any public hearing comments. Review, discuss and respond to any Clearinghouse comments.

11) Authorization

Sharon Henes *12/18/19*

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	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board **to amend** CSB 4.11 (9) and **to create** CSB 4.04 (2) (gb) and (gd), 4.09 (1) (c) and (d) and 4.093 (2m), relating to operation of prescription drug monitoring program.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.385, Stats.

Statutory authority: s. 961.385 (2), Stats.

Explanation of agency authority:

The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs. The section goes on to state several items the board shall do, including defining what constitutes suspicious or critically dangerous conduct or practices for purposes of the rules promulgated under s. 961.385 (2) (c), Stats.

Related statute or rule: s. 961.385, Stats.

Plain language analysis:

Section 1 requires the drug dosage units and partial fill indicator to be submitted to the prescription drug monitoring program.

Section 2 clarifies that healthcare professionals may access monitored prescription drug history reports about a patient for scientific research purposes if the patient is a direct patient of the healthcare professional and the patient has given informed consent. In addition, the proposed rule clarifies that a healthcare professional may access monitored prescription drug history reports about a patient for purposes of conducting an overdose fatality review.

Section 3 allows department staff who are charged with investigations to be able to access audit trails related to the log of monitored prescription drug history reports and prescription drug monitoring program data disclosed and a log of requests for prescription drug monitoring program data or monitored prescription drug history reports even when no information was disclosed.

Section 4 clarifies research purposes to be for scientific research purposes and that the Controlled Substances Board may require evidence of institutional review board approval for the research.

Summary of, and comparison with, existing or proposed federal regulation: None

Comparison with rules in adjacent states:

Illinois: Illinois does not require submission of the drug dosage unit or partial fill indicator. Illinois does not authorize access for practitioner scientific research.

Iowa: Iowa does not require submission of the drug dosage unit or partial fill indicator. Iowa does not authorize access for practitioner scientific research. Summary, statistical, or aggregate data to public or private entities for statistical, public research, public policy, or educational purposes.

Michigan: Michigan does not require submission of drug dosage units or partial fill indicator. Data may be provided to employees or agents of the Department of Licensing and Regulatory Affairs. Michigan does not authorize access for scientific research.

Minnesota: Minnesota requires the submission of drug dosage units and partial fill indicator. Personnel of the Minnesota Board of Pharmacy may have access to audit trails. Minnesota does not authorize access for scientific research.

Summary of factual data and analytical methodologies:

The Controlled Substances Board reviewed the rule to make clarifications and updates based upon stakeholder feedback.

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on January 10, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 4.04 (2) (gb) and (gd) is created to read:

CSB 4.04 (2) (gb) The drug dosage units.
(gd) The partial fill indicator.

SECTION 2. CSB 4.09 (1) (c) and (d) are created to read:

CSB 4.09 (1) (c) Scientific research purposes if all of the following requirements are met:

1. The patient is a direct patient of the healthcare professional.
2. The healthcare professional has obtained informed consent from the patient to access monitored prescription drug history reports for scientific research purposes.

(d) Purposes of conducting an overdose fatality review.

SECTION 3. CSB 4.093 (2m) is created to read:

CSB 4.093 (2m) Department staff who are charged with investigating dispensers, dispenser delegates, pharmacists, pharmacist delegates, practitioners, and practitioner delegates may access the audit trails related to s. CSB 4.12 (3) (f) and (g).

SECTION 4. CSB 4.11 (9) is amended to read:

CSB 4.11 (9) The board may disclose PDMP data without personally identifiable information that could be reasonably used to identify any patient, healthcare professional, practitioner delegate, pharmacist delegate, or dispenser for public health and <u>scientific</u> research purposes. <u>The board may require evidence of institutional review board approval.</u>

SECTION 5. 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
December 9, 2019

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 4

4. Subject
Operation of PDMP

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

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

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 ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ 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 proposed rule clarifies and updates minor provisions based upon stakeholder feedback including the following: clarifying disclosure of PDMP data for public health and research purposes, creating a provision to allow for disclosure of audit trails to designated staff of a federal or state governmental agency, and adding "partial fill indicator" and "drug dosage units" to the list of required submissions.

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 proposed rule was posted for economic comments for 14 days 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)
There is no economic or fiscal impact. Pharamcies are already submitting the information.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit to implementing the rule is providing clarity and meeting stakeholder recommendations.

16. Long Range Implications of Implementing the Rule
Updates to the rule ensures the chapter is statutorily compliant and current with professional standards and practices.

17. Compare With Approaches Being Used by Federal Government
None.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Illinois: Illinois does not require submission of the drug dosage unit or partial fill indicator. Illinois does not authorize access for practitioner scientific research.

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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Michigan: Michigan does not require submission of drug dosage units or partial fill indicator. Data may be provided to employees or agents of the Department of Licensing and Regulatory Affairs. Michigan does not authorize access for scientific research.

Minnesota: Minnesota requires the submission of drug dosage units and partial fill indicator. Personnel of the Minnesota Board of Pharmacy may have access to audit trails. Minnesota does not authorize access for scientific research.

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
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 renumber and amend** CSB 3.04 (7); **to amend** CSB 3.02 (4), 3.03 (2), 3.04 (1) (a) and (note), (b), (c), and (d), (3) (intro) and (b), (4) (a) (intro.) and (5) (a) (intro.); **and to create** 3.03 (2m), 3.042, and 3.08 (1) (f) and (g) relating to special use authorizations.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.335, Stats.

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

Explanation of agency authority:

The controlled substances board may promulgate rules relating to the granting of special use permits including, but not limited to, requirements for the keeping and disclosure of records, filing of applications and suspension or revocation of permits. [s. 961.335 (8), Stats.]

Related statute or rule: s. 961.335, Stats.

Plain language analysis:

Section 1 updates the rule to reflect current drafting standards by removing the phrase “but are not limited to.”

Sections 2 and 3 creates the current CSB 3.03 (2) into two separate subsections to create clarity. Special use authorizations are issued to individuals only. If issued to an individual who is designated by a college or university, or research unit, the students, laboratory technicians, research specialists or chemical analysts under the individual’s supervision do not need to obtain a special use authorization.

Section 4 updates language and creates clarity. This section removes “checklists” from the application and updates the note to reflect the current address. The reference to s. 961.335 is removed because the statute does not state the fee is $25; rather it says up to $25. The current

rule creates difficulty in applying for a special use authorization because it requires proof an application is submitted to the federal Drug Enforcement Administration and the Drug Enforcement Administration will not accept an application without proof the individual has a special use authorization. To resolve this situation, the proposed rule requires an affidavit that the individual intends to file an application with the Drug Enforcement Administration. Lastly this section removes proof of compliance with the requirements for security and instead requires a plan for security.

Section 5 clarifies individuals providing euthanasia at humane shelters shall provide the documentation in the application including their completion of a board-approved euthanasia by injection course. In addition, for dog trainers and animal control applicants, it removes the phrase "unless other documentation is required by the board" to clarify that the letter is the requirement.

Section 6 moves the board's discretion to request an appearance to the general application requirements to create clarity.

Section 7 creates the storage requirements. Controlled substances shall be stored in a safe or steel cabinet, the safe or cabinet must be bolted or cemented to the floor if it is less than 750 pounds so that it can't be readily removed, meet requirements for forced entry, and housed in a room which is locked during non-use hours. Other secure storage areas may be approved by the Controlled Substances Board if the storage will protect the controlled substances from theft and unauthorized use. The controlled substances must be locked up unless in use by the authorized user.

Section 8 clarifies it is a violation to not obtain a drug enforcement administration registration or if there is a violation of a state or federal law relating to controlled substances.

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

The federal government requires security controls for non-practitioners storing controlled substances. The drugs are to be stored in a safe or steel cabinet with the following specifications: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques. If the safe or steel cabinet weighs less than 750 pounds, it must be bolted or cemented to the floor or wall in a way that it can't be readily removed. The room must limit access during working hours and provide security after working hours.

Comparison with rules in adjacent states:

Illinois: In Illinois, every person who, or proposes to, manufacture, distribute, or dispense any controlled substances; engages in chemical analysis, research, or instructional activities which utilize controlled substances; purchases, stores, or administers euthanasia drugs, provides canine odor detection services; must obtain a registration issued by the Department of Financial and Professional Regulation. Registered persons may possess, manufacture, distribute, or dispense controlled substances, or administer euthanasia drugs to the extent authorized by their

registration, Registration is site-specific, so persons operating at more than one site must have a separate registration for each. A registration to manufacture, distribute, or dispense a controlled substance or purchase, store, or administer euthanasia drugs may be denied, refused renewal, suspended or revoked if a person: provided false or fraudulent material information in any application; has been convicted of a felony related to any controlled substance; has had their federal DEA registration suspended or revoked; has been convicted of bribery, perjury or other infamous crime; violated any provision of the controlled substances act; or failed to provide effective controls against the diversion of controlled substances in other than legitimate medical, scientific or industrial channels.

Iowa:

In Iowa, researchers, analytical laboratories, animal shelters, dog training facilities, and teaching institutions are required to apply for a controlled substances registration permit with the Pharmacy Board. Registration applies to one site only, so persons operating at more than one site must have separate registrations for each. Registered persons may possess, manufacture, distribute, dispense, or conduct research using controlled substances to the extent authorized by their registration only and in conformity with the other provisions of Iowa's controlled substances registration law. A registration to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities or conduct chemical analysis with controlled substances may be denied if the board determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the board shall consider the following factors: maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels; compliance with applicable state and local law; any convictions related to any controlled substance; past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion; furnishing false or fraudulent material in any application for registration; suspension or revocation of the federal DEA registration; and any other factors relevant to and consistent with the public health and safety.

Michigan:

In Michigan, an individual in charge of a licensed dog pound or animal shelter, must obtain both a Drug Enforcement Agency (DEA) controlled substance registration and a Michigan controlled substance license for the limited purpose of buying, possessing, and administering a commercially prepared, premixed solution of sodium pentobarbital to practice euthanasia on animals. Michigan officers or state employees are exempted from licensure if that person is engaged in the enforcement of a state or local law relating to controlled substances and who is duly authorized to possess controlled substances in the course of that person's duties. Licensed researchers and manufacturers of a controlled substance may conduct research with those substances, perform chemical analysis, manufacture the substance, distribute the substance to other persons who are licensed or authorized, and conduct instructional activities with the substances. Certain activities involving schedule 1 controlled substances may require a separate license. The license shall be granted unless the issuance of the license would be inconsistent with the public interest. In determining the public interest, the following shall be considered: maintenance of effective controls against diversion to other than legitimate and professionally

recognized therapeutic, scientific, or industrial channels; compliance with applicable state and local law; conviction relating to a controlled substance; past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion; furnishing false or fraudulent material in an application for a controlled substance license; suspension or revocation of the federal DEA registration; and any other factor relevant to and consistent with the public health and safety.

Minnesota:

In Minnesota, any qualified person may use controlled substances in the course of a bona fide research project but cannot administer or dispense such drugs to human beings unless such drugs are prescribed, dispensed and administered by a person lawfully authorized to do so. Researchers involved in the use of controlled substances must apply annually for registration with the state Board of Pharmacy. Registration requires that the registrant have policies and procedures for effective controls against theft and diversion of all stocked inventory, unauthorized access, substance waste, and returns. The board may deny, suspend, revoke, or refuse to renew any registration based upon the following: fraud or deception in connection with securing the registration; habitual indulgence in the use of narcotics, stimulants, or depressant drugs or habitual indulgence in intoxicating liquors in a manner which could cause conduct endangering public health; unprofessional conduct or conduct endangering public health; gross immorality; conviction of theft of drugs or the unauthorized use, possession or sale thereof; and violation of the provisions of the rules of the board.

Summary of factual data and analytical methodologies:

The Controlled Substances Board reviewed the chapter for statutory compliance and obsolete practices. The Controlled Substances Board also took into consideration obstacles encountered by individuals who apply and hold special use authorizations.

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on January 10, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 3.02 (4) is amended to read:

CSB 3.02 (4) "Special use" means to manufacture, obtain, possess, use, administer, or dispense a controlled substance for purposes that include~~, but are not limited to,~~ scientific research, instructional activities, chemical analysis, drug-detecting animal training, and euthanasia in humane shelters.

SECTION 2. CSB 3.03 (2) is amended to read:

CSB 3.03 (2) An SUA permit may be issued to an individual only. ~~Entities are not eligible to receive an SUA permit, except that an individual may be designated and authorized to receive the permit for a college or university department, research unit, or similar administrative organization unit. Students, laboratory technicians, research specialists, or chemical analysts under the designee's supervision may possess and use the substances named in the designee's permit for the authorized purposes without obtaining an individual permit.~~

SECTION 3. CSB 3.03 (2m) is created to read:

CSB 3.03 (2m) A SUA permit may be issued to an individual who is designated and authorized to receive a SUA permit for a college or university department, research unit, or similar administrative organizational unit. Students, laboratory technicians, research specialists, or chemical analysts under the individual's supervision, may, without obtaining a special use authorization, possess and use a controlled substance, for the purposes authorized in the permit received for the department or unit.

SECTION 4. CSB 3.04 (1) (a), (a) (note), (b) (c), and (d) are amended to read:

CSB 3.04 (1) (a) Submit a completed application ~~and any required checklists using forms provided by the board~~. A complete application shall include a detailed description of the anticipated uses for each identified controlled substance in Schedules I to V of ch. 961, Stats.,

including each identified controlled substance by name and schedule and the protocols for such uses.

Note: Application forms ~~and checklists~~ are available ~~upon request to the board office at 1400 E. Washington Ave.~~ on the department's website at dsps.wi.og, or by request from the Department of Safety and Professional Services, P.O. Box 8935, Madison, Wisconsin 53708, or ~~online at http://dsps.wi.ogv, under "Professions", then "Controlled Substance Special Use Authorization."~~ call (608) 266-2112.

(b) Pay the applicable permit fee of $25 ~~as set forth in s. 961.335, Stats~~. No fee for an SUA permit may be charged to an employee of a state agency or institution if the permit is necessary to perform employment functions.

(c) Provide ~~proof~~ an affidavit that the applicant ~~has submitted~~ intends to file an application for registration with the federal drug enforcement administration.

(d) Provide ~~proof of the applicant's compliance with the board's requirements~~ a plan for maintaining the physical security of the controlled substances identified in the application.

SECTION 5. CSB 3.04 (3) (intro.) and (b), (4) (a) (intro.), and (5) (a) (intro.) are amended to read:

CSB 3.04 (3) In addition to sub. (1), individuals providing euthanasia at humane shelters shall also provide all of the following:

(b) Documentation of the individual's completion of a board-approved euthanasia by injection course ~~by each staff member performing euthanasia~~.

(4) (a) ~~Unless other documentation is required by the board, a~~ A letter from the sheriff or chief of police, in the jurisdiction where the controlled substances are stored, that includes all of the following for dog training purposes:

(5) (a) ~~Unless other documentation is required by the board, a~~ A letter from the sheriff or chief of police, in the jurisdiction where the controlled substances are stored, that includes all of the following for euthanasia purposes:

SECTION 6. CSB 3.04 (7) is renumbered to CSB 3.04 (1) (g) and amended to read:

CSB 3.04 (1) (g) The board may request an appearance before the board ~~if additional information is required~~.

SECTION 7. CSB 3.042 is created to read:

CSB 3.042 Storage. (1) Individuals holding a SUA permit shall meet all of the following security requirements for storage of controlled substances:

(a) In a safe or steel cabinet or box.

(b) If the safe or steel cabinet or box weighs less than 750 pounds, it must be bolted or cemented to the floor or wall in such a way that it cannot be readily removed.

(c) The safe or steel cabinet or box must be able to withstand attempts at forced entry by individuals using common tools for a period of 10 minutes or lock manipulation for 20 hours. Fire resistance is not required.

(d) A central safe used for other security purposes may be used if the controlled substances are locked in metal boxes sufficient to prevent casual access by others authorized to use the safe.

(e) The safe or steel cabinet or box must be housed in a room which is locked during non-use hours.

(2) Notwithstanding sub. (1), other secure storage areas may be approved by the board if the manner stored will protect the controlled substances from theft and unauthorized use.

(3) Controlled substances shall be kept locked up except when they are in active use by the authorized individual or under the direct supervision of an authorized individual under s. CSB 3.03 (2m).

SECTION 8. CSB 3.08 (1) (f) and (g) are created to read:

CSB 3.08 (1) (f) Failure to obtain a drug enforcement administration registration.

(g) A violation of state or federal law relating to controlled substances.

SECTION 9. 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
December 9, 2019

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

4. Subject
Special use permits

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

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

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 ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ 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
This chapter was created in 2012. This proposed rule is a clean-up to clarify provisions based upon feedback received from stakeholders since the creation of the chapter. In addition, in consideration of the opioid epidemic, the Board reviewed provisions to ensure adequate access to controlled substances is balanced with public welfare and safety.

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 proposed rule was posted for economic impact 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 specific businesses, business sectors, public utility rate payers, local governmental units and the state's economy as a whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
Updates to the rule ensures the chapter is statutorily compliant and current with professional standards and practices.

16. Long Range Implications of Implementing the Rule
The long range benefit is creating clarity regarding the special use authorizations.

17. Compare With Approaches Being Used by Federal Government
The federal government requires security controls for non-practitioners storing controlled substances. Our security provisions match the Drug Enforcement Administration's requirements.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Illinois: In Illinois, every person who, or proposes to, manufacture, distribute, or dispense any controlled substances;

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

engages in chemical analysis, research, or instructional activities which utilize controlled substances; purchases, stores, or administers euthanasia drugs, provides canine odor detection services; must obtain a registration issued by the Department of Financial and Professional Regulation. Registered persons may possess, manufacture, distribute, or dispense controlled substances, or administer euthanasia drugs to the extent authorized by their registration, Registration is site-specific, so persons operating at more than one site must have a separate registration for each.
Iowa: In Iowa, researchers, analytical laboratories, animal shelters, dog training facilities, and teaching institutions are required to apply for a controlled substances registration permit with the Pharmacy Board. Registration applies to one site only, so persons operating at more than one site must have separate registrations for each. Registered persons may possess, manufacture, distribute, dispense, or conduct research using controlled substances to the extent authorized by their registration only and in conformity with the other provisions of Iowa's controlled substances registration law. A registration to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities or conduct chemical analysis with controlled substances may be denied if the board determines that the issuance of the registration would be inconsistent with the public interest.
Michigan: In Michigan, an individual in charge of a licensed dog pound or animal shelter, must obtain both a Drug Enforcement Agency (DEA) controlled substance registration and a Michigan controlled substance license for the limited purpose of buying, possessing, and administering a commercially prepared, premixed solution of sodium pentobarbital to practice euthanasia on animals. Michigan officers or state employees are exempted from licensure if that person is engaged in the enforcement of a state or local law relating to controlled substances and who is duly authorized to possess controlled substances in the course of that person's duties. Licensed researchers and manufacturers of a controlled substance may conduct research with those substances, perform chemical analysis, manufacture the substance, distribute the substance to other persons who are licensed or authorized, and conduct instructional activities with the substances. Certain activities involving schedule 1 controlled substances may require a separate license.
Minnesota: In Minnesota, any qualified person may use controlled substances in the course of a bona fide research project but cannot administer or dispense such drugs to human beings unless such drugs are prescribed, dispensed and administered by a person lawfully authorized to do so. Researchers involved in the use of controlled substances must apply annually for registration with the state Board of Pharmacy. Registration requires that the registrant have policies and procedures for effective controls against theft and diversion of all stocked inventory, unauthorized access, substance waste, and returns.

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 358-4617

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
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
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	18 December 2019 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
10 January 2020	☒ Yes ☐ No	Preliminary Public Hearing on Scope Statement 108-19 relating to Scheduling of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 Preliminary Public Hearing on Scope Statement 111-19 relating to Designating Gabapentin as a Monitored Drug

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:

Hold Public Hearings at 9:30 a.m.

11) Authorization

Sharon Henes *12/18/19*

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.

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.66

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

Rule Type: Permanent

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

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

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

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

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

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

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

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

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

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

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

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

25 hours

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

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

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

On December 28, 2018, the United States Department of Justice, Drug Enforcement Administration published its order of temporary scheduling in the Federal Register placing 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 into Schedule I of the federal Controlled Substances Act. The scheduling action was effective on December 28, 2018.

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

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

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

Authorized Signature

May 10, 2019
Date Submitted

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 4

Relating to: Designating Gabapentin as a Monitored Drug

Rule Type: Permanent

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

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

Gabapentin is a non controlled substance. Gabapentin does show characteristics of various medications associated with misuse and addiction such as benzodiazepines. It is highly sought after for use in potentiating opioids. When combined with opioids, the risk of respiratory depression and opioid-related mortality increases significantly.

In addition to our neighboring state of Michigan, Tennessee and Kentucky have scheduled Gabapentin as a Schedule V controlled substance.

In addition to our neighboring state of Minnesota, approximately 8 other states designate Gabapentin as a monitored drug to be reported to prescription drug monitoring programs.

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

The existing policy is Gabapentin in not reported to the Prescription Drug Monitoring Program. The policy proposed is to designate Gabapentin as a monitored prescription drug as having a substantial potential for abuse and required to be reported to the Prescription Drug Monitoring Program. The inclusion in the Prescription Drug Monitoring Program would be beneficial for prescribers to be aware if a patient has a prescription for Gabapentin prior to prescribing an opioid.

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

961.385 (1) (a) “Monitored prescription drug” means a substance identified in s. 961.16, 961.18, 961.20, or 961.22 or a drug identified by the board by rule as having a substantial potential for abuse.

961.358 (2) (intro.) The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs.

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

50 hours

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

Pharmacies, pharmacists, prescribers, and law enforcement.

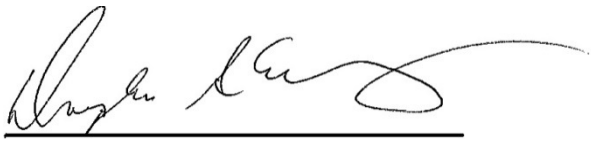
7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

None

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

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

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



Authorized Signature

August 9, 2018
Date Submitted

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:
Kimberly Wood, Program Assistant Supervisor-Adv.	1/2/2020
	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?
1/10/2020	☒ Yes ☐ No	Administrative Matters: 1) Election of Officers 2) Appointment of Liaisons and Alternates 3) Delegation of Authorities

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	N/A

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

1) The Board should conduct Election of its Officers for 2020
2) The Chairperson should review and appoint/reappoint Liaisons and Alternates as appropriate
3) The Board should review and then consider continuation or modification of previously delegated authorities or any additional delegations that may be deemed necessary

11) Authorization

Kimberly Wood *1/2/2020*

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.

CONTROLLED SUBSTANCES BOARD

2019 Elections and Liaison Appointments

***Denotes Liaison and Workgroup Appointments updated after the 2/27/19 Pharmacy Examining Board meeting. At this meeting, the Pharmacy Examining Board changed their representative for the Controlled Substances Board.**

2019 ELECTION RESULTS	
Chairperson	Doug Englebert
Vice Chairperson	Alan Bloom
Secretary	Yvonne Bellay
2019 LIAISON APPOINTMENTS	
Special Use Authorization Liaison(s)	Alan Bloom, Yvonne Bellay
SCAODA Representative	Subhadeep Barman
Legislative Liaison(s)	Timothy Westlake *Alternate: Doug Englebert*
***PDMP Liaison(s)**	Timothy Westlake *Alternates: Subhadeep Barman,* *~~Philip Trapskin~~John Weitekamp-Pharmacy Issues*
***Referral Criteria Workgroup**	Doug Englebert, Peter Kallio, Timothy Westlake, ~~Philip Trapskin~~ John Weitekamp

DELEGATION MOTIONS

Document Signature Delegations

MOTION: Philip Trapskin moved, seconded by Yvonne Bellay, to delegate authority to the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to sign documents on behalf of the Board. In order to carry out duties of the Board, the Chair, chief presiding officer, or longest serving member of the Board. Motion carried unanimously.

MOTION: Philip Trapskin moved, seconded by Yvonne Bellay, in order to carry out duties of the Board, the Chairperson, chief presiding officer, or longest serving board member, has the ability to delegate signature authority for purposes of facilitating the completion of assignments during or between meetings. The members of the Board hereby delegate to the Executive Director or DPD Division Administrator, the authority to sign on behalf of a board member as necessary. Motion carried unanimously.

Delegated Authority for Urgent Matters

MOTION: Philip Trapskin moved, seconded by Yvonne Bellay, that in order to facilitate the completion of urgent matters between meetings, the Board delegates its authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession), to appoint liaisons to the Department to act in urgent matters. Motion carried unanimously.

Special Use Authorization Liaison Delegation

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

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

Quarterly Report Delegation

MOTION: Philip Trapskin moved, seconded by Yvonne Bellay, to authorize the Chair to approve all PDMP Quarterly Reports. Motion carried unanimously.

Legislative Liaison Delegation

MOTION: Philip Trapskin moved, seconded by Yvonne Bellay, to delegate authority to the Legislative Liaison(s) to address Board issues related to legislative matters excluding media requests. Motion carried unanimously.

SCAODA Representative Delegation

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

PDMP Liaison Delegation

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

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:
Kimberly Wood, Program Assistant Supervisor-Adv.	11/27/2019
	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
1/10/2020	☐ Yes ☒ No	2020 Meeting Dates

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	N/A

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

Please review the finalized 2020 meeting dates. Any conflicts should be identified so to ensure quorum.

Info Only

January 10, 2020
March 13, 2020
May 15, 2020
July 10, 2020
September 11, 2020
November 13, 2020

11) Authorization

Kimberly Wood — *11/27/19*

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.

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Andrea Magermans	12/16/2019 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
1/10/2020	☒ 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
    a. Recent and Upcoming Releases
    b. Interstate data sharing
        i. PMPi and RxCheck active
        ii. WI currently sharing data with 24 state PDMPs
        iii. New States: ID, NC
        iv. Pending states: AL
        v. States through RxCheck available from within EHR SSO: WA, UT
    c. EHR Integration Status
        i. 17 health systems currently live with EHR SSO (approximately 50% of monthly patient queries)
        ii. VHA integration pilot through Appriss Gateway
2. WI ePDMP Outreach Calendar
3. Dispenser Compliance Audit

11) Authorization

Signature of person making this request **Date**

Andrea Magermans 12/16/19

Supervisor (if required) **Date**

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

Directions for including supporting documents:
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Wisconsin ePDMP
2019-2020 Development and Release Summary

updated 12.16.2019

Release Date	Description
Pending	
R19 **September 2020 (tentative)**	Prescriber Metrics Notifications • Proactive notice to prescribers to review metrics, based on time and/or prescribing thresholds
R18 **July 2020 (tentative)**	New Design Enhancements • Updated layout and design of Patient Report including alerts and dispensing details, based on user feedback • Opioid naïve alert; history of buprenorphine alert Additional EHR Enhancements • Expanded navigation from within EHR • Multi-state default settings
R17 **April 2020 (tentative)**	Pharmacy-Related Enhancements • Improvements to workflow for error corrections/void • Display of Date Sold, if provided in the submission New Design Enhancements • Better access to history of recent Patient Reports for Delegates • Additional data element on overdose alerts entered by law enforcement to capture administration of Naloxone • MME calculator Additional EHR Enhancements • Expanded patient search from within EHR
Completed	
R16 **Dec 2019**	Patients Panel Improvements • Additional data fields EHR Enhancements • Additional state query from within the EHR, as contractually allowable (initially RxCheck states only) • Delegate Management ability from within EHR • Ability of Delegates to identify as licensed/unlicensed
Minor Interim Release **Oct 2019**	Patient matching updates • Specific improvement for linking patients based on nicknames
R15.1 **Sept 2019**	Performance improvements for Medical Coordinator role

Wisconsin ePDMP
2019-2020 Development and Release Summary

updated 12.16.2019

R15 **Aug 2019**	User Management Enhancements • Annual acceptance of Term and Conditions of the WI ePDMP • Renewal process for Medical Coordinator access to metrics • Periodic review of linked delegates
R14 **April 2019**	RxCheck • Technical tasks to establish connection to RxCheck interstate data sharing hub
R12 and R13 **March 2019**	Data Quality Software Stability Work • Technical tasks to simplify workflows and improve identification/resolution of workflow issues
R11 **February 2019**	DHS Extract • Addition of patient geocode latitude and longitude Quality Assurance and Support Items

Wisconsin ePDMP
EHR Single-Sign-On Summary

updated 12.11.2019

Pending Health Systems and EHR Platforms
HealthPartners (in discussion/contracting)
Athena (in discussion/contracting)
Essentia (in discussion/contracting)
OCHIN (in discussion/contracting)
Prairie Clinic / NextGen (in discussion)
Connected Health Systems (approx. 50% of monthly patient queries)
Aspirus Health Care
Aurora Health Care
Children's Hospital of Wisconsin
Froedtert & the Medical College of Wisconsin
GHC of South Central Wisconsin
Gundersen Health System
HSHS / Prevea Health
Marshfield Clinic
Mayo Clinic
Mercyhealth
Monroe Clinic
ProHealth Care
SSM Health
Thedacare
UnityPoint
UW Health
WISHIN

APPRISS® HEALTH

Veteran's Health Administration Integration Pilot Introduction

*Not for distribution

Mission Act

VA Directive 1306 states, "Patient safety is enhanced when VA providers have complete information about a Veteran's controlled substance prescriptions. Prescription Drug Monitoring Programs (PDMPs) provide information to help VA providers prevent harm to VA patients that could occur because the provider was unaware the patient was prescribed a controlled substance medication by a non-VA provider."

SEC. 134. DEPARTMENT OF VETERANS AFFAIRS PARTICIPATION IN NATIONAL NETWORK OF STATE-BASED PRESCRIPTION DRUG MONITORING PROGRAMS

- **ACCESS TO PROGRAMS.**— (1) Any licensed health care provider or delegate of such a provider shall be considered an authorized recipient or user for the purpose of querying and receiving data from the national network of State-based prescription drug monitoring programs to support the safe and effective prescribing of controlled substances to covered patients.

Mission Act

APPRISS HEALTH

SEC. 134. DEPARTMENT OF VETERANS AFFAIRS PARTICIPATION IN NATIONAL NETWORK OF STATE-BASED PRESCRIPTION DRUG MONITORING PROGRAMS

- "(2) Under the authority granted by paragraph (1)—
  - "(A) licensed health care providers or delegates of such providers shall query such network in accordance with applicable regulations and policies of the Veterans Health Administration; and
  - "(B) notwithstanding any general or specific provision of law, rule, or regulation of a State, no State may restrict the access of licensed health care providers or delegates of such providers from accessing that State's prescription drug monitoring programs.
- "(3) No State shall deny or revoke the license, registration, or certification of a licensed health care provider or delegate who otherwise meets that State's qualifications for holding the license, registration, or certification on the basis that the licensed health care provider or delegate queried or received data, or attempted to query or receive data, from the national network of State-based prescription drug monitoring programs under this section.

Veteran's Health Administration (VHA) Integration Project Overview

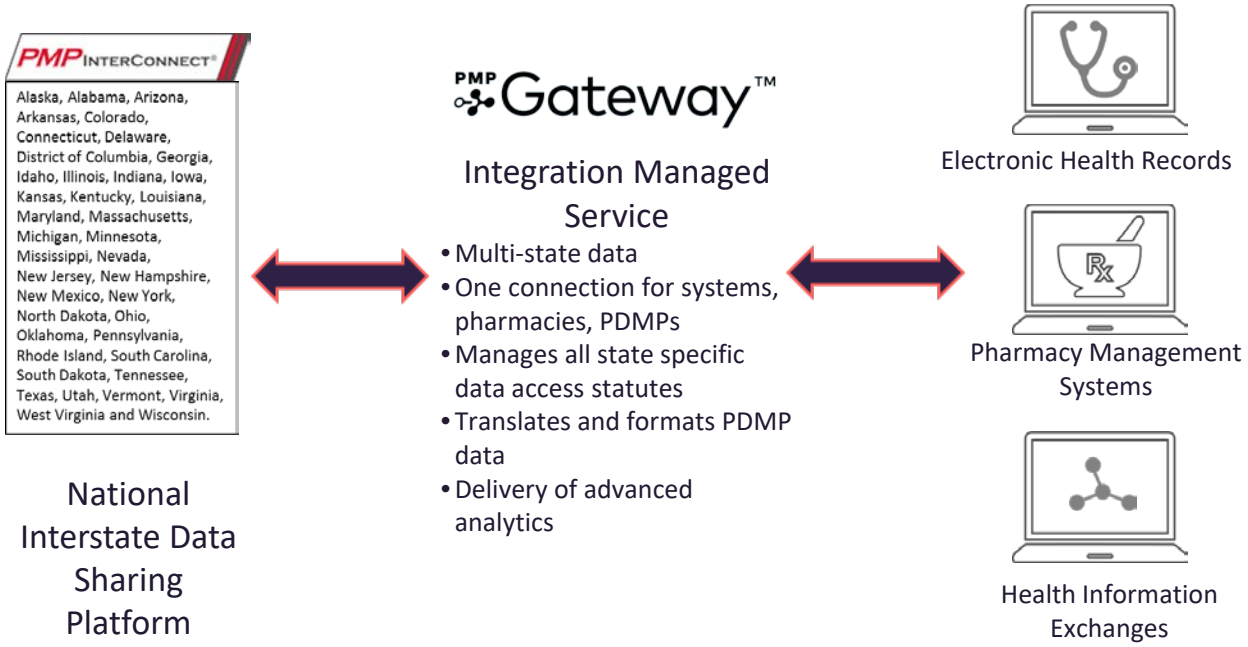
- Appriss Health is part of a team contracted with the VHA to facilitate integration of State PDMP information within the VHA electronic health record system called VistA for Mission Act compliance.

- The scope includes access to the national network of PDMPs via PMP InterConnect and the Appriss PMP Gateway integration protocol for all VHA medical facilities throughout the U.S. and U. S. Territories. That includes 170 Medical Centers and 1,074 Outpatient facilities with over 100,000 users.

- **Phase 1** = Four state pilot selected by the VHA for Q1 2020

- **Phase 2** = National release targeted for mid 2020

Integration Method - PMP Gateway?



Gateway Maintains Security and Transparency

State Oversight

- Audit trails for who accesses and date/time
- Enforces roles-based security so that state authorized roles may access PDMP
- Users can only access profiles for EHR registered patients within the treatment workflow
- No open searching

Audit Detail

- Appriss can provide a data extract to the state that contains details of every single transaction from every licensee (healthcare entity)
- Data extract contains the following data elements
  - Licensee (Organizational Account)
  - Provider First Name
  - Provider Last Name
  - Provider Identifier (DEA, NPI, or state license number)
  - Provider License Type (Only provided if license number is used for provider identifier)
  - Provider Role
  - Location Name (Name of facility where request originates)
  - Location Identifier (DEA, NPI, or NCPDP)
  - Location State
  - Request Date
  - Request Time
  - PMP Disclosure ID (Identifies the response from the PMP by the identifier assigned by the PMP)
- This extract enables PMP administrators to get even greater visibility into specific users that have accessed a state's PMP data

Pilot Overview

- Pilot states include WI, NC, CO, PA
- Pilot location: Madison, WI (Site name: William S. Middleton Memorial Veterans Hospital)
- High level pilot milestones:
  - State to provide an end point for PDMP test database
  - State will provide approval to utilize VHA specific test cases within their test database
  - State will make resources available to load the attached test cases in their data base

2020 – WI ePDMP Outreach Calendar

	JANUARY	FEBRUARY	MARCH
1			
2			
3			
4			
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10			2020 Comprehensive Opioid Abuse Program (COAP) National Forum
11			2020 Comprehensive Opioid Abuse Program (COAP) National Forum
12			2020 Comprehensive Opioid Abuse Program (COAP) National Forum
13			
14			
15			
16	Washington County Heroin Task Force meeting		
17			
18			
19			
20	Wisconsin Coroner/Medical Examiner Association Conference		
21	Wisconsin Coroner/Medical Examiner Association Conference		
22			
23			
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31			

2020 – WI ePDMP Outreach Calendar

	April	May	June
1			
2			
3			
4			
5			
6			
7	Outagamie County OFR Meeting		
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Wisconsin ePDMP
Dispenser Compliance Audit Update

updated 12.11.2019

December 2019 audit of PDMP Dispenser Compliance, based on submissions in November 2019

Most Recent Audit	
Total licensed pharmacies	2,401
Total non-exempt pharmacies	1,668
In-state non-exempt pharmacies	1,106
In-state non-exempt with submissions	1,066
In-State Compliance Percentage	96.4%
In-state non-exempt with no submissions in November	42
Out-of-state non-exempt pharmacies	562
Out-of-state non-exempt with submissions	439
Out-of-State Compliance Percentage	78.1%
Out-of-state non-exempt with no submissions in November	123
Total Compliance Percentage (All Non-Exempt Pharmacies)	90.2%