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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Tom Ryan (608) 266-2112
November 10, 2023

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

AGENDA

9:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. **Adoption of Agenda (1-3)**

B. **Approval of Minutes September 8, 2023 (4-6)**

C. Reminders: Conflicts of Interests, Scheduling Concerns

D. Introductions, Announcements and Recognition

E. Administrative Matters – Discussion and Consideration
   1) Department, Staff, and Board Updates
   2) Board Members – Term Expiration Dates
      a. Alton, Troy – Dentistry Examining Board Representative
      b. Barman, Subhadeep – 5/1/2019
      c. Bellay, Yvonne – DATCP Representative
      d. Bloom, Alan – 5/1/2020
      e. Eberhardy, Cullen – AG Representative
      f. Englebert, Doug – DHS Representative
      g. Schmeling, Gregory – Medical Examining Board Representative
      h. Weinman, Robert – Board of Nursing Representative
      i. Weitekamp, John – Pharmacy Examining Board Representative
   3) Alternates
      a. Bistan, Matthew – Dentistry Examining Board Representative
      b. Ferguson, Kris – Medical Examining Board Representative
      c. McFarland, Rosalyn – Board of Nursing Representative

F. **Administrative Rule Matters – Discussion and Consideration (7)**
   1) Pharmacy Examining Board Rules Committee Request Relating to Wis. Stat. s. 450.11 **(8-21)**
   2) Scope Statement:
      a. CSB. 2003. Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances **(22-24)**
   3) Preliminary Rule Draft:
      a. CSB 2.96, Scheduling Amineptine **(25-27)**

b. CSB 2.97, Scheduling Zipeprol **(28-30)**
c. CSB 2.98, Excluding [^{18}F}FP-CIT **(31-34)**
d. CSB 2.99, Scheduling Mesocarb **(35-37)**
e. CSB 4, Relating to National Provider Identifier (NPI) Requirement**(38-41)**

4) Pending and Possible Rulemaking Projects
a. Rule Projects Chart **(42-43)**

G. **Prescription Drug Monitoring Program (PDMP) Updates – Discussion and Consideration (44)**
1) WI ePDMP Operations
a. Recent and Upcoming Releases **(45-46)**
b. EHR Integration Status **(47-48)**
2) WI ePDMP Outreach **(49)**

H. **Board Member Reports – Discussion and Consideration**
1) Medical Examining Board
2) Dentistry Examining Board
3) Board of Nursing
4) Pharmacy Examining Board

I. **Report from the Referral Criteria Work Group – Discussion and Consideration**

J. **Presentation, Nilajah Hardin: Controlled Substance Scheduling Overview (50-57)**

K. **Presentation, Jennifer Naugle & Cullen Eberhardy: Drug Trends in Wisconsin (58-74)**

L. Liaison Reports

M. Deliberation on Special Use Authorizations – Discussion and Consideration

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 Administrative Rule Matters
12) Liaison Reports
13) Public Health Emergencies
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 Special Use Authorizations – Discussion and Consideration

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

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Tom Ryan (608) 266-2112
November 10, 2023

CONTROLLED SUBSTANCES BOARD

2023 WISCONSIN ETHICS AND PUBLIC RECORDS LAW FACILITATED TRAINING

10:00 A.M. OR IMMEDIATELY FOLLOWING THE FULL BOARD MEETING

A quorum of the Controlled Substances Board may be present; however, no Board business will be conducted.

NEXT MEETING: 2024 (TO BE DETERMINED)

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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 virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. 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. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, or the Meeting Staff at 608-267-7213.

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
SEPTEMBER 8, 2023

PRESENT: Yvonne Bellay, Alan Bloom, Doug Englebert, Cullen Eberhardy, Robert Weinman, John Weitekamp *(arrived at 9:32 a.m.)*, Gregory Schmeling

EXCUSED: Troy Alton, Subhadeep Barman

STAFF: Tom Ryan, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Dialah Azam, Board Administration Specialist; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 9:31 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

Amendments to the Agenda:

- Item D.1.b Gregory Schmaling **CHANGE** to Schmeling
- Item F.1 Adoption Order **CHANGE** to Final Rule Draft

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

(John Weitekamp arrived at 9:32 a.m.)

APPROVAL OF MINUTES OF MAY 12, 2023

MOTION: Alan Bloom moved, seconded by Yvonne Bellay, to adopt the Minutes of May 12, 2023 as published. Motion carried unanimously.

INTRODUCTIONS, ANNOUNCEMENTS AND RECOGNITION

Recognition: Sandy Koresch, AAG Representative (Resigns: 7/14/2023)

MOTION: John Weitekamp moved, seconded by Yvonne Bellay, to recognize and thank Sandy Koresch for her years of dedicated service to the Board and State of Wisconsin. Motion carried unanimously.

Recognition: Lemuel Yerby, Medical Examining Board Representative (Resigns: 7/21/23)

MOTION: Gregory Schmeling moved, seconded by Alan Bloom, to recognize and thank Lemuel Yerby for his years of dedicated service to the Board and State of Wisconsin. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Final Rule Drafts

MOTION: Alan Bloom moved, seconded by Cullen Eberhardy, to approve the Legislative Report and Draft for the following rules for submission to the Governor's Office and Legislature:

- Clearinghouse Rule 23-018 on CSB 2.92, relating to Scheduling 35 Anabolic Steroids
- Clearinghouse Rule 23-019 on CSB 2.93, relating to Scheduling Daridorexant
- Clearinghouse Rule 23-020 on CSB 2.94, relating to Scheduling 7 Synthetic Benzimidazole-Opioids
- Clearinghouse Rule 23-021 on CSB 2.95, relating to Scheduling Ganaxolone

Motion carried unanimously.

Scope Statements

MOTION: Yvonne Bellay moved, seconded by Alan Bloom, to approve the following Scope Statements for submission to the Department of Administration and Governor's Office and for publication:

- CSB 2.001, relating to Scheduling Methiopropamine
- CSB 2.002, relating to Excluding Fenfluramine

Additionally, the Board authorizes the Chairperson to approve these Scope Statements for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on these Scope Statements, the Chairperson is authorized to approve the required notices of hearing.
Motion carried unanimously.

Affirmative Action Order

CSB. 2.003, Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances

MOTION: Robert Weinman moved, seconded by Cullen Eberhardy, to transfer Flualprazolam from schedule IV to schedule I and add Etizolam, Clonazolam, Flubromazolam, and Diclazepam to schedule I by affirmative action. The order shall take effect upon publication in the Administrative Register. Motion carried unanimously.

REPORT FROM THE REFERRAL CRITERIA WORK GROUP

MOTION: Alan Bloom moved, seconded by John Weitekamp, to accept the recommendations of the Referral Criteria Work Group and refer the specified providers to the appropriate examining boards for further proceedings. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 10:17 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:
Nilajah Hardin **Administrative Rules Coordinator**	**10/30/23** **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?
11/10/23	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. **Pharmacy Examining Board Rules Committee Request Relating to Wis. Stat. s. 450.11** 2. **Scope Statement:** a. **CSB. 2003. Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances** 3. **Preliminary Rule Draft:** a. **CSB 2.96, Scheduling Amineptine** b. **CSB 2.97, Scheduling Zipeprol** c. **CSB 2.98, Excluding [^{18} F}FP-CIT** d. **CSB 2.99, Scheduling Mesocarb** e. **CSB 4, Relating to National Provider Identifier (NPI) Requirement** 4. **Pending or Possible Rulemaking Projects** a. **Rule Projects Chart**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	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:

Review and take action on Pharmacy Examining Board Rules Committee Request, Scope Statement, and Preliminary Rules Drafts.

Attachments:

- Pharmacy Examining Board Rules Committee Request – Wis. Stat. 450.11, CSB 4, and Phar 8
- Scope Statement – CSB 2.003
- Preliminary Rule Draft – CSB 2.96-2.99 and 4
- Rule Projects Chart

(All Board Rule Projects can be Viewed Here if Needed: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx)

11) Authorization

Nilajah D. Hardin — 10/30/23

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.**

(4) Nothing in this section may be construed to abrogate a pharmacist's legal and ethical obligations to comply with the laws of this state.

History: 2009 a. 28, 276.

450.10 Disciplinary proceedings; immunity; orders. **(1)** (a) In this subsection, "unprofessional conduct" includes any of the following, but does not include the dispensing of an antimicrobial drug for expedited partner therapy as described in s. 450.11 (1g) or the delivery of an opioid antagonist as described in s. 450.11 (1i):

1. Making any materially false statement or giving any materially false information in connection with an application for a license or registration or for renewal or reinstatement of a license or registration.

2. Violating this chapter or, subject to s. 961.38 (4r), ch. 961 or any federal or state statute or rule which substantially relates to the practice of the licensee or registrant.

3. Engaging in the practice of pharmacy or practicing as a pharmacy technician while the person's ability to practice is impaired by alcohol or other drugs or physical or mental disability or disease.

4. Engaging in false, misleading or deceptive advertising.

5. Making a substantial misrepresentation in the course of practice which is relied upon by another person.

6. Engaging in conduct in the practice of the licensee or registrant that evidences a lack of knowledge or ability to apply professional principles or skills.

7. Obtaining or attempting to obtain compensation by fraud or deceit.

8. Violating any order of the board.

(b) Subject to subch. II of ch. 111 and the rules adopted under s. 440.03 (1), the board may reprimand the licensee or registrant or deny, revoke, suspend, or limit the license or registration or any combination thereof of any person licensed under this chapter who has:

1. Engaged in unprofessional conduct.

2. Been adjudicated mentally incompetent by a court.

3. Been found guilty of an offense the circumstances of which substantially relate to the practice of the licensee or registrant.

(2) In addition to or in lieu of a reprimand or denial, limitation, suspension, or revocation of a license or registration under sub. (1), the board may, for the violations enumerated under sub. (1), assess a forfeiture of not more than $1,000 for each separate offense. Each day of violation constitutes a separate offense.

(3) (a) In this subsection, "health care professional" means any of the following:

1. A pharmacist or pharmacy technician licensed or registered under this chapter.

2. A nurse licensed under ch. 441.

3. A chiropractor licensed under ch. 446.

4. A dentist licensed under ch. 447.

5. A physician, physician assistant, podiatrist, physical therapist, physical therapist assistant, occupational therapist, occupational therapy assistant, or genetic counselor licensed under ch. 448, a physical therapist or physical therapist assistant who holds a compact privilege under subch. XI of ch. 448, or an occupational therapist or occupational therapy assistant who holds a compact privilege under subch. XII of ch. 448.

NOTE: Subd. 5. is shown as affected by 2021 Wis. Acts 23 and 251 and as merged by the legislative reference bureau under s. 13.92 (2) (i). The cross–reference to subch. XI of ch. 448 was changed from subch. X of ch. 448 and the cross–reference to subch. XII of ch. 448 was changed from subch. XI of ch. 448 by the legislative reference bureau under s. 13.92 (1) (bm) 2. to reflect the renumbering under s. 13.92 (1) (bm) 2. of subchs. X and XI of ch. 448.

5m. A dietitian certified under subch. V of ch. 448.

5q. An athletic trainer licensed under subch. VI of ch. 448.

6. An optometrist licensed under ch. 449.

7. An acupuncturist certified under ch. 451.

8. A veterinarian licensed under ch. 89.

9. A psychologist who is licensed under ch. 455, who is exercising the temporary authorization to practice, as defined in s. 455.50 (2) (o), in this state, or who is practicing under the authority to practice interjurisdictional telepsychology, as defined in s. 455.50 (2) (b).

10. A social worker, marriage and family therapist, or professional counselor certified or licensed under ch. 457.

11. A speech–language pathologist or audiologist licensed under subch. II of ch. 459 or a speech and language pathologist licensed by the department of public instruction.

12. A naturopathic doctor or limited–scope naturopathic doctor licensed under ch. 466.

(b) Any health care professional who in good faith provides another health care professional with information concerning a violation of this chapter or ch. 961 by any person shall be immune from any civil or criminal liability that results from any act or omission in providing such information. In any administrative or court proceeding, the good faith of the health care professional providing such information shall be presumed.

(4) (a) The secretary may, in case of the need for emergency action, issue general and special orders necessary to prevent or correct actions by any pharmacist under this section that would be cause for suspension or revocation of a license.

(b) Special orders may direct a pharmacist to cease and desist from engaging in particular activities.

History: 1985 a. 146; 1987 a. 264, 399; 1989 a. 31, 316; 1991 a. 39, 160; 1993 a. 222, 443; 1995 a. 27 s. 9145 (1); 1995 a. 448; 1997 a. 27, 67, 75, 175; 1999 a. 9, 32, 180; 2001 a. 70, 80; 2009 a. 280; 2013 a. 200; 2015 a. 55; 2019 a. 100; 2021 a. 23 s. 71; 2021 a. 100, 123, 130, 131, 251; s. 13.92 (1) (bm) 2.; s. 13.92 (2) (i).

Cross–reference: See also ch. Phar 10, Wis. adm. code.

Applying administrative rules describing unprofessional conduct. Noesen v. Department of Regulation & Licensing, 2008 WI App 52, 311 Wis. 2d 237, 751 N.W.2d 385, 06–1110.

450.11 Prescription drugs and prescription devices. **(1)** DISPENSING. Except as provided in sub. (1i) (b) 2., no person may dispense any prescribed drug or device except upon the prescription order of a practitioner. All prescription orders shall, except as provided in sub. (1a), specify the date of issue, the name and address of the practitioner, the name and quantity of the drug product or device prescribed, directions for the use of the drug product or device, the symptom or purpose for which the drug is being prescribed if required under sub. (4) (a) 8., and, if the order is written by the practitioner, the signature of the practitioner. Except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2) (a) 1., 448.035 (2), 448.037 (2) (a) 1., 448.9725 (2), and 448.9727 (2) (a) 1. and except for standing orders issued under s. 441.18 (2) (a) 2., 448.037 (2) (a) 2., or 448.9727 (2) (a) 2., all prescription orders shall also specify the name and address of the patient. A prescription order issued under s. 118.2925 (3) shall specify the name and address of the school. A prescription order issued under s. 255.07 (2) shall specify the name and address of the authorized entity or authorized individual. Any oral prescription order shall be immediately reduced to writing by the pharmacist and filed according to sub. (2).

(1a) CHART ORDERS. A prescription order entered on the chart or medical record of an inpatient or resident of a health care facility by a practitioner is not required to include the address of the practitioner.

(1b) IDENTIFICATION CARD REQUIRED FOR CERTAIN CONTROLLED SUBSTANCES. (a) In this subsection:

1. "Health care facility" means a facility, as defined in s. 647.01 (4); any hospital, nursing home, community–based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10; and any other facility identified by the board by rule.

2. "Identification card" means any of the following:

a. An operator's license issued under ch. 343 or under a comparable law of another state.

b. An identification card issued under s. 343.50 or under a comparable law of another state.

c. An identification card issued by a U.S. uniformed service.

d. A U.S. or foreign passport.

e. A tribal identification card, as defined in s. 134.695 (1) (cm).

(b) Except as provided under par. (e), a controlled substance included in schedule II or III of ch. 961 may not be dispensed, and may not be delivered to a representative of the ultimate user, without an identification card belonging to the person to whom the drug is being dispensed or delivered.

(bm) A pharmacist, pharmacy technician, or other person dispensing or delivering a drug shall legibly record the name on each identification card presented under par. (b) to the pharmacist, pharmacy technician, or other person, and the name of each person to whom a drug is dispensed or delivered subject to par. (e) 2., and shall maintain that record for a time established by the board by rule or, for a record that is subject to s. 961.385, until the name is delivered to the controlled substances board under s. 961.385, whichever is sooner.

(c) If the person to whom a drug subject to par. (b) is being delivered is not the ultimate user of the drug, the person delivering the drug may ask the ultimate user of the drug to designate a person who is authorized to pick up the drug on behalf of the ultimate user and may inform the person to whom the drug is being delivered that his or her identification is being recorded.

(d) A pharmacist or pharmacy technician is immune from any civil or criminal liability and from discipline under s. 450.10 for any act taken by the pharmacist or pharmacy technician in reliance on an identification card that the pharmacist reasonably believed was authentic and displayed the name of the person to whom the drug was being delivered if the sale was made in good faith.

(e) No identification card is required under par. (b) if any of the following applies:

1. The drug is administered or dispensed directly to the ultimate user by a practitioner.

2. The pharmacist, pharmacy technician, or other person dispensing or delivering the drug has personal knowledge of the person to whom the drug is dispensed or delivered and that the person is the ultimate user or the ultimate user's authorized representative.

3. The drug is delivered to a health care facility to be administered in the health care facility.

(f) The board may, by rule, establish an exemption from the requirements under this subsection for the delivery of a drug by mail if the board determines that the exemption is necessary.

(1g) DISPENSING CERTAIN ANTIMICROBIAL DRUGS FOR EXPEDITED PARTNER THERAPY. (a) In this subsection:

1. "Antimicrobial drug" has the meaning given in s. 448.035 (1) (b).

2. "Expedited partner therapy" has the meaning given in s. 448.035 (1) (c).

(b) A pharmacist may, upon the prescription order of a practitioner providing expedited partner therapy, as specified in s. 448.035 or 448.9725, that complies with the requirements of sub. (1), dispense an antimicrobial drug as a course of therapy for treatment of chlamydial infections, gonorrhea, or trichomoniasis to the practitioner's patient or a person with whom the patient has had sexual contact for use by the person with whom the patient has had sexual contact. The pharmacist shall provide a consultation in accordance with rules promulgated by the board for the dispensing of a prescription to the person to whom the antimicrobial drug is dispensed. A pharmacist providing a consultation under this paragraph shall ask whether the person for whom the antimicrobial drug has been prescribed is allergic to the antimicrobial drug and advise that the person for whom the antimicrobial drug has been prescribed must discontinue use of the antimicrobial drug if the person is allergic to or develops signs of an allergic reaction to the antimicrobial drug.

(c) 1. Except as provided in subd. 2., a pharmacist is immune from civil liability for injury to or the death of a person who takes an antimicrobial drug dispensed for that person under this subsection in connection with expedited partner therapy if the antimicrobial drug is dispensed as provided under par. (b).

2. The immunity under subd. 1. does not extend to the distribution or dispensing of an antimicrobial drug by a pharmacist whose act or omission involves reckless, wanton, or intentional misconduct.

(1i) OPIOID ANTAGONISTS. (a) *Prescription and liability.* 1. A pharmacist may, upon and in accordance with the prescription order of an advanced practice nurse prescriber under s. 441.18 (2) (a) 1., of a physician under s. 448.037 (2) (a) 1., or of a physician assistant under s. 448.9727 (2) (a) 1. that complies with the requirements of sub. (1), deliver an opioid antagonist to a person specified in the prescription order and may, upon and in accordance with the standing order of an advanced practice nurse prescriber under s. 441.18 (2) (a) 2., of a physician under s. 448.037 (2) (a) 2., or of a physician assistant under s. 448.9727 (2) (a) 2. that complies with the requirements of sub. (1), deliver an opioid antagonist to an individual in accordance with the order. The pharmacist shall provide a consultation in accordance with rules promulgated by the board for the delivery of a prescription to the person to whom the opioid antagonist is delivered.

2. A pharmacist who, acting in good faith, delivers an opioid antagonist in accordance with subd. 1., or who, acting in good faith, otherwise lawfully dispenses an opioid antagonist, shall be immune from criminal or civil liability and may not be subject to professional discipline under s. 450.10 for any outcomes resulting from delivering or dispensing the opioid antagonist.

(b) *Possession, dispensing, and delivery.* 1. Any person may possess an opioid antagonist.

2. a. Subject to subd. 2. b. to d., any person may deliver or dispense an opioid antagonist.

b. An advanced practice nurse prescriber may only deliver or dispense an opioid antagonist in accordance with s. 441.18 (2) or in accordance with his or her other legal authority to dispense prescription drugs.

c. A physician may only deliver or dispense an opioid antagonist in accordance with s. 448.037 (2) or in accordance with his or her other legal authority to dispense prescription drugs.

cm. A physician assistant may only deliver or dispense an opioid antagonist in accordance with s. 448.9727 (2) or in accordance with his or her other legal authority to dispense prescription drugs.

d. A pharmacist may only deliver or dispense an opioid antagonist in accordance with par. (a) 1. or in accordance with his or her other legal authority to dispense prescription drugs.

(c) *Immunity.* 1. In this paragraph, "opioid–related drug overdose" has the meaning given in s. 256.40 (1) (d).

2. Subject to par. (a) 2. and ss. 441.18 (3), 448.037 (3), and 448.9727 (3), any person who, acting in good faith, delivers or dispenses an opioid antagonist to another person shall be immune from civil or criminal liability for any outcomes resulting from delivering or dispensing the opioid antagonist.

3. Subject to ss. 256.40 (3) (b) and 895.48 (1g), any person who, reasonably believing another person to be undergoing an opioid–related drug overdose, administers an opioid antagonist to that person shall be immune from civil or criminal liability for any outcomes resulting from the administration of the opioid antagonist to that person.

(1m) ELECTRONIC TRANSMISSION. Except as provided in s. 89.068 (1) (c) 4., a practitioner may transmit a prescription order electronically only if the patient approves the transmission and the prescription order is transmitted to a pharmacy designated by the patient.

(2) PRESCRIPTION ORDER FILE. Every prescription order shall be filed in a suitable book or file and preserved for at least 5 years. Prescription orders transmitted electronically may be filed and preserved in electronic format.

(3) PREPARATION OF PRESCRIPTION DRUGS. Except as provided in sub. (1i) (b) and ss. 118.2925 (4), 255.07 (3), and 450.076, no person other than a pharmacist or practitioner or their agents and employees as directed, supervised, and inspected by the pharmacist or practitioner, including pharmacy technicians, may prepare, compound, dispense, or prepare for delivery for a patient any prescription drug.

(4) LABEL REQUIRED. (a) Except as provided under par. (b), no prescribed drug or device may be dispensed unless there is a label attached to the container disclosing all of the following:

1. The name and address of the dispensing practitioner or licensed facility from which the prescribed drug or device was dispensed.

1m. The telephone number of the pharmacy, if the prescribed drug or device is dispensed by an out–of–state pharmacy licensed under s. 450.065.

2. The date on which the prescription was dispensed.

3. The number of the prescription order as recorded in the prescription order file of the facility from which the prescription was dispensed.

4. The name of the practitioner who prescribed the drug or device.

5. a. Except as provided in subd. 5. b. to d., the full name of the patient.

b. For an antimicrobial drug dispensed under sub. (1g), the full name of the patient, if known, or the words, "expedited partner therapy" or the letters "EPT."

c. For an opioid antagonist when delivered under sub. (1i) (a), the name of the person to whom the opioid antagonist is delivered.

d. For an epinephrine delivery system under s. 118.2925 (3) or 255.07 (2), the name of the school, authorized entity, authorized individual, or other person specified under s. 255.07 (3).

6. Directions for use of the prescribed drug or device as contained in the prescription order.

7. The name and strength of the prescribed drug dispensed, unless the prescribing practitioner requests omission of the name and strength of the drug dispensed.

8. The symptom or purpose for which the drug is being prescribed if the prescription order specifies the symptom or purpose under sub. (4m).

(b) Paragraph (a) does not apply to complimentary samples of drug products or devices dispensed by a practitioner to his or her patients.

(4g) BRAND NAME PERMITTED ON LABEL; DRUGS AND DRUG PRODUCTS. (a) In this subsection:

1. "Brand name" has the meaning given in s. 450.12 (1) (a).

2. "Drug product equivalent" has the meaning given in s. 450.13 (1e).

3. "Generic name" has the meaning given in s. 450.12 (1) (b).

(b) If a pharmacist, pursuant to a prescription order that specifies a drug product by its brand name, dispenses the drug product equivalent of the drug product specified in the prescription order, the label required under sub. (4) (a) may include both the generic name of the drug product equivalent and the brand name specified in the prescription order, unless the prescribing practitioner requests that the brand name be omitted from the label.

(c) This subsection does not apply to a prescription order for a biological product.

(4i) BRAND NAME PERMITTED ON LABEL; BIOLOGICAL PRODUCTS. (a) In this section:

1. "Brand name" has the meaning given in s. 450.122 (1) (a).

2. "Interchangeable biological product" has the meaning given in s. 450.135 (1).

3. "Proper name" has the meaning given in s. 450.122 (1) (b).

(b) If a pharmacist, pursuant to a prescription order that specifies a biological product by its brand name, dispenses the interchangeable biological product of the biological product specified in the prescription order, the label required under sub. (4) (a) may include both the proper name of the interchangeable biological product and the brand name specified in the prescription order.

(4m) LABEL OPTIONS. If a patient indicates in writing to a practitioner who makes a prescription order for the patient that the patient wants the symptom or purpose for the prescription to be disclosed on the label, the practitioner shall specify the symptom or purpose in the prescription order.

(5) INITIAL FILLS AND REFILLS. (a) Except as provided in pars. (bm) and (br), no prescription may be refilled unless the requirements of sub. (1) and, if applicable, sub. (1m) have been met and written, oral, or electronic authorization has been given by the prescribing practitioner. Unless the prescribing practitioner has specified in the prescription order that dispensing a prescribed drug in an initial amount followed by periodic refills as specified in the prescription order is medically necessary, a pharmacist may exercise his or her professional judgment to dispense varying quantities of the prescribed drug per fill up to the total number of dosage units authorized by the prescribing practitioner in the prescription order including any refills, subject to par. (b).

(b) 1. The authority of a pharmacist under par. (a) to dispense varying quantities of a drug applies only with respect to the refills, if any, specified in the prescription order and does not apply with respect to the initial quantity specified in the prescription order, except that a pharmacist may dispense a varying initial quantity of a drug using that authority if such quantity of that drug was previously dispensed to the patient in the previous 2–year period under an earlier prescription.

2. The authority of a pharmacist under par. (a) to dispense varying quantities of a drug does not apply with respect to controlled substances.

3. A pharmacist may not use the authority under par. (a) to dispense varying quantities of a drug to dispense more than a 90–day supply of a drug in a single fill or refill.

(bm) 1. In the event a pharmacist receives a request for a prescription to be refilled and the prescription cannot be refilled as provided in par. (a), the pharmacist may, subject to subd. 2. a. to e., extend the existing prescription order and dispense the drug to the patient, if all of the following apply:

a. The pharmacist has been unsuccessful in attempting to procure a new prescription order or refill authorization for the drug after attempting to contact the prescribing practitioner or his or her office.

b. The patient is on a consistent drug therapy program and the patient has previously refilled the prescription at that pharmacy or through another pharmacy in the same pharmacy chain.

c. The drug is essential to the life of the patient, or the interruption of the drug therapy could result in undesirable consequences for the patient's health.

d. The pharmacist has not received and is not aware of written or oral instructions from the prescribing practitioner prohibiting further dispensing pursuant to or extension of the prescription order.

2. a. A prescribing practitioner may indicate, by writing on the face of the prescription order or, with respect to a prescription order transmitted electronically, by designating in electronic format the phrase "No extensions," or words of similar meaning, that no extension of the prescription order may be made under subd. 1. If such indication is made, the pharmacist may not extend the prescription order under subd. 1.

b. A pharmacist acting under subd. 1. may not extend a prescription order to dispense more than a 7–day supply of the prescribed drug, except that if the drug is typically packaged in a form that requires a pharmacist to dispense the drug in a quantity greater than a 7–day supply, the pharmacist may extend the prescription

order as necessary to dispense the drug in the smallest quantity in which it is typically packaged.

c. A pharmacist may not extend a prescription order under subd. 1. for a drug that is a controlled substance.

d. A pharmacist may not extend a prescription order under subd. 1. for a particular patient if a prescription order was previously extended under subd. 1. for that patient in the previous one–year period for that drug.

e. A pharmacist shall, at the earliest reasonable time after acting under subd. 1., notify the prescribing practitioner or his or her office.

(br) 1. In the event a pharmacist receives a request for a prescription to be refilled and the prescription cannot be refilled as provided in par. (a), the pharmacist may, subject to subd. 2. a. to e., extend the existing prescription order and dispense the drug to the patient, if the pharmacist has not received and is not aware of written or oral instructions from the prescribing practitioner prohibiting further dispensing pursuant to or extension of the prescription order.

2. a. A prescribing practitioner may indicate, by writing on the face of the prescription order or, with respect to a prescription order transmitted electronically, by designating in electronic format the phrase "No extensions," or words of similar meaning, that no extension of the prescription order may be made under subd. 1. If such indication is made, the pharmacist may not extend the prescription order under subd. 1.

b. A pharmacist acting under subd. 1. may not extend a prescription order to dispense more than a 30–day supply of the prescribed drug, except that if the drug is typically packaged in a form that requires a pharmacist to dispense the drug in a quantity greater than a 30–day supply, the pharmacist may extend the prescription order as necessary to dispense the drug in the smallest quantity in which it is typically packaged.

c. A pharmacist may not extend a prescription order under subd. 1. for a drug that is a controlled substance.

d. A pharmacist may not extend a prescription order under subd. 1. for a particular patient if a prescription order was previously extended under subd. 1. for that patient during the period described in subd. 3.

e. A pharmacist shall, at the earliest reasonable time after acting under subd. 1., notify the prescribing practitioner or his or her office, but is not required to attempt to procure a new prescription order or refill authorization for the drug by contacting the prescribing practitioner or his or her office prior to acting under subd. 1. After acting under subd. 1., the pharmacist may notify the patient or other individual that any further refills will require the authorization of a prescribing practitioner.

3. This paragraph applies only during the public health emergency declared on March 12, 2020, by executive order 72, and for 30 days after the conclusion of that public health emergency. During that time, this paragraph supersedes par. (bm) to the extent of any conflict.

(c) An accurate record of refill dispensing shall be maintained showing the date and amount.

(6) SALES OF PRESCRIPTION DRUGS. In the event of any sale of prescription drugs in bankruptcy, at public auction or any other sale of prescription drugs other than in the normal course of business or practice, the seller shall give written notice of the sale to the board at least one week prior to the date of sale and shall make a complete and accurate written report of the sale to the board within 10 days after the sale, showing the name and address of all of the purchasers of prescription drugs together with an itemized inventory of the prescription drugs sold to each purchaser. This subsection does not apply to the sale of a manufacturer, distributor or pharmacy as an ongoing business or practice if the parties first notify the board of the impending sale.

(7) PROHIBITED ACTS. (a) No person may obtain or attempt to obtain a prescription drug, or procure or attempt to procure the administration of a prescription drug, by fraud, deceit or willful misrepresentation or by forgery or alteration of a prescription order; or by willful concealment of a material fact; or by use of a false name or address.

(b) Information communicated to a physician, physician assistant, or advanced practice nurse prescriber in an effort to procure unlawfully a prescription drug or the administration of a prescription drug is not a privileged communication.

(c) No person may willfully make a false statement in any prescription order, report or record required by this section.

(d) No person may, for the purpose of obtaining a prescription drug, falsely assume the title of, or represent himself or herself to be, a manufacturer, distributor, pharmacist, pharmacy technician, or practitioner.

(e) No person may make or utter any false or forged prescription order.

(f) No person may willfully affix any false or forged label to a package or receptacle containing prescription drugs.

(g) Except as authorized by this chapter, no person may possess, with intent to manufacture or deliver, a prescription drug. Intent under this paragraph may be demonstrated by, without limitation because of enumeration, evidence of the quantity and monetary value of the substance possessed, the possession of manufacturing implements or paraphernalia, and the activities or statements of the person in possession of the prescription drug prior to, during and after the alleged violation.

(h) Except as provided in sub. (1i) (b), no person may possess a prescription drug unless the prescription drug is obtained in compliance with this section.

(i) No pharmacist, manufacturer, distributor, owner or operator of a pharmacy or agent of a pharmacist, manufacturer, distributor or such an owner or operator may give any compensation or anything of value to a practitioner for the purpose of providing, or inducing the practitioner to obtain, any equipment, computer software or access to a service that may be used for the electronic transmission of a prescription order.

(8) RULE–MAKING AUTHORITY. The department of justice may promulgate rules necessary for the enforcement of this section. In addition to all law enforcement officers and agencies, the enforcement of this section is the responsibility of the department and:

(a) The board, insofar as this section applies to pharmacists and pharmacy technicians.

(b) The medical examining board, insofar as this section applies to physicians.

(bm) The podiatry affiliated credentialing board, insofar as this section applies to podiatrists.

(c) The veterinary examining board, insofar as this section applies to veterinarians.

(d) The dentistry examining board, insofar as this section applies to dentists.

(e) The board of nursing, insofar as this section applies to advanced practice nurse prescribers.

(f) The physician assistant affiliated credentialing board, insofar as this section applies to physician assistants.

(9) PENALTIES AND ENFORCEMENT PROCEEDINGS. (a) Except as provided in par. (b), any person who violates this section may be fined not more than $500 or imprisoned not more than 6 months or both.

(b) Any person who delivers, or who possesses with intent to manufacture or deliver, a prescription drug in violation of this section is guilty of a Class H felony.

(bm) A violation of sub. (1b) is not punishable under par. (a) or (b).

(c) In any action or proceeding brought for the enforcement of this section, it shall not be necessary to negate any exception or

exemption contained in this section, and the burden of proof of any such exception or exemption shall be upon the defendant.

History: 1985 a. 146; 1997 a. 27, 175, 283; 2001 a. 109; 2005 a. 187, 195, 196, 242; 2007 a. 97; 2009 a. 113, 280; 2011 a. 159, 161; 2013 a. 199, 200, 239; 2015 a. 3, 35, 55, 115, 291; 2017 a. 18, 19, 133, 149, 226, 364; 2019 a. 185; 2021 a. 23, 100, 218; 2023 a. 27.

Arrest did not terminate possession or control of a prescription drug. State v. Brantner, 2020 WI 21, 390 Wis. 2d 494, 939 N.W.2d 546, 18–0053.

450.115 Drug disposal programs and authorizations. (1) In this section:

(a) "Guardian" means the person named by the court under ch. 880, 2003 stats., or ch. 48 or 54 that has the duty and authority of guardianship.

(am) "Hospice worker" means a person who is employed by a hospice, as defined in s. 50.90 (1).

(b) "Personal representative" means an executor, administrator, or special administrator of a decedent's estate, a person legally authorized to perform substantially the same functions, or a successor to any of those persons.

(c) "Trustee" means a person that holds in trust title to or power over property. "Trustee" includes an original, added, or successor trustee.

(d) "Ward" means a person for whom a guardian has been appointed.

(2) Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:

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

(b) The transfer of a prescription drug by a person that lawfully possesses the prescription drug to a drug disposal program that is authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a), and that accepts the prescription drug.

(c) Subject to sub. (4), the possession of a prescription drug under a written authorization described in sub. (3).

(3) (a) A guardian may grant written authorization to an adult who is related to the guardian's ward by blood, marriage, or adoption within the 3rd degree of kinship as computed under s. 990.001 (16), or to a domestic partner of the ward under ch. 770, for the disposal of a prescription drug that belongs to the ward.

(b) A personal representative or a trustee may grant written authorization to an adult beneficiary, as defined in s. 701.1102 (1m), of the estate or trust for the disposal of a prescription drug that belongs to the estate or trust.

(c) A person who is a competent adult may grant written authorization to that person's domestic partner under ch. 770 or to another adult who is related to that person by blood, marriage, or adoption within the 3rd degree of kinship as computed under s. 990.001 (16), for the disposal of a prescription drug that lawfully belongs to that person.

(d) A personal representative, trustee, or an adult beneficiary, as defined in s. 701.1102 (1m), of an estate or trust may grant written authorization to a hospice worker for the disposal of a controlled substance that belongs to the estate or trust.

(4) A written authorization under sub. (3) is valid only to the extent permitted under federal law and only if all of the following conditions are satisfied:

(a) The authorization describes with reasonable specificity each prescription drug or controlled substance that is to be disposed of.

(b) The authorization is in the physical possession of the person authorized to dispose of the prescription drug or controlled substance and each prescription drug or controlled substance described in the authorization is, within 24 hours after the authorization is signed by the person granting the authorization, transferred to a drug disposal program under s. 165.65 or otherwise lawfully disposed of.

(c) The authorization and each prescription drug or controlled substance to be disposed of were obtained without consideration.

History: 2013 a. 198; 2015 a. 197; 2017 a. 99.

450.12 Labeling of prescription drugs and prescription drug products. (1) In this section:

(a) "Brand name" means the name, other than the generic name, that the labeler of a drug or drug product places on its commercial container at the time of packaging.

(b) "Generic name" means the official or established name given a drug by the U.S. department of health and human services or the U.S. adopted names council.

(2) The manufacturer's or distributor's commercial container of every prescription drug or prescription drug product delivered to any pharmacist, practitioner, hospital or nursing home shall bear a label containing the generic name of the drug, if any, the brand name of the drug or drug product, if any, the name and address of the manufacturer of the drug or drug product and, if different from the manufacturer, the name and address of the distributor of the drug or drug product.

(3) Every prescription order or medication profile record shall include the brand name, if any, or the name of the manufacturer or distributor of the drug product dispensed.

(4) This section does not apply with respect to biological products.

History: 1985 a. 146; 2017 a. 149.

450.122 Labeling of biological products. (1) In this section:

(a) "Brand name" means the name, other than the proper name, that the labeler of a biological product places on its commercial container at the time of packaging.

(b) "Proper name" means the nonproprietary name for a biological product designated by the federal food and drug administration licensure for use upon each package of the product.

(2) The manufacturer's or distributor's commercial container of every biological product delivered to any pharmacist, practitioner, hospital, or nursing home shall bear a label containing the proper name of the biological product, the brand name of the biological product, if any, the name and address of the manufacturer of the biological product, and, if different from the manufacturer, the name and address of the distributor of the biological product.

(3) Every prescription order or medication profile record for a biological product shall include the brand name, if any, and the name of the manufacturer of the biological product.

History: 2017 a. 149; 2021 a. 238 s. 45.

450.125 Drugs for animal use. In addition to complying with the other requirements in this chapter for distributing and dispensing, a pharmacist who distributes or dispenses a drug for animal use shall comply with s. 89.068.

History: 1991 a. 306; 2015 a. 55.

450.13 Using drug product equivalent in dispensing prescriptions. (1e) DEFINITION. In this section, "drug product equivalent" means a drug product that is designated the therapeutic equivalent of another drug product by the federal food and drug administration as set forth in the latest edition of or supplement to the federal food and drug administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

(1s) DRUG PRODUCT OR EQUIVALENT TO BE USED. Except as provided in sub. (2), a pharmacist shall dispense every prescription using either the drug product prescribed or its drug product equivalent, if its drug product equivalent is lower in price to the consumer than the drug product prescribed, and shall inform the consumer of the options available in dispensing the prescription.

(2) EXCEPTION. A prescribing practitioner may indicate, by writing on the face of the prescription order or, with respect to a prescription order transmitted electronically, by designating in electronic format the phrase "No substitutions" or words of similar meaning or the initials "N.S.", that no substitution of the drug

Chapter CSB 4

PRESCRIPTION DRUG MONITORING PROGRAM

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CSB 4.15 Disclosure of suspicious or critically dangerous conduct or practices.

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

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

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; correction made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. am., eff. 4–1–17; CR 17–028: am. Register December 2017 No. 744, eff. 1–1–18.

CSB 4.02 Definitions. As used in this chapter:

(1) "Access" means to have the ability to view monitored prescription drug history reports, audit trails, and PDMP data as authorized by s. CSB 4.09.

(2) "Administer" has the meaning given in s. 961.385 (1) (a), Stats.

(2m) "Agent" has the meaning given in s. 961.385 (1) (ab), Stats.

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

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

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

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

(4) "Board" means the Controlled Substances Board.

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

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

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

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

(5k) "DEA registration number" means the registration number issued to a dispenser or practitioner by the federal department of justice, drug enforcement administration.

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

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

(7) "Dispense" has the meaning given in s. 961.385 (1) (af), Stats.

(8) "Dispenser" means all of the following:

(a) A pharmacy.

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

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

(9) "Dispenser delegate" means any of the following:

(a) A managing pharmacist of a pharmacy.

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

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

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

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

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

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

(11r) "Managing pharmacist" means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

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

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

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

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

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

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

(a) PDMP data.

(b) Reports submitted to the program pursuant to s. 961.37, Stats.

(c) Information submitted to the program by a healthcare professional.

(d) Information from the analytics platform.

(13) "Patient" has the meaning given in s. 961.385 (1) (aj), Stats.

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

(15) "PDMP data" means the information compiled and analyzed by the PDMP system from dispensing data submitted to it by dispensers.

(15b) "PDMP system" means the web−based application, analytics platform, and all related hardware and software that facilitates the submission of dispensing data and the access to and disclosure of PDMP data, monitored prescription drug history reports, audit trails, and prescribing metrics reports.

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

(15g) "Pharmacist" has the meaning given in s. 961.385 (1) (aL), Stats. For the purposes of this program, the board recognizes a pharmacist licensed by another state that engages in the practice of pharmacy within the contiguous borders of this state or who practices at a pharmacy licensed under s. 450.065, Stats. as a person authorized to engage in the practice of pharmacy.

(15r) "Pharmacist delegate" means an agent of a pharmacist to whom the pharmacist has delegated the task of accessing monitored prescription drug history reports.

(16) "Pharmacy" has the meaning given in s. 961.385 (1) (an), Stats., including a pharmacy that chooses to solely dispense to animal patients.

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

(18) "Practitioner delegate" means an agent of a practitioner to whom the practitioner has delegated the task of accessing monitored prescription drug history reports.

(18m) "Prescribing metrics report" means all of the following information about a practitioner compiled by the PDMP system and disclosed as authorized in s. CSB 4.09:

(a) PDMP data.

(b) Audit trails.

(c) Reports submitted to the program pursuant to s. 961.37, Stats., about a patient to whom the practitioner has issued a prescription order.

(d) Information from the analytics platform.

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

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

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

(21m) "Prosecutorial unit" has the meaning given in s. 978.001 (2), Stats.

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

History: CR 12−009: cr. Register October 2012 No. 682, eff. 1−1−13; correction in (5) (b) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13−065: cr. (3m), (13e), am. (16), (17), r. (22) Register February 2014 No. 698, eff. 3−1−14; (13e) renum. to (14e) under s. 13.92 (4) (b) 1., Stats., Register February 2014 No. 698; correction in (17) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14−003: am. (8) (a), renum. (9) to (9) (intro.) and am., cr. (9) (a), (b), (11g), (11r), am. (15) (intro.), cr. (15g), (15r), am. (17) Register August 2014 No. 704, eff. 9−1−14; correction in (3), (9) (b), (10), (12) (a) 1., 2., (15) (b), (15g), (17), (20) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15−101: am. (4) Register June 2016 No. 726, eff. 7−1−16; EmR1706: emerg. am. (1), (2), cr. (2m), (3s), (4m), (5m), am. (7), cr. (11c), (11n), am. (11r), cr. (11w), am. (12) (a) 1., cr. (12m), am. (13), r. (14), cons. and renum. (15) (intro.) and (a) to (15) and am., r. (15) (b), cr. (15b), (15e), am. (15g), (15r), (16), (17), (18), cr. (18m), (21m), eff. 4−1−17; CR 17−028: am. (1), (2), cr. (2m), (3s), (4m), (5m), am. (7), cr. (11c), (11n), am. (11r), cr. (11w), am. (12) (a) 1., cr. (12m), am. (13), r. (14), cons. and renum. (15) (intro.) and (a) to (15) and am., r. (15) (b), cr. (15b), (15e), am. (15g), (15r), (16), (17), (18), cr. (18m), (21m) Register December 2017 No. 744, eff. 1−1−18; **(5k) renumbered from CSB 4.04 (1) (a) under s. 13.92 (4) (b) 1., Stats., Register August 2021 No. 788.**

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

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

(2) Gabapentin.

History: CR 12−009: cr. Register October 2012 No. 682, eff. 1−1−13; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13−065: am. (intro.) Register February 2014 No. 698, eff. 3−1−14; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15−101: r. (3) Register June 2016 No. 726, eff. 7−1−16; EmR1706: emerg. r. (2), eff. 4−1−17; CR 17−028: r. (2) Register December 2017 No. 744, eff. 1−1−18; **CR 20−080: cr. (2) Register August 2021 No. 788, eff. 9−1−21.**

CSB 4.04 Compilation of dispensing data. (1) As used in this section, "NDC number" means national drug code number, the universal product identifier used in the U.S. to identify a specific drug product.

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

(a) The dispenser's full name.

(b) The dispenser's DEA registration number.

(c) The date dispensed.

(d) The prescription number.

(e) The NDC number of the monitored prescription drug.

(f) The quantity dispensed.

(g) The estimated number of days of drug therapy.

(gb) The drug dosage units.

(gd) The partial fill indicator.

(ge) The classification code for payment type.

(gm) The number of refills authorized by the prescriber.

(gs) The refill number of the prescription.

(h) The practitioner's full name.

(i) The practitioner's DEA registration number.

(j) The date prescribed.

(L) The patient's full name or if the patient is an animal, the animal's name and the owner's last name.

(m) The patient's address, or if the patient is an animal, patient's owner's address, including street address, city, state, and ZIP code.

(n) The patient's date of birth, or if the patient is an animal, patient's owner's date of birth.

(o) The patient's gender.

(p) The name recorded under s. 450.11 (1b) (bm), Stats.

(4) The board may refer a dispenser and dispenser delegate that fail to compile dispensing data as required by sub. (2) to the appropriate licensing or regulatory board for discipline.

History: CR 12−009: cr. Register October 2012 No. 682, eff. 1−1−13; CR 13−065: am. (1) (b), (e), (3) (b), (d), (i), (k) Register February 2014 No. 698, eff. 3−1−14; CR 14−003: am. (title), renum. (2) to (2) (intro.) and am., cr. (2) (ge), (gm), (gs), renum. (3) (a) to (g) and (h) to (j) to (2) (a) to (g) and (h) to (j), r. (3) (k), renum. (3) (L) to (o) to (2) (L) to (o) and am. (L) to (n), am. (4) Register August 2014 No. 704, eff. 9−1−14; correction in (2) (intro.) made under s. 35.17, Stats., and in (4) made under s. 13.92 (4) (b) 7., Stats., Register August 2014 No. 704; correction in (2) (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15−070: cr. (2) (p) Register April 2016 No. 724, eff. 4−9−17; numbering correction in (2) (p) under s. 13.92 (4) (b) 1. Register April 2016 No. 724; republished to correct CR 15−070: cr. (2) (p) effective date Register May 2016 No. 725; EmR1706: emerg. r. (1) (b), (d), (e), am. (2) (b), (e), (i), (4), eff. 4−1−17; CR 17−028: r. (1) (b), (d), (e), am. (2) (b), (e), (i), (4) Register December 2017 No. 744, eff. 1−1−18; CR 19−156: cr. (2) (gb), (gd) Register August 2020 No. 776, eff. 9−1−20; **(1) (a) renumbered to CSB 4.02 (5k), and (1) (intro.) and (c) consolidated and renumberd to (1) under s. 13.92 (4) (b) 1., Stats., correction in (1) made under s. 35.17, Stats., Register August 2021 No. 788.**

CSB 4.05 Electronic submission of dispensing data. (1) Unless exempt under s. CSB 4.08, a dispenser shall electronically submit dispensing data to the PDMP in any of the following ways:

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

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

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

(4) The board may refer a dispenser and dispenser delegate that fail to submit dispensing data as required by sub. (1) to the appropriate licensing or regulatory board for discipline.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 13–065: am. (2) Register February 2014 No. 698, eff. 3–1–14; CR 14–003: am. (1), (4) Register August 2014 No. 704, eff. 9–1–14; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. renum. (1) to (1) (intro.), cr. (1) (a), (b), r. (2), (3), r. and recr. (4), eff. 4–1–17; CR 17–028: renum. (1) to (1) (intro.), cr. (1) (a), (b), r. (2), (3), r. and recr. (4) Register December 2017 No. 744, eff. 1–1–18.

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

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

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

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

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

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

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

(5) The board may refer a dispenser and dispenser delegate that fail to submit dispensing data or a zero report as required by subs. (1) and (2), or be granted an emergency waiver under sub. (3), or a dispenser and a dispenser delegate that submit false information to the PDMP to the appropriate licensing or regulatory board for discipline.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 13–065: am. (1), (2), (3) (intro.), r. (4) to (6), (9), renum. (7) to (4) and am., renum. (8) to (5) Register February 2014 No. 698, eff. 3–1–14; CR 14–003: am. (2), (5) Register August 2014 No. 704, eff. 9–1–14; EmR1706: emerg. am. (1), (2), (3), (5), eff. 4–1–17; CR 17–028: am. (1), (2), (3), (5) Register December 2017 No. 744, eff. 1–1–18.

CSB 4.07 Correction of dispensing data. (1) A dispenser shall electronically correct dispensing data in the PDMP system within 5 business days of discovering an omission, error, or inaccuracy in previously submitted dispensing data.

(2) The board may refer a dispenser and dispenser delegate that fail to correct dispensing data as required by sub. (1) to the appropriate licensing or regulatory board for discipline.

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

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. Register August 2014 No. 704, eff. 9–1–14; EmR1706: emerg. r. and recr. eff. 4–1–17; CR 17–028: r. and recr. Register December 2017 No. 744, eff. 1–1–18.

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

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

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

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

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

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

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

(4) A dispenser who is not otherwise required to have a DEA registration number is not required to compile or submit dispensing data when dispensing Gabapentin.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. (1) (a), cr. (3) Register August 2014 No. 704, eff. 9–1–14; CR 15–101: am. (1) Register June 2016 No. 726, eff. 7–1–16; EmR1706: emerg. cr. (2m), eff. 4–1–17; CR 17–028: cr. (2m) Register December 2017 No. 744, eff. 1–1–18; **CR 20–080: cr. (4) Register August 2021 No. 788, eff. 9–1–21.**

CSB 4.09 Access to monitored prescription drug history reports and PDMP data about a patient. (1) Healthcare professionals may access monitored prescription drug history reports about a patient for any of the following reasons:

(a) The healthcare professional is directly treating or rendering assistance to the patient.

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

(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.

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

(a) A pharmacist or practitioner who is directly treating or rendering assistance to the patient has delegated the task of obtaining monitored prescription drug history reports about the patient to the pharmacist delegate or practitioner delegate.

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

(3) Healthcare professionals, pharmacist delegates, and practitioner delegates may only disclose a monitored prescription drug history report about a patient obtained pursuant to sub. (1) or (2) in the following situations:

(a) To the patient as part of treating or rendering assistance to the patient.

(b) To another healthcare professional or a medical coordinator for consultation about the health of the patient or as part of treating or rendering assistance to the patient.

(c) To the pharmacist or practitioner who is directly treating or rendering assistance to the patient.

(d) To a law enforcement agency as required by s. 146.82, Stats.

(4) To obtain access to monitored prescription drug history reports as authorized in subs. (1) and (2), healthcare professionals, pharmacist delegates, and practitioner delegates shall do one of the following:

(a) Create an account with the PDMP system.

(b) Create an account with a prescription monitoring program operated by a relevant agency in another jurisdiction with which the board exchanges monitored prescription drug history reports or PDMP data pursuant to s. CSB 4.14.

(c) Create an account with a pharmacy or other entity at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports or that is connected to and lawfully obtains data from the state−designated entity under ch. 153, Stats.

(d) Create an account with a hospital or other entity at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports or that is connected to and lawfully obtains data from the state−designated entity under ch. 153, Stats.

History: CR 12−009: cr. Register October 2012 No. 682, eff. 1−1−13; CR 14−003: am. (1), renum. (2) to (2) (intro.) and am., cr. (2) (a) to (d), am. (3) Register August 2014 No. 704, eff. 9−1−14; corrections in (1), (2) (b), (3) (a) Register September 2015 No. 717; EmR1706: emerg. r. and recr., eff. 4−1−17; CR 17−028: r. and recr. Register December 2017 No. 744, eff. 4−1−17; s. 35.17 corrections in (3) (intro.), (4) (intro.), Register December 2017 No. 744; CR 19−156: cr. (1) (c), (d) Register August 2020 No. 776, eff. 9−1−20.

CSB 4.093 Monitored prescription drug history reports and audit trails about healthcare professionals. (1) Healthcare professionals may access audit trails about themselves and their practitioner delegates or pharmacist delegates.

(2) A practitioner may access the audit trails accessible to healthcare professionals and a prescribing metrics report about themself.

(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).

(3) Medical coordinators may access prescribing metrics reports and audit trails about a healthcare professional whom the medical coordinator coordinates, directs, or supervises or for whom the medical coordinator establishes standard operating procedures that contain no personally identifiable information about a patient if the medical coordinator is conducting any of the following activities:

(a) Evaluating the job performance of the healthcare professional.

(b) Performing quality assessment and improvement activities, including outcomes evaluation or development of clinical guidelines for the healthcare professional.

(4) To obtain access to prescribing metrics reports and audit trails as authorized in subs. (1) and (2), healthcare professionals, pharmacist delegates, and practitioner delegates shall create an account with the PDMP system.

(5) To obtain access to prescribing metrics reports, and audit trails about a healthcare professional, a medical coordinator shall create an account with the PDMP system.

History: EmR1706: emerg. cr. eff. 4−1−17; CR 17−028: cr. Register December 2017 No. 744, eff. 4−1−17; s. 35.17 correction in (4), Register December 2017 No. 744; CR 19−156: cr. (2m) Register August 2020 No. 776, eff. 9−1−20.

CSB 4.097 Deny, suspend, revoke or otherwise restrict or limit access. (1) The board may deny, suspend, revoke, or otherwise restrict or limit a healthcare professional's, pharmacist delegate's, practitioner delegate's, or medical coordinator's access to monitored prescription drug history reports, prescribing metrics reports, PDMP data, and audit tails for any of the following reasons:

(a) The healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator is suspected of attempting to access, accessing, or disclosing a monitored prescription drug history report, prescribing metrics report, PDMP data, or audit trail in violation of s. 146.82 or 961.385, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records.

(b) The healthcare professional is no longer licensed in this state or in another state and recognized by this state as a person to whom the board may grant access pursuant to s. CSB 4.09 or 4.093.

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

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

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

(f) The healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator is convicted of a crime substantially related to the prescribing, administering, or dispensing of a monitored prescription drug.

(g) The pharmacist delegate or practitioner delegate is no longer delegated the task of accessing monitored prescription drug history reports.

(h) The medical coordinator no longer coordinates, directs, supervises, or establishes standard operating procedures for a healthcare professional.

(2) The board may temporarily suspend access to monitored prescription drug history reports, prescribing metrics reports, PDMP data, and audit trails upon discovering circumstances that indicate a healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator has performed any of the actions identified in sub. (1) (a).

History: EmR1706: emerg. cr., eff. 4−1−17; CR 17−028: cr. Register December 2017 No. 744, eff. 1−1−18.

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

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

(c) The denial, suspension, revocation or other restriction or limitation imposed on the healthcare professional's, pharmacist delegate's, practitioner delegate's, or medical coordinator's account pursuant to s. CSB 4.097.

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

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

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

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

(4) No discovery is permitted.

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

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

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

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; correction in (1) (b) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14–003: am. (1) (intro.), (2) (intro.), (b), (3), (6), (7) Register August 2014 No. 704, eff. 9–1–14; correction in (1) (a) to (c) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15–101: am. (1) (c), (2) (a) Register June 2016 No. 726, eff. 7–1–16; s. 35.17 correction in (1) (c), Register June 2016 No. 726; EmR1706: emerg. am. (1) (intro.), r. (1) (a), am. (1) (c), (2) (intro.), (a), (3), (6), (7), eff. 4–1–17; CR 17–028: am. (1) (intro.), r. (1) (a), am. (1) (c), (2) (intro.), (a), (3), (6), (7) Register December 2017 No. 744, eff. 1–1–18; correction in (1) (c) made under s. 13.92 (4) (b) 7., Stats., December 2017 No. 744.

CSB 4.105 Practitioners' requirement to review monitored prescription drug history reports. (1) A practitioner, or a practitioner delegate assisting the practitioner in accordance with the standards of practice for the practitioner's profession, shall review the monitored prescription drug history report about a patient before the practitioner issues a prescription order for the patient unless any of the following conditions are met:

(a) The patient is receiving hospice care, as defined in s. 50.94 (1) (a).

(b) The prescription order is for a number of doses that is intended to last the patient 3 days or less and is not subject to refill.

(c) The monitored prescription drug is lawfully administered to the patient.

(d) The practitioner is unable to review the patient's monitored prescription drug history reports before issuing a prescription order for the patient due to an emergency.

(e) The practitioner is unable to review the patient's records under their program because the PDMP system is not operational or due to other technological failure that the practitioner reports to the board.

(2) Reviews of reports or other information not provided by the board as part of the program that summarize or analyze PDMP data do not satisfy the requirement to review a monitored prescription drug history report under sub. (1).

(3) The board may refer a practitioner that fails to review a monitored prescription drug history report about a patient prior to issuing a prescription order for that patient to the appropriate licensing or regulatory board for discipline.

History: EmR1706: emerg. cr., eff. 4–1–17; CR 17–028: cr. Register December 2017 No. 744, eff. 1–1–18.

CSB 4.11 Methods of obtaining monitored prescription drug history reports. (1) The board shall disclose the monitored prescription drug history report about a patient to the patient if he or she does all of the following:

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

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

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

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

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

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

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

(a) Creates an account with the PDMP system.

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

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

(d) If the PDMP system is unable to fulfill a request from designated staff through their account with the PDMP system, the board may disclose the minimum necessary amount of information necessary to designated staff of a federal or state governmental agency upon written request that cites the agency's specific authorization to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records.

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

(a) Creates an account with the PDMP system.

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

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

(7) The board shall disclose the minimum necessary amount of information in a monitored prescription drug history report about a patient or patient address to a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal

laws and regulations relating to the privacy of patient health care records if the person does all of the following:

(a) Creates an account with the PDMP system.

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

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

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

(a) Creates an account with the PDMP system.

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

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

(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 scientific research purposes. The board may require evidence of institutional review board approval.

(10) The board shall disclose the minimum necessary amount of information in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of a law enforcement agency or prosecutorial unit if the designated staff does all of the following:

(a) Creates an account with the PDMP system.

(b) Provides documentation demonstrating the law enforcement agency or prosecutorial unit is engaged in one of the following activities:

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

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

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

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: r. (3), (4), am. (6) (intro.), renum. (9) (intro.) to (9) and am., r. (9) (a) to (c) Register August 2014 No. 704, eff. 9–1–14; correction in (5) (intro.), (6) (intro.), (7) (intro.), (8) (intro.), (10) (intro.) Register September 2015 No. 717; CR 15–101: am. (1) (intro.), (b), (2) (intro.), (c), (7) (intro.), (c), (8) (intro.), (c) Register June 2016 No. 726, eff. 7–1–16; EmR1706: emerg. am (Title), (1), (2) (intro.), (c), (5) (intro.), (a), (c), cr. (d), am. (6) (intro.), (a), (c), (7) (intro.), (a), (c), (8) (intro.), (a), (c), (9), (10) eff. 4–1–17; CR 17–028: (Title), (1), (2) (intro.), (c), (5) (intro.), (a), (c), cr. (d), am. (6) (intro.), (a), (c), (7) (intro.), (a), (c), (8) (intro.), (a), (c), (9), (10) Register December 2017 No. 744, eff. 1–1–18; CR 19–156: am. (9) Register August 2020 No. 776, eff. 9–1–20.

CSB 4.12 Use of PDMP data by the board and department. (1) The board shall develop and maintain a PDMP database to store dispensing data and PDMP data in a secure environment and an encrypted format.

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

(a) The submission of dispensing data to the PDMP database.

(b) The creation of monitored prescription drug history reports about specific patients, practitioners, and dispensers.

(c) The access to and the obtaining of monitored prescription drug history reports, prescribing metrics reports, and audit trails.

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

(a) A log of dispensing data submitted to the PDMP database by each dispenser.

(b) A log of persons to whom the Board has granted direct access to the PDMP system under ss. CSB 4.09 or 4.093 and a log of each time a person attempts to access PDMP data or a monitored prescription drug history report.

(c) A log of prescription monitoring programs operated by a relevant agency in another jurisdiction with which the board exchanges PDMP data pursuant to s. CSB 4.14 and a log of each time a person from another jurisdiction attempts to access PDMP data.

(d) A log of pharmacies or other entities at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports and a log of each time a person from a pharmacy or other entity attempts to access PDMP data or a monitored prescription drug history report.

(e) A log of hospitals or other entities at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports and a log of each time a person from a hospital or other entity attempts to access PDMP data or a monitored prescription drug history report.

(f) A log of monitored prescription drug history reports and PDMP data disclosed pursuant to s. CSB 4.11, including the name of the person to whom the information was disclosed.

(g) A log of requests for PDMP data or monitored prescription drug history reports even when no information was disclosed.

(6) Staff assigned administrative duties over the PDMP, vendors, contractors, and other agents of the board shall only have access to the minimum amount of PDMP data necessary for all of the following purposes:

(a) The design, implementation, operation, and maintenance of the program, including the PDMP database, PDMP system, the disclosure of information via other entities pursuant to s. CSB 4.09 (4), and the exchange of information pursuant to s. CSB 4.15 as part of the assigned duties and responsibilities of their employment.

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

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

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

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

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

(d) Other legally authorized purposes.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. (4), cr. (4g), (4r) Register August 2014 No. 704, eff. 9–1–14; correction in (6) (b) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. am. (title), (1), r. (2), cr. (2m), r. and recr. (3), r. (4), (4g), (4r), (5), am. (6) (intro.), (a), cr. (6) (am), am. (6) (c), cr. (6) (cg), (cr), eff. 4–1–17; CR 17–028: am. (title), (1), r. (2), cr. (2m), r. and recr. (3), r. (4), (4g), (4r), (5), am. (6) (intro.), (a), cr. (6) (am), am. (6) (c), cr. (6) (cg), (cr), Register December 2017 No. 744, eff. 1–1–18; ; correction in (3) (b) made under s. 13.92 (4) (b) 7., Stats., December 2017 No. 744.

CSB 4.13 Confidentiality of PDMP records. (1) The dispensing data, PDMP data, audit trails, monitored prescription drug history reports, and prescribing metrics reports maintained,

created, or stored as a part of the program are not subject to inspection or copying under s. 19.35, Stats.

(2) A person who discloses or a person whose delegate discloses dispensing data, PDMP data, audit trails, monitored prescription drug history reports, or prescribing metrics reports in violation of s. 146.82 or 961.385, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records, may be referred to the appropriate licensing or regulatory board for discipline, or the appropriate law enforcement agency for investigation and possible prosecution if the board determines that a criminal violation may have occurred.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. am., eff. 4–1–17; CR 17–028: am. Register December 2017 No. 744, eff. 1–1–18.

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

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

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

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

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

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

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

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

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

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

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. (1) (intro.) Register August 2014 No. 704, eff. 9–1–14; EmR1706: emerg. am. (title), (1) (intro.), eff. 4–1–17; CR 17–028: am. (title), (1) (intro.) Register December 2017 No. 744, eff. 1–1–18.

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

(2) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist or pharmacy:

(a) The pharmacist or pharmacy's monitored prescription drug dispensing practices deviate from accepted pharmacist or pharmacy practices.

(b) There are unusual patterns in the payment methodology used by patients to whom monitored prescription drugs are dispensed by the pharmacist or pharmacy.

(c) The history of actions taken against the pharmacist or pharmacy by other state agencies, agencies of another state, or law enforcement.

(d) The type and number of monitored prescription drugs dispensed by the pharmacist or at the pharmacy.

(e) The pharmacist or pharmacy has dispensed forged prescription orders for a monitored prescription drug.

(f) The distance patients travel to have monitored prescription drugs dispensed at the pharmacy.

(g) The number of patients dispensed monitored prescription drugs at the pharmacy or by the pharmacist who satisfy any of the criteria identified in sub. (4).

(3) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a practitioner:

(a) The practitioner's monitored prescription drug prescribing practices deviate from accepted prescribing practices.

(b) The practitioner prescribes potentially dangerous combinations of monitored prescription drugs to the same patient.

(c) The type and number of monitored prescription drugs prescribed by the practitioner.

(d) The history of actions taken against the practitioner by other state agencies, agencies of another state, or law enforcement.

(e) The distance patients travel to obtain monitored prescription drug prescriptions from the practitioner.

(f) The number of patients to whom the practitioner prescribed a monitored prescription who satisfy any of the criteria identified in sub. (4).

(4) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a patient:

(a) The number of practitioners from whom the patient has obtained a prescription for a monitored prescription drug.

(b) The number of pharmacies from where the patient was dispensed a monitored prescription drug.

(c) The number of prescriptions for a monitored prescription drug obtained by the patient.

(d) The number of monitored prescription drug doses dispensed to the patient.

(e) Whether the monitored prescription drugs dispensed to the patient include dangerous levels of any drug.

(f) The number of times the patient is prescribed or dispensed a monitored prescription drug before the previously dispensed amount of the same or a similar monitored prescription drug would be expected to end.

(g) The payment methodology used by the patient to obtain controlled substances at a pharmacy.

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

(a) A relevant patient.

(b) A relevant pharmacist or practitioner.

(c) A relevant state board or agency.

(d) A relevant agency of another state.

(e) A relevant law enforcement agency.

(6) Upon determining that a criminal violation may have occurred, the board may refer a pharmacist, pharmacy, or practitioner to the appropriate law enforcement agency for investigation and possible prosecution. The board may disclose monitored prescription drug history reports, audit trails, and PDMP data to the law enforcement agency as part of the referral.

History: CR 15–101: cr. Register June 2016 No. 726, eff. 7–1–16; CR 17–028: am. (1), (5) (intro.), cr. (6) Register December 2017 No. 744, eff. 1–1–18.

Chapter Phar 8

REQUIREMENTS FOR CONTROLLED SUBSTANCES

Phar 8.01 Federal registration and compliance with federal, state, and local laws and regulations.
Phar 8.02 Purpose of issue of prescription order.
Phar 8.03 Valid prescription requirements.
Phar 8.04 Notification of suspicious orders for and theft or loss of controlled substances.
Phar 8.05 Recordkeeping.
Phar 8.06 Identification card requirement under s. 450.11 (1b), Stats.
Phar 8.07 Partial Dispensing.
Phar 8.08 Controlled substances in emergency kits for long–term care facilities.

Note: Chapter Phar 8 as it existed on September 30, 2022, was repealed and a new chapter Phar 8 was created Register September 2022 No. 801, effective October 1, 2022.

Phar 8.01 Federal registration and compliance with federal, state, and local laws and regulations. (1) FEDERAL REGISTRATION REQUIRED. To possess, manufacture, distribute, dispense, or conduct research with controlled substances in this state, pharmacies and pharmacists shall register with the drug enforcement administration as required under federal law.

(2) CONTROLLED SUBSTANCES AUTHORIZATION UNDER FEDERAL REGISTRATION. As provided under s. 961.32 (1m) (a), Stats., pharmacies and pharmacists registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, and conduct research with those substances in this state to the extent authorized by their federal registration and in conformity with the provisions of ch. 961, Stats.

(3) COMPLIANCE WITH LAWS AND REGULATIONS. Failure to register with the drug enforcement administration or otherwise comply with applicable federal, state, and local laws and regulations relating to possessing, manufacturing, distributing, dispensing, or conducting research with controlled substances constitutes unprofessional conduct for purposes of s. 450.10, Stats.

Note: The United States Department of Justice Drug Enforcement Administration has published a pharmacist's manual, which provides an informational outline of the federal Controlled Substances Act. It can be found online at: https://www.deadiversion.usdoj.gov/pubs/manuals/index.html.

(4) EMERGENCY KITS IN LONG–TERM CARE FACILITIES. Nothing in these rules shall prohibit long–term care facilities from obtaining an emergency kit, from a DEA registered pharmacy, in compliance with federal law.

History: CR 21–071: cr. Register September 2022 No. 801, eff. 10–1–22.

Phar 8.02 Purpose of issue of prescription order. Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

History: CR 21–071: cr. Register September 2022 No. 801, eff. 10–1–22.

Phar 8.03 Valid prescription requirements. (1) A pharmacist may not dispense controlled substances for a prescription the pharmacist knows, or reasonably should know, is not a valid prescription under applicable federal, state, and local laws and regulations.

(2) An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid. A pharmacist knowingly dispensing pursuant to such a purported order, as well as the practitioner issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

History: CR 21–071: cr. Register September 2022 No. 801, eff. 10–1–22.

Phar 8.04 Notification of suspicious orders for and theft or loss of controlled substances. A pharmacy or pharmacist shall notify the board of a suspicious order or series of orders for controlled substances or the theft or loss of controlled substances on the same day notification is required to be provided to the drug enforcement administration. Notification to the board shall include all information required to be provided in the notification to the drug enforcement administration.

History: CR 21–071: cr. Register September 2022 No. 801, eff. 10–1–22.

Phar 8.05 Recordkeeping. (1) Records shall be maintained as required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats.

(2) The managing pharmacist shall oversee quarterly inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.

History: CR 21–071: cr. Register September 2022 No. 801, eff. 10–1–22.

Phar 8.06 Identification card requirement under s. 450.11 (1b), Stats. (1) DEFINITION. In this section and s. 450.11 (1b) (e) 3., Stats., "health care facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community–based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.

(2) EXEMPTION. There shall be an exemption to the requirement for an identification card when the drug is lawfully delivered to the patient's home, or any address requested by the patient, through mail, common carrier or delivery service. A valid signature is required upon delivery.

History: CR 21–071: cr. Register September 2022 No. 801, eff. 10–1–22.

Phar 8.07 Partial Dispensing. (1) A pharmacist may partially dispense a prescription containing a controlled substance listed in schedule III, IV and V.

(2) (a) The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if one of the following conditions applies:

1. If the pharmacist is unable to supply the full quantity called for in a written, electronic, or emergency oral prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written hard copy prescription order or written record of the electronic or emergency oral prescription order.
2. If the patient requests partial dispensing.
3. If the prescribing practitioner requests partial dispensing.

(b) The remaining portion of any partially dispensed prescription under this subsection may be dispensed within 72 hours

of the first partial dispensing. If the remaining portion is not dispensed within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.

(3) Prescription orders for schedule II controlled substances written for patients in long−term care facilities (LTCF) or for patients with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities to include individual dosage units. The prescribing practitioner may document a terminal illness by writing upon the face of the prescription order the phrase "terminal illness" or words of similar meaning. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescribing practitioner prior to partially dispensing the prescription. Documentation of a terminal illness, whether substantiated by the presence of an appropriate phrase written upon the face of the prescription order or through pharmacist contact with the prescribing practitioner, shall be placed within the individual medication profile record maintained under s. Phar 7.07. The pharmacist shall record on the prescription order whether the patient is "terminally ill" or an "LTCF patient." A prescription order that is partially dispensed and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been dispensed in violation of this subsection. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription order or on another appropriate record, uniformly maintained and readily retrievable, the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. Subsequent partial dispensing is not permitted under this section if the patient becomes deceased, or is no longer diagnosed as terminally ill, or no longer resides within an LTCF. The total quantity of a schedule II controlled substance dispensed by partial dispensing may not exceed the total quantity prescribed. Prescription orders for schedule II controlled substances for patients in an LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless terminated earlier by the discontinuance of medication.

(4) Information pertaining to current prescription orders for schedule II controlled substances for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

(a) Display or printout of: the original prescription order designation; date of issue; identification of prescribing practitioner; identification of patient; name and address of the LTCF or name and address of the hospital or residence of the patient; identification of medication authorized, including dosage form, strength and quantity; listing of partial quantities that have been dispensed under each prescription order and the information required in sub. (3).

(b) Immediate (real time) updating of the prescription order record each time there is partial dispensing of the prescription.

(c) Retrieval of partially dispensed schedule II prescription information identical to that required by s. Phar 7.05 (2) for all prescription renewal information.

History: CR 21−071: cr. Register September 2022 No. 801, eff. 10−1−22; correction in numbering in (2) made under s. 13.92 (4) (b) 1., Stats., and correction in (2) (b), (3) made under s. 13.92 (4) (b) 7., Stats., Register September 2022 No. 801.

Phar 8.08 Controlled substances in emergency kits for long−term care facilities. long−term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances:

(1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.

(2) The pharmaceutical services committee of the facility shall establish security safeguards for each emergency kit stored in the LTCF which shall include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

(3) A pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.

(4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.

(5) Noncompliance with this section may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.

History: CR 21−071: cr. Register September 2022 No. 801, eff. 10−1−22; correction in (5) made under s. 13.92 (4) (b) 3., Stats., Register September 2022 No. 801.

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2.003

Relating to: Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances

Rule Type: Permanent

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

2. Detailed description of the objective of the proposed rule:
The objective of the proposed rule is to transfer Flualprazolam from schedule IV to schedule I and add Etizolam, Clonazolam, Flubromazolam, and Diclazepam to schedule I of Wis. Stat. ch. 961.

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 July 26, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the following 5 synthetic benzodiazepine substances to schedule I of the federal Controlled Substances Act:

- Etizolam
- Flualprazolam
- Clonazolam
- Flubromazolam
- Diclazepam

The scheduling action is effective July 26, 2023.

The Controlled Substances Board did not receive an objection to similarly listing the above 5 synthetic benzodiazepine substances as schedule I controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing the above 5 synthetic benzodiazepine substances as schedule I controlled substances.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Methiopropamine under chapter 961, Stats. by creating the following:

CSB 2.003 Transfer of Flualprazolam and Addition of 4 Other Synthetic Benzodiazepine Substances to Schedule I. **(1)** Section 961.20 (2) (ef), Stats. is repealed.

(2) Section 961.14 (5) (aa), (ab), (ac), (ad), and (ae) Stats., are created to read:

961.14 (5) (aa) Clonazolam (6-(2-chlorophenyl)-1-methyl-8-nitro-4 *H* -benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ab) Diclazepam (7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2 *H* -benzo[*e*][1,4]diazepin-2-one).

(ac) Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6 *H* -thieno[3,2-*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ad) Flualprazolam (8-chloro-6-(2-fluorophenyl)-1-methyl-4 *H* -benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ae) Flubromazolam.(8-bromo-6-(2-fluorophenyl)-1-methly-4 *H* -benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

The Affirmative Action order, dated September 19, 2023, took effect on September 25, 2023, upon 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):
Section 961.11 (1), Stats. provides that "[t]he 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."

Section 961.11(4), Stats. provides that "[i]f 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:
Approximately 80 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 July 26, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the following 5 synthetic benzodiazepine substances to schedule I of the federal Controlled Substances Act:

- Etizolam
- Flualprazolam
- Clonazolam
- Flubromazolam
- Diclazepam

The scheduling action is effective July 26, 2023

8. Anticipated economic impact of implementing the rule: None to minimal.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, DSPSAdminRules@wisconsin.gov

Approved for publication:

Authorized Signature

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

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 2.96 relating to scheduling Amineptine.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:
Section 961.11 (1), Stats. provides that "[t]he 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."

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

Related statute or rule: s. 961.14, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On November 17, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Amineptine into schedule I of the federal Controlled Substances Act. The scheduling action is effective December 19, 2022.

Plain language analysis:
This rule schedules Amineptine as a schedule I controlled substance.

The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Amineptine as a schedule I controlled substance.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Amineptine under chapter 961, Stats. by creating the following:

CSB 2.96 Addition of Amineptine to schedule I. Section 961.14 (7) (r), Stats., is created to read:

> **961.14 (7) (r)** 7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid, commonly known as Amineptine.

The Affirmative Action order, dated February 24, 2023, took effect on March 6, 2023, when it was published in the Administrative Register and expires upon promulgation of a final rule.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:
Illinois: Illinois has not listed Amineptine as a schedule I controlled substance [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not listed Amineptine as a schedule I controlled substance [Iowa Code 124.204].

Michigan: Michigan has not listed Amineptine as a schedule I controlled substance [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not listed Amineptine as a schedule I controlled substance [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Amineptine 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:

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

Fiscal Estimate:
The proposed rule will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by November 10, 2023, to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.96 is created to read:

CSB 2.96 Addition of Amineptine to schedule I. Section 961.14 (7) (r), Stats., is created to read:

> **961.14 (7) (r)** 7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid, commonly known as Amineptine.

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 2.97, relating to scheduling Zipeprol.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:
Section 961.11 (1), Stats. provides that "[t]he 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."

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

Related statute or rule: s. 961.14, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On November 21, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Zipeprol into schedule I of the federal Controlled Substances Act. The scheduling action is effective December 21, 2022.

Plain language analysis:
This rule schedules Zipeprol as a schedule I controlled substance.

The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Zipeprol as a schedule I controlled substance.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Zipeprol under chapter 961, Stats. by creating the following:

CSB 2.97 Addition of Zipeprol to schedule I. Section 961.14 (2) (zm), Stats., is created to read:

> **961.14 (2) (zm)** Zipeprol (1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol).

The Affirmative Action order, dated February 24, 2023, took effect on March 6, 2023, when it was published in the Administrative Register and expires upon promulgation of a final rule.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:
Illinois: Illinois has not listed Zipeprol as a schedule I controlled substance [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not listed Zipeprol as a schedule I controlled substance [Iowa Code 124.204].

Michigan: Michigan has not listed Zipeprol as a schedule I controlled substance [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not listed Zipeprol as a schedule I controlled substance [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Zipeprol 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:
The rule schedules Zipeprol as a Schedule I controlled substance which will not have any effect on small business.

Fiscal Estimate:
The proposed rule will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by November 10, 2023, to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.97 is created to read:

CSB 2.97 Addition of Zipeprol to schedule I. Section 961.14 (2) (zm), Stats., is created to read:

> **961.14 (2) (zm)** Zipeprol (1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol).

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 2.98, relating to Excluding [18 F]FP-CIT.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

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

Explanation of agency authority:
Section 961.11 (1), Stats. provides that "[t]he 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."

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

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On November 21, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [^{18} F]FP-CIT from schedule II of the federal Controlled Substances Act. The scheduling action is effective December 21, 2022.

Plain language analysis:
This rule excludes [^{18} F]FP-CIT from schedule II.

The Controlled Substances Board did not receive an objection to similarly excluding [^{18} F]FP-CIT from schedule II under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order removing [^{18} F]FP-CIT as a schedule II controlled substance.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat [^{18} F]FP-CIT under ch. 961, Stats. by creating the following:

CSB 2.98 Excluding [^{18} F]FP-CIT from schedule II. Section 961.16 (2) (b), Stats., is amended to read:

> **961.16 (2) (b)** Coca leaves and any salt, compound, derivative, or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [^{123}I]Ioflupane ~~is~~ and [^{18} F]FP-CIT are excluded from this paragraph. The following substances and any of their salts, esters, isomers, and salts of esters and isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:

The Affirmative Action order, dated February 24, 2023, took effect on March 6, 2023 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:
Illinois: Illinois has not excluded [^{18} F]FP-CIT from their schedule II controlled substances list [720 Illinois Compiled Statutes 570/206].

Iowa: Iowa has not excluded [^{18} F]FP-CIT from their schedule II controlled substances list [Iowa Administrative Code s. 124.206].

Michigan: Michigan has not excluded [^{18} F]FP-CIT from their schedule II controlled substances list [Michigan Compiled Laws s. 333.7214].

Minnesota: Minnesota has not excluded [^{18} F]FP-CIT from their schedule II controlled substances list [Minnesota Statutes 152.02 (3)].

Summary of factual data and analytical methodologies:
This rule excludes [^{18} F]FP-CIT from schedule II 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 excludes [^{18} F]FP-CIT from schedule II which will not have any effect on small business.

Fiscal Estimate:
The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by November 10, 2023, to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.98 is created to read:

CSB 2.98 Excluding [^{18} F]FP-CIT from schedule II. Section 961.16 (2) (b), Stats., is amended to read:

> **961.16 (2) (b)** Coca leaves and any salt, compound, derivative, or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [^{123}I]Ioflupane ~~is~~ and [^{18} F]FP-CIT are excluded from this paragraph. The following substances and any of their salts, esters, isomers, and salts of esters and isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:

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 2.99, relating to scheduling Mesocarb.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:
Section 961.11 (1), Stats. provides that "[t]he 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."

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

Related statute or rule: s. 961.14, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On November 22, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Mesocarb into schedule I of the federal Controlled Substances Act. The scheduling action is effective December 22, 2022.

Plain language analysis:
This rule schedules Mesocarb as a schedule I controlled substance.

The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Mesocarb as a schedule I controlled substance.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Mesocarb under chapter 961, Stats. by creating the following:

CSB 2.99 Addition of Mesocarb to schedule I. Section 961.14 (7) (s), Stats., is created to read:

> **961.14 (7) (s)** N-phenyl-N'–(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate, commonly known as Mesocarb.

The Affirmative Action order, dated February 24, 2023, took effect on March 6, 2023, when it was published in the Administrative Register and expires upon promulgation of a final rule.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:
Illinois: Illinois has not listed Mesocarb as a schedule I controlled substance [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not listed Mesocarb as a schedule I controlled substance [Iowa Code 124.204].

Michigan: Michigan has not listed Mesocarb as a schedule I controlled substance [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not listed Mesocarb as a schedule I controlled substance [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Mesocarb 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:

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

Fiscal Estimate:
The proposed rule will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, 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 by November 10, 2023, to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.99 is created to read:

CSB 2.99 Addition of Mesocarb to schedule I. Section 961.14 (7) (s), Stats., is created to read:

> **961.14 (7) (s)** N-phenyl-N'–(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate, commonly known as Mesocarb.

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 RULEMAKING 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 4.02 (12s), 4.04 (2) (bm) and (im), 4.04 (5), and 4.097 (1) (i), and amend CSB 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), 4.08 (1) (b) (Note) and CSB 4.08 (4), relating to national provider identifier requirement.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 961.385 (2) (b) and (7s), Stats.

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

Explanation of agency authority:
961.385 (2) (b) states that the board shall establish by rule and have the prescription drug monitoring program "Identify specific data elements to be contained in a record documenting the dispensing of a monitored prescription drug, including the method of payment and, subject to sub. (2m), the name recorded under s. 450.44 (1b) (bm). In identifying specific data elements, the board shall consider data elements identified by similar programs in other states and shall ensure, to the extent possible, that records generated by the program are easily shared with other states."

Related statute or rule: None.

Plain language analysis:
The objective of the proposed rule is to add the National Provider Identifier (NPI) for all dispensing and prescribing Prescription Drug Monitoring Program (PDMP) records by creating CSB 4.02 (12s), 4.04 (2) (im), and 4.04 (5). The Board also modified the exemption requirement under CSB 4.08 (4) that allowed dispensers to be exempt from reporting Gabapentin prescribing if they do not have a DEA number. The exemption is now only required if the practitioner does not have a DEA or an NPI number. Section CSB 4.097 (1) (i) was created to reflect that access to the PDMP can be restricted for failure to provide an NPI number. Updates were also made to the mailing address for the Department in ss CSB 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), and 4.08 (1) (b) (Note).

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

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: No comments were received.

Comparison with rules in adjacent states:

Illinois: The Illinois Prescription Monitoring Program does not require an NPI number to be reported [720 Illinois Compiled Statutes Chapter 570 Section 316].

Iowa: The Iowa Prescription Monitoring Program does not require an NPI number to be reported [657 Iowa Administrative Code Chapter 37 Section 12].

Michigan: The Michigan Automated Prescription System, the states electronic system for monitoring schedule II to V controlled substances, does not require an NPI number to be reported [Michigan Administrative Rules R 338.3162b].

Minnesota: The Minnesota Prescription Monitoring Program requires the NPI number of the prescriber and the NPI number of the dispenser to be reported for all controlled substances dispensed in the state [Minnesota Statutes Chapter 152 Section 152.126 Subdivision 4].

Summary of factual data and analytical methodologies:
The Board reviewed Wisconsin Administrative Code Chapter CSB 4 in consultation with Wisconsin Prescription Drug Monitoring Program staff to determine where the NPI number requirement can be added and if updates to other sections in the chapter were needed.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis: The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission: Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 4.02 (12s), 4.04 (2) (bm) and (im), and 4.04 (5) are created to read:

CSB 4.02 (12s) "NPI number" means national provider identifier number, the unique number used in the U.S. to identify each health care provider.

CSB 4.04 (2) (bm) The dispenser's NPI number.

CSB 4.04 (2) (im) The prescriber's NPI number.

CSB 4.04 (5) Beginning December 1, 2024 and except for those individuals who are exempt under s. CSB 4.08 (4), all healthcare professionals shall comply with the application of an NPI number to each prescription record required to be reported to the PDMP.

Commented [NH1]: This date is a suggestion for mandatory compliance with the NPI requirement.

SECTION 2. CSB 4.05 (1) (b) (Note), 4.06 (3) (b) (Note), 4.07 (2) (Note), 4.08 (1) (b) (Note), and 4.08 (4) are amended to read:

CSB 4.05 (1) (b) (Note) The guide for dispensers which specifies the data standards in version 4 release 2 of the ASAP implementation guide for prescription monitoring programs and other electronic formats identified by the board may be obtained online at https://pdmp.wi.gov or obtained at no charge from the Department of Safety and Professional Services, ~~1400 East Washington Avenue~~4822 Madison Yards Way, P.O. Box 8366, Madison, WI ~~53708~~53705.

CSB 4.06 (3) (b) (Note) The application for an emergency waiver may be obtained online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, ~~1400 East Washington Avenue~~4822 Madison Yards Way, P.O. Box 8366, Madison, WI ~~53708~~53705.

CSB 4.07 (2) (Note) The written notice to the board may be submitted through an account with the board, sent by electronic mail or sent by U.S. mail to the Department of Safety

and Professional Services ~~1400 East Washington Avenue~~,4822 Madison Yards Way, P.O. Box 8366, Madison, WI ~~53708~~53705.

CSB 4.08 (1) (b) (Note) The application for an exemption may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services ~~1400 East Washington Avenue~~,4822 Madison Yards Way, P.O. Box 8366, Madison, WI ~~53708~~53705. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

CSB 4.08 (4) A dispenser who is not otherwise required to have a DEA registration number or NPI number is not required to compile or submit dispensing data when dispensing Gabapentin.

SECTION 3. CSB 4.097 (1) (i) is created to read:

CSB 4.097 (1) (i) Beginning December 1, 2024, the healthcare professional fails to enter an NPI number into the PDMP system where required.

SECTION 4. 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)

Controlled Substances Board
Rule Projects (updated 10/30/23)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
23-018	091-22	05/21/2025	CSB 2.92	Scheduling 35 Anabolic Steroids	Legislative Review	Board Review of Adoption Order
23-019	092-22	05/21/2025	CSB 2.93	Scheduling Daridorexant	Legislative Review	Board Review of Adoption Order
23-020	093-22	05/21/2025	CSB 2.94	Scheduling 7 Synthetic Benzimidazole-Opioids	Legislative Review	Board Review of Adoption Order
23-021	094-22	05/21/2025	CSB 2.95	Scheduling Ganaxolone	Legislative Review	Board Review of Adoption Order
Not Assigned Yet	051-23	02/07/2026	CSB 2.96	Scheduling Amineptine	Board Review of Preliminary Rule Draft	EIA Comment Period and Clearinghouse Review
Not Assigned Yet	052-23	02/07/2026	CSB 2.97	Scheduling Zipeprol	Board Review of Preliminary Rule Draft	EIA Comment Period and Clearinghouse Review
Not Assigned Yet	053-23	02/07/2026	CSB 2.98	Excluding [^{18} F] FP-CIT	Board Review of Preliminary Rule Draft	EIA Comment Period and Clearinghouse Review
Not Assigned Yet	054-23	02/07/2026	CSB 2.99	Scheduling Mesocarb	Board Review of Preliminary Rule Draft	EIA Comment Period and Clearinghouse Review
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.001	Scheduling Methiopropamine	Scope Statement Submitted for Publication in Administrative Register	Scope Statement Approved for Implementation
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.002	Excluding Fenfluramine	Scope Statement Submitted for Publication in Administrative Register	Scope Statement Approved for Implementation
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.003	Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances	Board Review of Scope Statement	Scope Statement Submitted for Governor Approval and for Publication

Controlled Substances Board
Rule Projects (updated 10/30/23)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	095-22	05/21/2025	CSB 4	National Provider Identifier Requirement	Board Review of Preliminary Rule Draft	EIA Comment Period and Clearinghouse Review
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 4	Monitored Prescription Drug History Reports	Drafting	Board Review of Preliminary Rule Draft

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:
Marjorie Liu **Program Lead, PDMP**	10/30/2023 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?
11/10/2023	☒ Yes ☐ No	Prescription Drug Monitoring Program (PDMP) Updates – Discussion and Consideration

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete **Appearance Request** for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	

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

1. WI ePDMP Operations
    a. Recent and Upcoming Releases
    b. EHR Integration Status
2. WI PDMP Outreach

11) Authorization

Marjorie Liu — Oct 30, 2023

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**

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2021-2023 Development and Release Summary

Updated 10.30.2023

Release Date	Description
Pending	
Completed	
R32.1-32.4 **October 2023**	EHR Support Iframe support Epic
R 32 **Harold Rogers Grant 2020** **10/15/2023**	Automation of top prescribing reports Site reskin/redesign Ability for users to change the order in which the sections of the patient report are presented. Adding a Buprenorphine Naïve Alert section to the patient report. Infrastructure and Technology stack changes to improve performance in the following areas: • Patient Matching • Dispensing Matching Reporting Statistics
R31 **March 2023**	Iframe support Epic
R30 **February 2023**	Iframe support Prescriber Practice Metric UI Text updates Maintenance Updates
R29 **October 2022**	Updated mapping tool Adjusted language for expired temporary licenses Modified file processing
R28 **July 2022**	Adding language related to Buprenorphine Alert Override • Minor text changes to submission error emails • Minor language changes around alert messaging Maintenance Updates
Harold Rogers Grant 2021 **Promotional Materials** **May 2022**	Promotional Materials for free EHR Integrations Maintenance Updates
R26 **April 2022**	Buprenorphine Alert Override • Ability to override prescriber facing alerts, metrics, and MME calculations for certain drugs. Maintenance Updates

	RxCheck 3.0 Upgrades
Harold Rogers Grant 2020 Component 1 December 2021	Security Enhancements • Two-Factor Authentication • Compromised Email Address Check Patient Report and other User Experience Updates
R25 November 2021	Maintenance Updates • Adjustments to triggering Annual Terms and Conditions prompt • Enhanced EHR Integration Testing capabilities Chatbot display changes
R24 August 2021	Text Updates • Gabapentin related text changes to the Submitter Error Email. Security-Related Enhancements
R23 July 2021	Text Updates • Gabapentin related text changes to the Submitter Error Email.
R22 July 2021	Pharmacy-Related Enhancements • Missing DEA Number Error Process Updates Administrative-Related Enhancements
R21 May 2021	New Design Enhancements • Proactive MC/HCP linkage renewals • Search enhancements Administrative-Related Enhancements Additional administrator tools
R20 March 2021	WI DOJ-Medical College of Wisconsin DataShare Project • Automatically send data extracts to DOJ-MCW • Automatically receive data extracts from DOJ-MCW Administrative-Related Enhancements • Additional improvements to query process • Additional administrator tools

WI ePDMP Integration Services Summary

Current as of 10.30.2023

Pending Health Systems and EHR Platforms	Status			Notes
QuadMed, LLC	Implementation in progress			
CompuGroup Medical	Implementation in progress			
Connected Health Systems (approx. 57% of monthly patient queries)	**Free Pricing Model**	**Implementation Date**	**Est. Total # of Users**	**Notes**
Advent Health	Y	03/05/2023		
Allina Health	**Y**	**09/18/2023**		
Ascension Wisconsin				
Aspirus Health Care				
Aurora Health Care				
Children's Hospital of Wisconsin	Y	09/01/2022	300	
Clark County	Y			
Clean Slate	Y	09/01/2022	26	
DrFirst				
Froedtert & the Medical College of Wisconsin				Pending signed Free agreement
GHC of South Central Wisconsin				
Gundersen Health System				Pending signed Free agreement
HealthPartners				
HSHS / Prevea Health	Y	01/01/2023		
M Health Fairview	Y	08/01/2022	30	
Marshfield Clinic	Y	09/01/2022	100	
Mayo Clinic				
Mercy Health	Y	08/01/2022	766	
Monroe Clinic				
NOVO Health Technology Group	Y	02/01/2023		
Ochin	Y	12/21/2022	100	Epic
ProHealth Care				

SSM Health				
Thedacare				Pending signed Free agreement
UnityPoint				
UW Health				
Wisconsin Statewide Health Information Network	Y	09/01/2022	3500	

DrFirst Facilities	
Alay Health Team	Watertown Rainbow Hospice
ASSOCIATED MENTAL HEALTH CONSULTANTS	Wauwatosa Children's Clinic
Behavioral Health Svcs of Racine Co.	Watertown Regional Medical Center
Door County Memorial Hospital	
Dr. Colleen Worth, DNP, APNP	
FAMILY PSYCHIATRIC CARE, LLC	
Fort Healthcare	
GI Associates LLC	
Heartland Hospice	
Lake Superior Community Health Center	
Lifestance Health WI	
Marshfield Clinic Health System	
Mile Bluff Medical Center	
Mindful Healing and Wellness LLC	
Oak Medical	
Oral Surgery Associates of Milwaukee	
Orthopedic Hospital of Wisconsin	
Pain Management and Treatment Center	
Reka Furedi MD	
Richland Hospital	
Watertown Rainbow Hospice	
Red Oak Counseling	
Regional Medical Center	
Rogers Memorial Hospital	
Sauk Prairie Memorial Hospital	

2023 WI PDMP Outreach Calendar

MONTH	EVENT	DESCRIPTION	DATES	NOTES
January	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	1/12/2023	Virtual; Quarterly Meeting
February				
March	RxCheck Governance Board Bi-Annual Meeting	Participant; bi-annual meeting for state PDMP administrators	3/9/2023	Virtual
April	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	4/13/2023	Virtual; Quarterly Meeting
May	MOU- St. Croix Chippewa Indians of WI	MOU fully executed to enable PDMP participation of the St. Croix tribal nation	5/22/2023	
June	WI NADDI Conference (National Association of Drug Diversion Investigators)	Presenter; NADDI annual training for WI healthcare professionals and law enforcement agents who focus on drug diversion prevention and detection	6/16/2023	Wauwatosa, WI
	TTAC North and East Region PDMP Meeting	Participant; regional meeting for state PDMP administrators organized by PDMP Training & Technical Assistance Center - attendance is required for BJA HR PDMP Grant recipients.	6/27-29/2023	Kansas City, MO
July	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	7/13/2023	Virtual; Quarterly Meeting
August	2023 PMP InterConnect Steering Committee Meeting	Participant; Annual national meeting for PDMP administrators organized by National Association of Boards of Pharmacy (NABP)	8/15-16/2023	Mount Prospect, IL
	2023 Comprehensive Opioid, Stimulant, and Substance Use Program (COSSUP) National Forum	Participant; Annual national meeting organized by US DOJ; attendance is required for BJA HR PDMP Grant recipients.	8/29-31/2023	Washington DC
September				
October	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	10/12/2023	Virtual; Quarterly Meeting
	NASCSA Conference (National Association of State Controlled Substances Authorities)	Participant; annual national meeting for government controlled substances authority, PDMP and healthcare professionals organized by NASCSA	10/23-10/26/2023	Minneapolis, MN
November				
December				

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:
Nilajah Hardin **Administrative Rules Coordinator**	**10/31/23** **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?
11/10/23	☒ Yes ☐ No	**Controlled Substance Scheduling Overview**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	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:

Attachments: 2023 CSB Rules – Presentation (PowerPoint File)

11) Authorization

Nilajah D. Hardin — 10/31/23

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**

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CONTROLLED SUBSTANCE SCHEDULING OVERVIEW

Nilajah Hardin

Administrative Rules Coordinator, DSPS

WHAT IS SCHEDULING?

- Process Completed by the Controlled Substances Board
- Drug with the potential for abuse designated as a controlled substance in WI
- Analogs of a substance can also be scheduled

SCHEDULING IN WI

SCHEDULING DRUGS AS CONTROLLED SUBSTANCES

1. Standard Scheduling
2. Emergency Scheduling
3. Scheduling Based on Federal Action

STANDARD SCHEDULING

- "The 8 Questions"
  - Potential for abuse
  - Scientific evidence of pharmacological effect
  - Current scientific knowledge on the substance
  - History and current pattern of abuse
  - Scope, duration and significance of abuse
  - Risk to public health
  - Potential to produce psychological or physical dependence
  - Whether the substance is an immediate precursor of an already scheduled substance

EMERGENCY SCHEDULING

- 3 Factors
  - History and current pattern of abuse for the drug
  - Scope, duration, and significance of abuse
  - Risk to public health
- Requested by a district attorney prosecuting a case
- Emergency Rules Process – drug scheduled for 1 year
- Permanent Rules Process - must be in place before emergency rule expires

SCHEDULING BASED ON FEDERAL ACTION

- Affirmative Action Process
  - DEA schedules a drug and it's published in the Federal Register
  - Board must wait 30 days from DEA publication before scheduling
  - Board approves and publishes an Affirmative Action Order
  - Affirmative Action Order schedules drug into the same schedule under WI
  - Affirmative Action Order is effective upon publication until permanent rule goes into effect
  - Board then follows Permanent Rules Process

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Cullen Eberhardy, Technical Leader – Controlled Substances Unit, Wisconsin Department of Justice, Division of Forensic Science, Wisconsin State Crime Lab - Milwaukee		**2) Date when request submitted:** 9/15/2023 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: 11/10/2023	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Drug Trends in Wisconsin	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☒ Yes ☐ No	**9) Name of Case Advisor(s), if applicable:** N/A	
10) Describe the issue and action that should be addressed: Board Member Cullen Eberhardy, the Department of Justice representative on the Board, will deliver a presentation about drug trends in Wisconsin.			
11) Authorization **Signature of person making this request** — **Date** **Supervisor (Only required for post agenda deadline items)** — **Date** **Executive Director signature (Indicates approval for post agenda deadline items)** — **Date**			
Directions for including supporting documents: 1. This form should be saved with any other documents submitted to the Agenda Items folders. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Board Member Cullen Eberhardy		**2) Date when request submitted:** 9/2023 **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: 11/10/23	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Drug Trends in Wisconsin	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☒ Yes Jennifer Naugle ☐ No	**9) Name of Case Advisor(s), if applicable:** N/A	
10) Describe the issue and action that should be addressed: Jennifer Naugle, Deputy Administrator, Wisconsin Department of Justice, Wisconsin State Crime Lab, will deliver a presentation on drug trends in Wisconsin.			
11) **Authorization**			
<NAME>			**<Date: M/D/YYYY>**
Signature of person making this request			**Date**
Supervisor (Only required for post agenda deadline items)			**Date**
Executive Director signature (Indicates approval for post agenda deadline items)			**Date**

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Wisconsin State Crime Laboratory System: *Controlled Substances Overview and Trends*

Cully Eberhardy
Controlled Substances Unit – Technical Leader
Wisconsin State Crime Laboratories

Outline

Overview of the Controlled Substances Unit

Types of Evidence

Trends

- THC, Meth, Cocaine, Heroin, Fentanyl and Fentanyl Analogs

Counterfeits

Xylazine

Questions

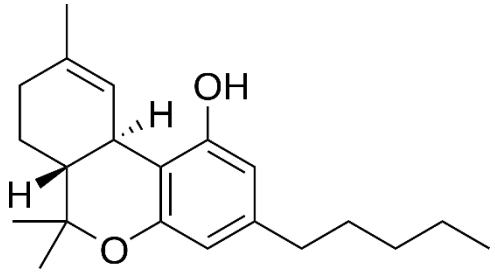
Overview of Controlled Substances Unit

Job Duties:

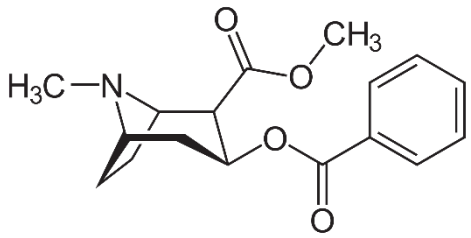
<u>Primary</u>:
Analyze evidence
Write reports
Court testimony
Technical review

<u>Other</u>:
Prepare reagents
Instrument maintenance
Manual edits

Wisconsin Statute 961 – Uniform Controlled Substances Act



Δ^9-Tetrahydrocannabinol



Cocaine

Workflow

Detailed notes → Weight → Analysis → Report writing → Testimony

Screening Tests (Category C)

Color tests, Microscopic exam, and Pharmaceutical Identifiers

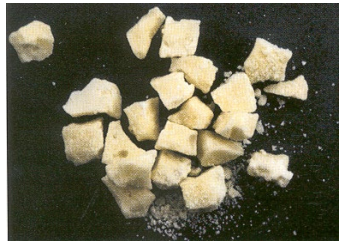
Indicative Tests (Category B)

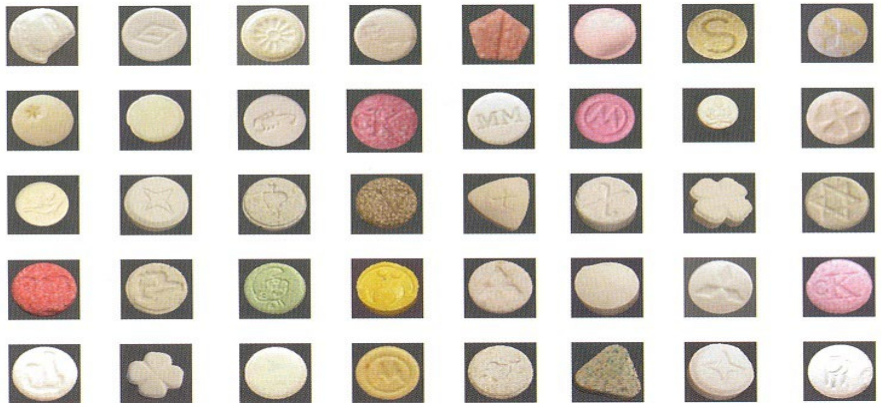
GC and Thin Layer Chromatography

Confirmatory Tests (Category A)

FTIR, GC/IR, and GC/MS

Types of Evidence





Plant materials

Powders/Chunky Substances

Tablets/Capsules

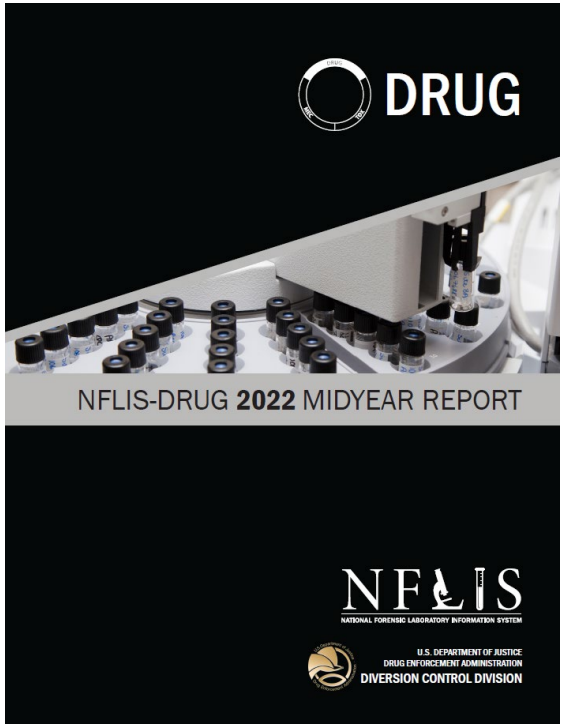
Residues/Paraphernalia

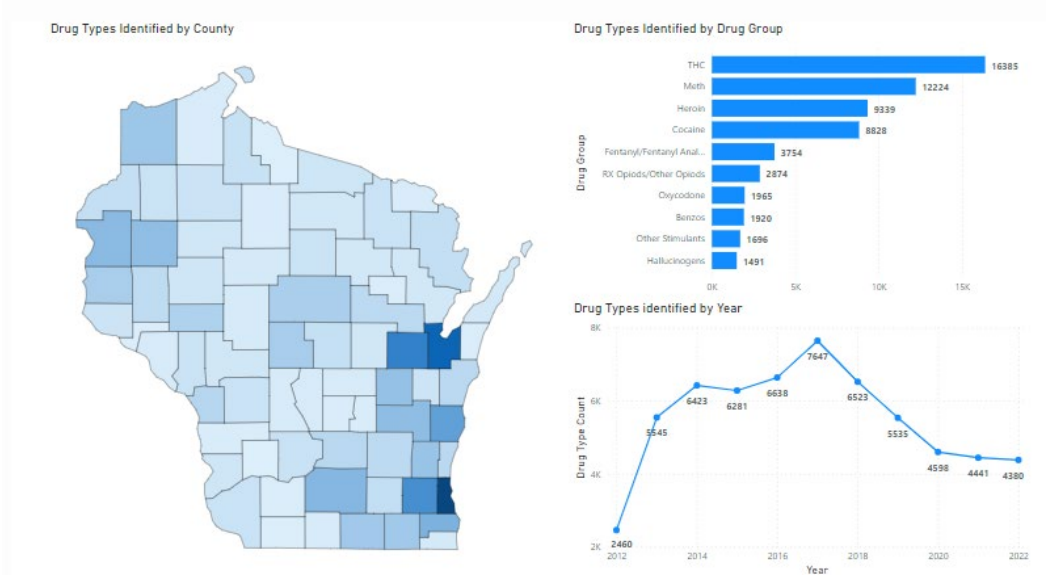
Food items

Clandestine Laboratories

Tracking Drug Data

National Forensic Laboratory Information System (NFLIS)
http://www.nflis.deadiversion.usdoj.gov

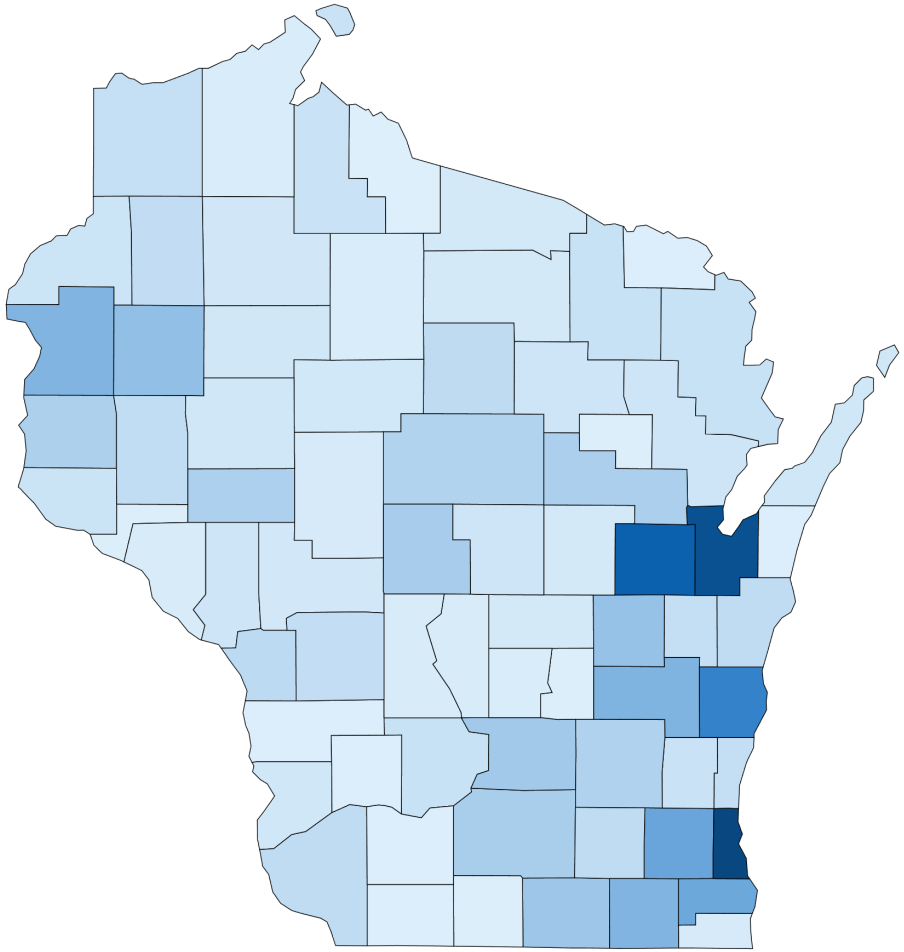




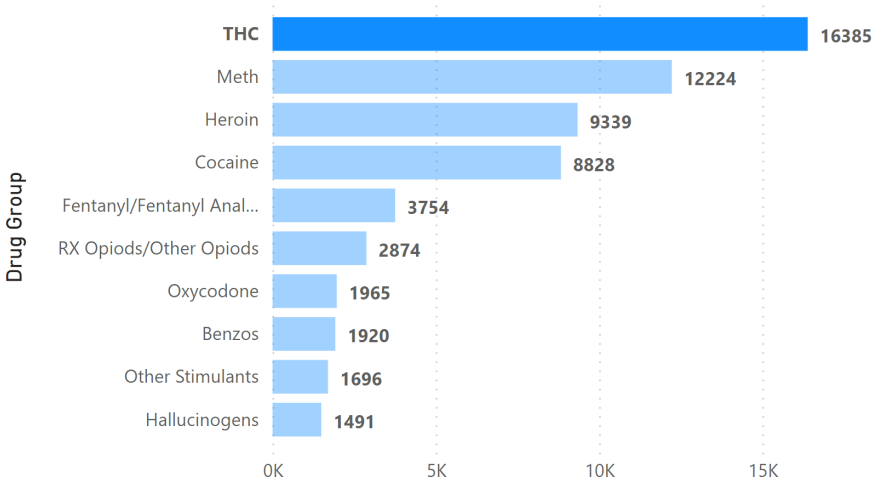
https://www.doj.state.wi.us/dfs/chemistry/wscl-drug-cases

Wisconsin Trends – Tetrahydrocannabinol (THC)

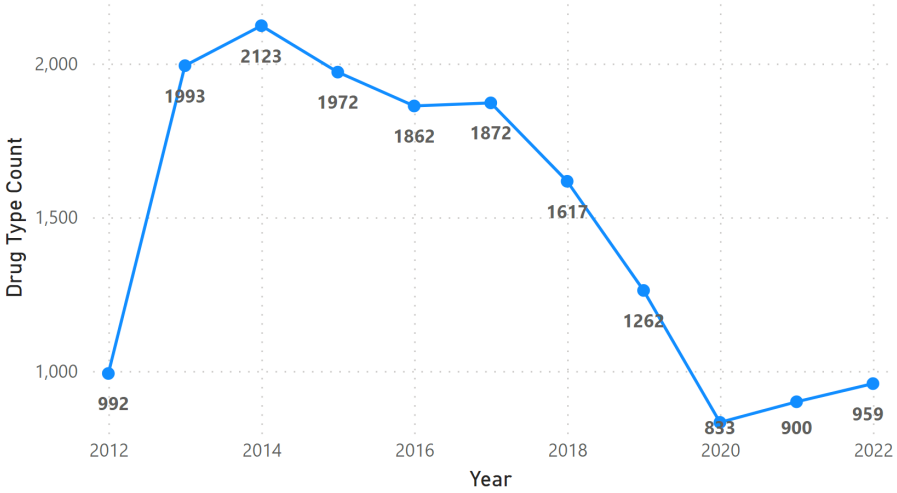
Drug Types Identified by County



Drug Types Identified by Drug Group



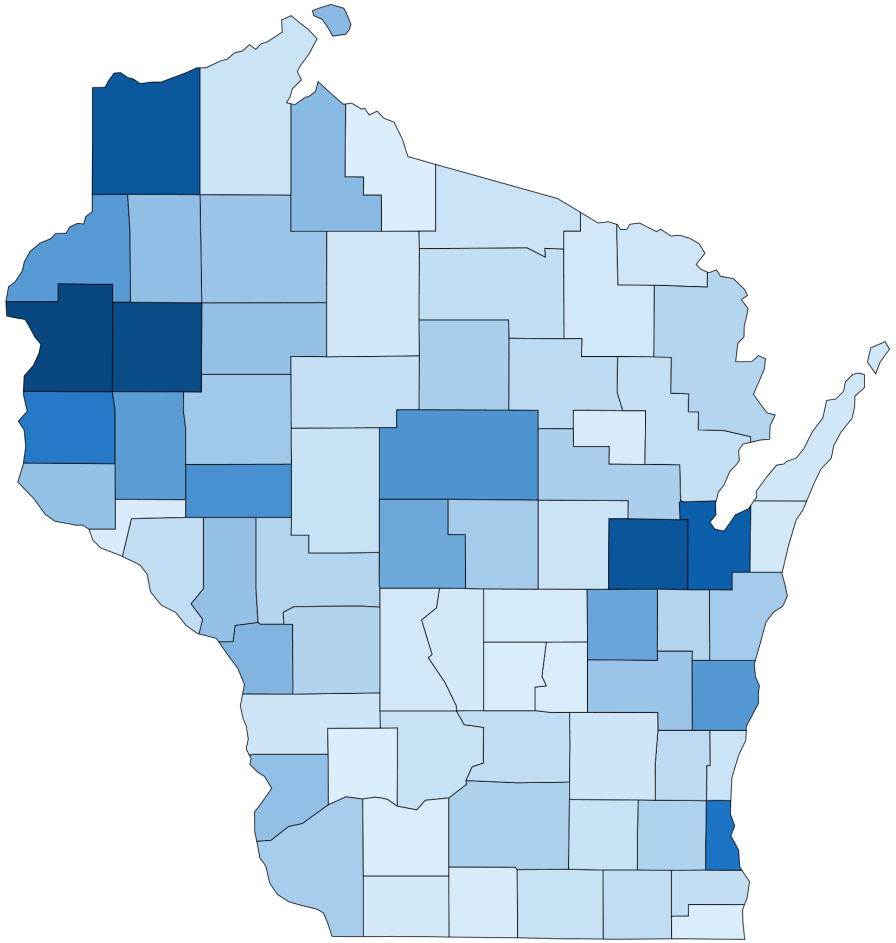
Drug Types identified by Year



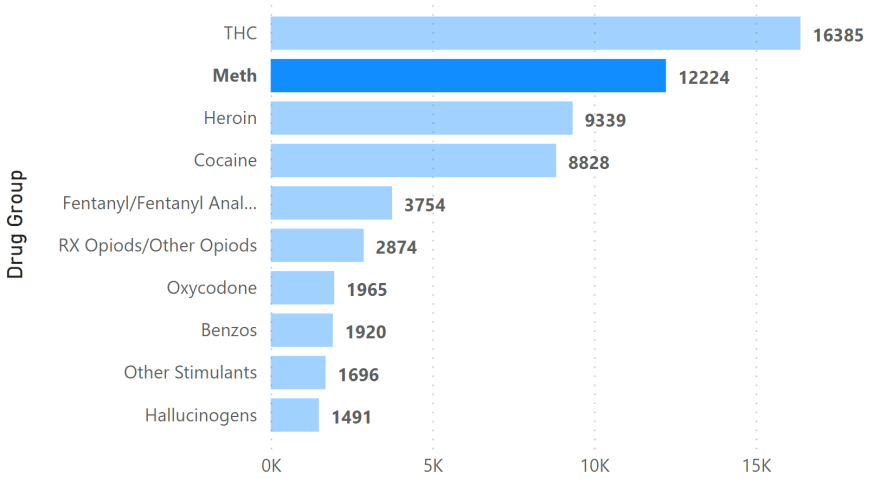
www.doj.state.wi.us/dfs/division-forensic-sciences

Wisconsin Trends – Methamphetamine

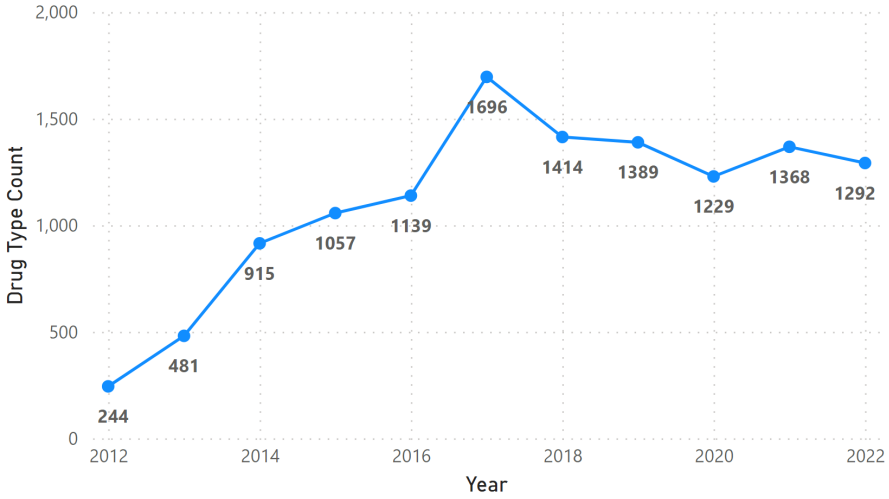
Drug Types Identified by County



Drug Types Identified by Drug Group



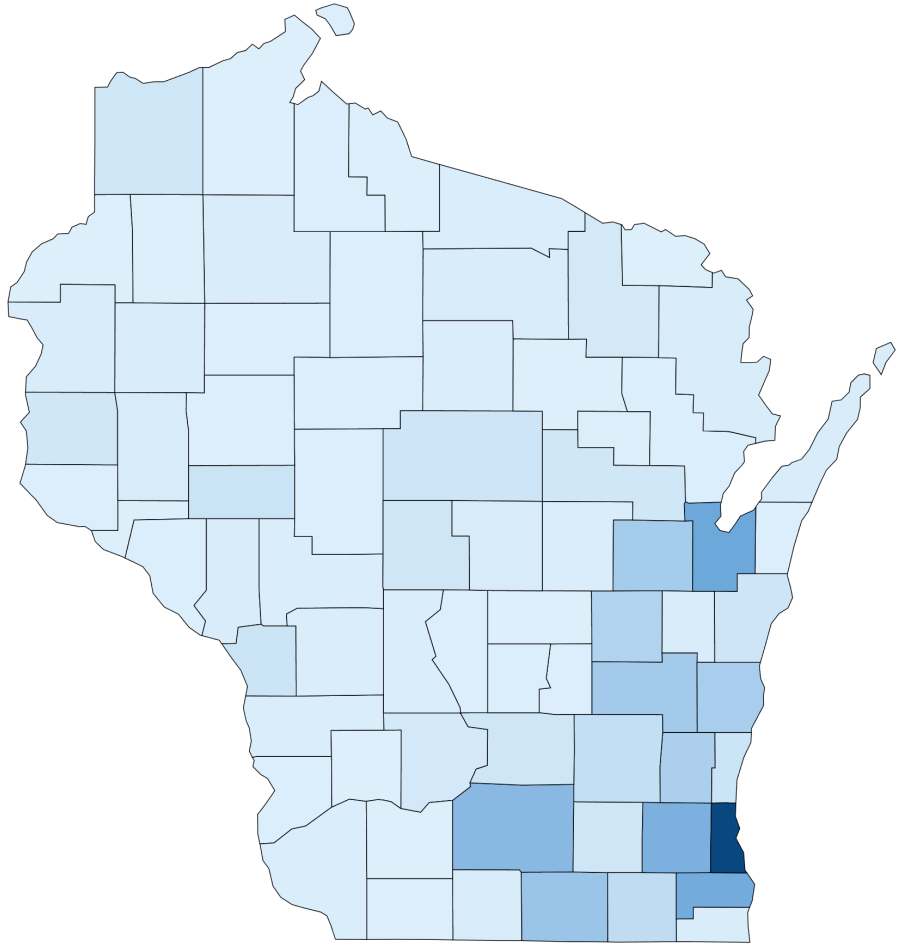
Drug Types identified by Year



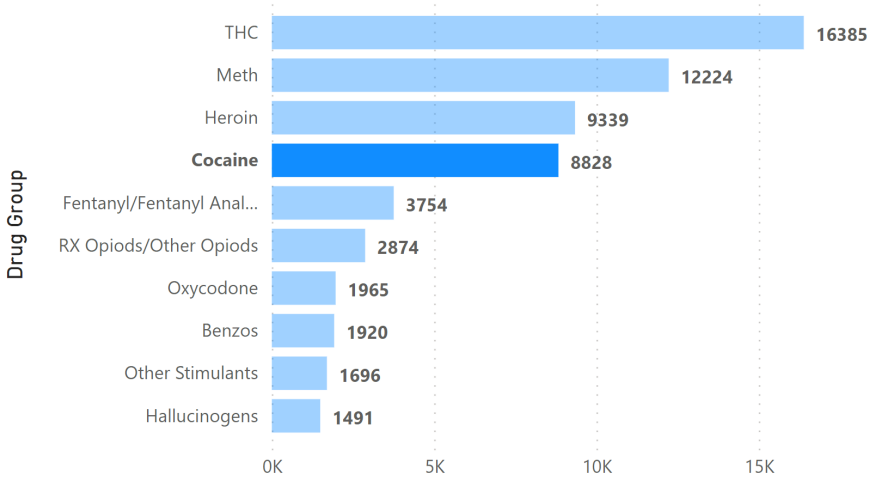
www.doj.state.wi.us/dfs/division-forensic-sciences

Wisconsin Trends – Cocaine

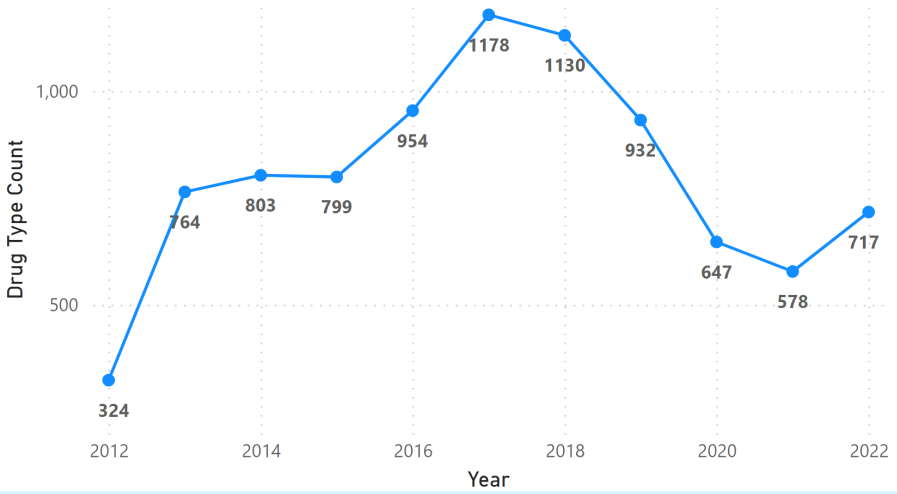
Drug Types Identified by County



Drug Types Identified by Drug Group



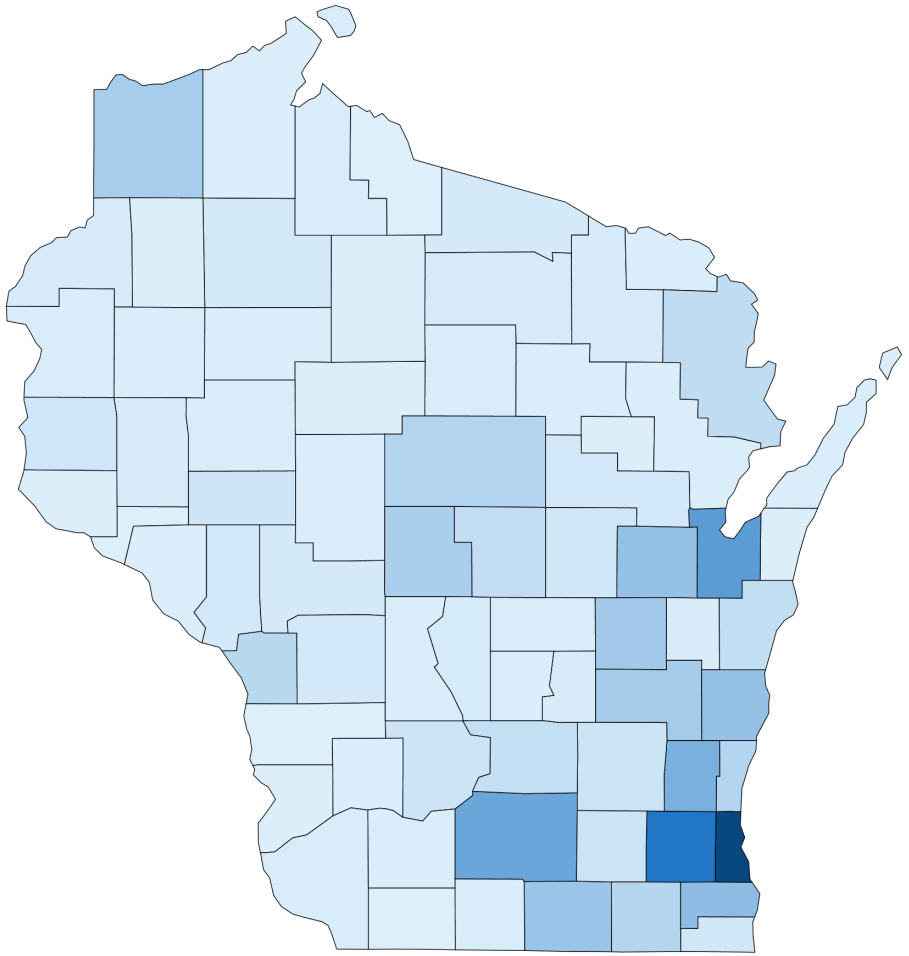
Drug Types identified by Year



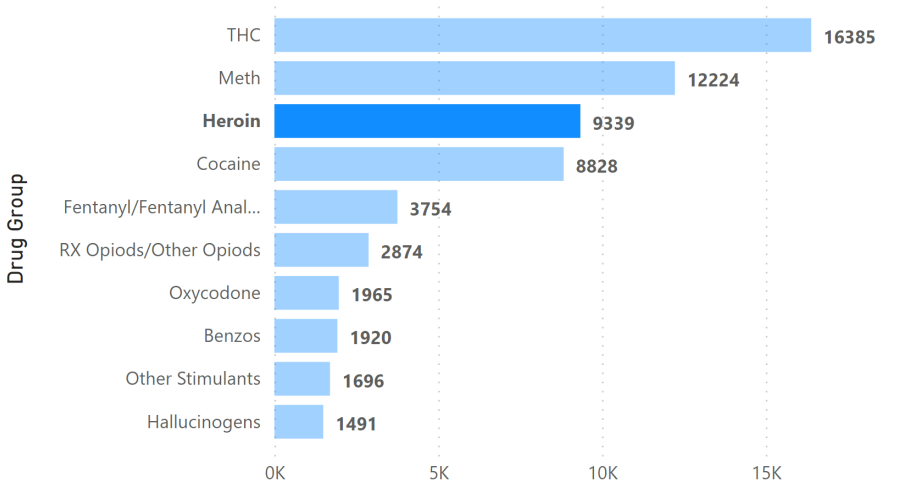
www.doj.state.wi.us/dfs/division-forensic-sciences

Wisconsin Trends – Heroin

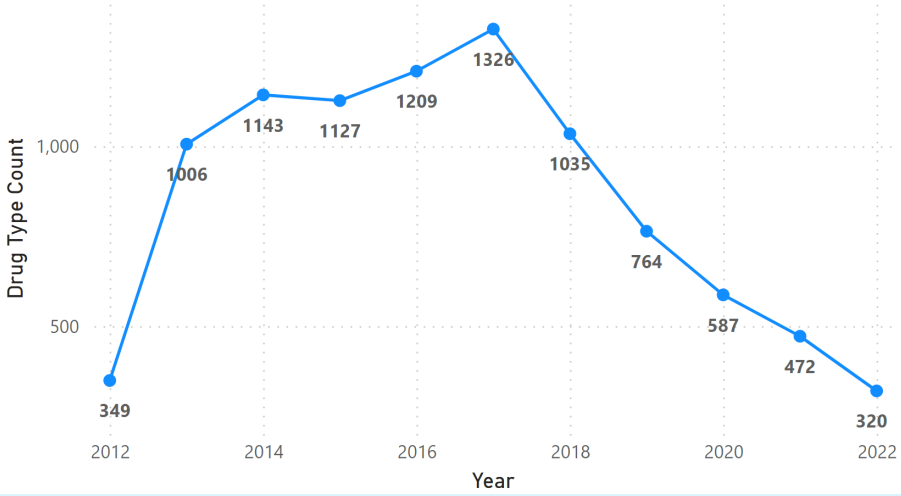
Drug Types Identified by County



Drug Types Identified by Drug Group



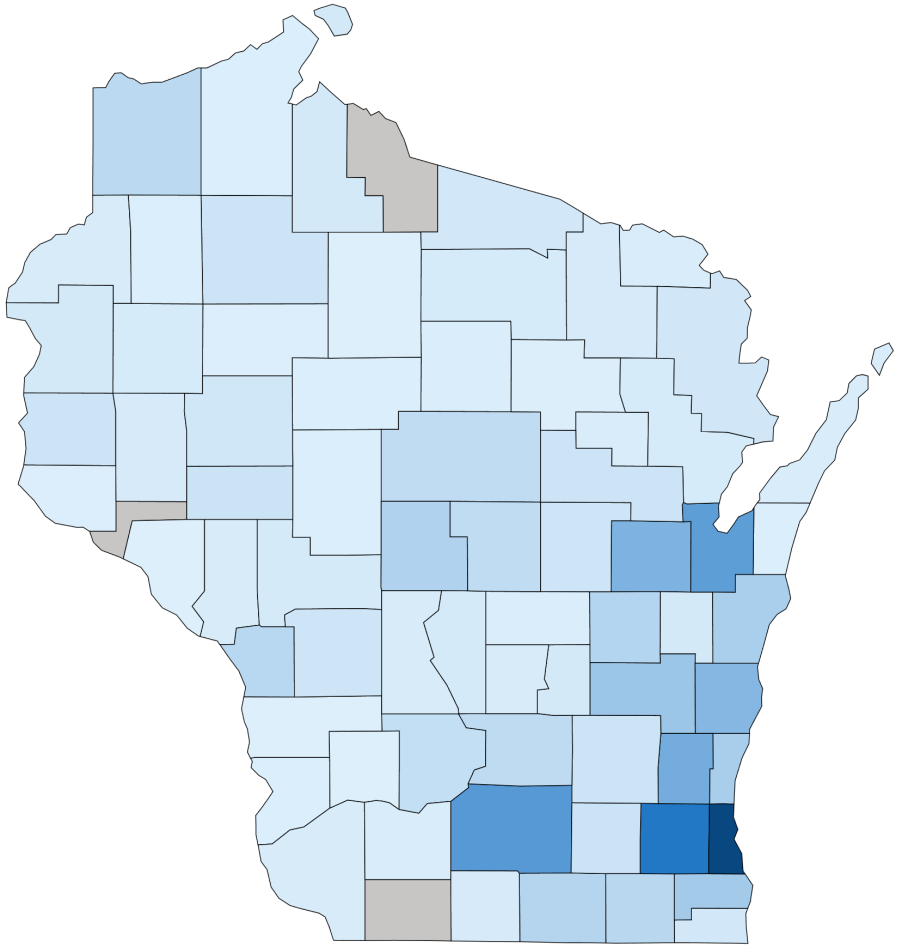
Drug Types identified by Year



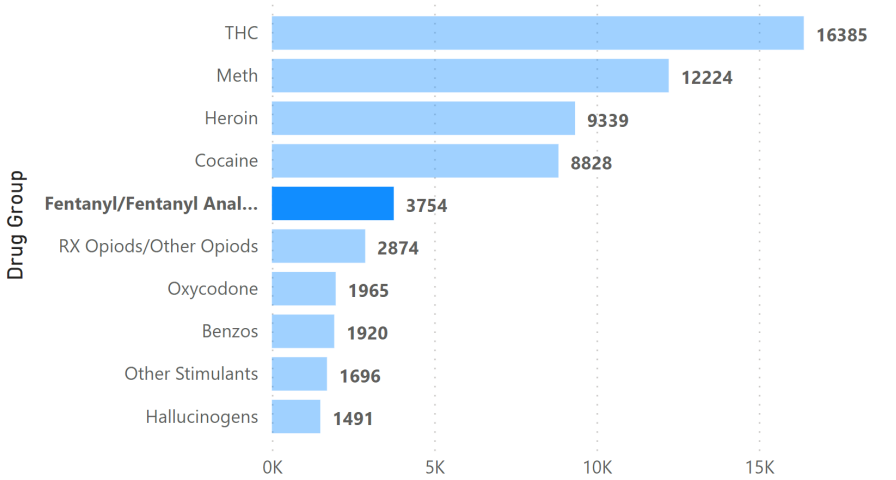
www.doj.state.wi.us/dfs/division-forensic-sciences

Wisconsin Trends – Fentanyl/Fentanyl Analogs

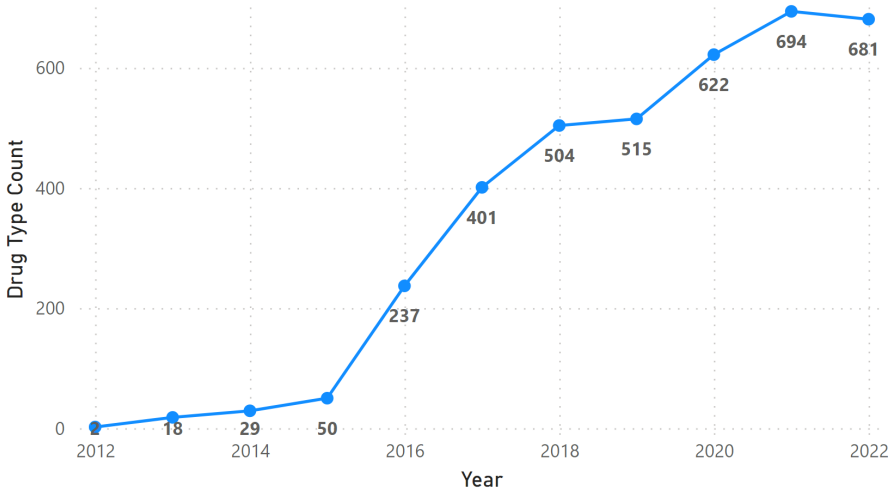
Drug Types Identified by County



Drug Types Identified by Drug Group

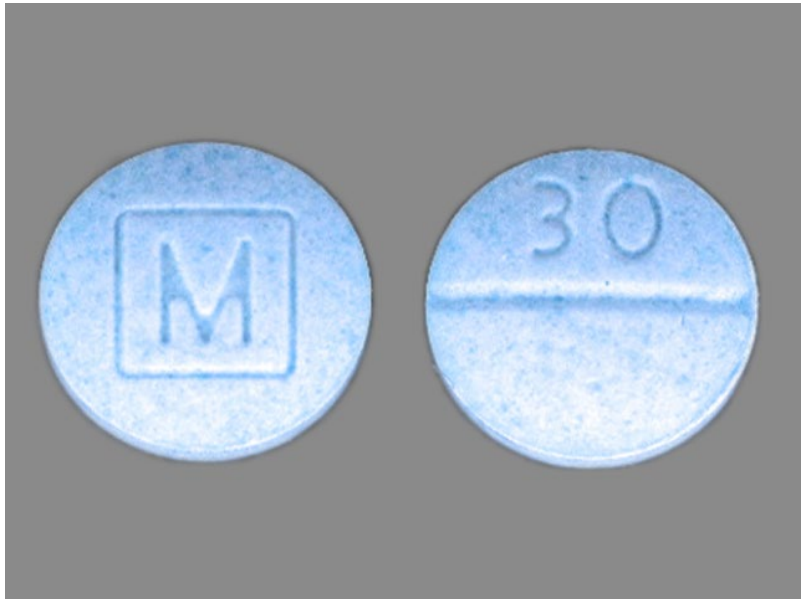


Drug Types identified by Year



www.doj.state.wi.us/dfs/division-forensic-sciences

Counterfeit Tablets



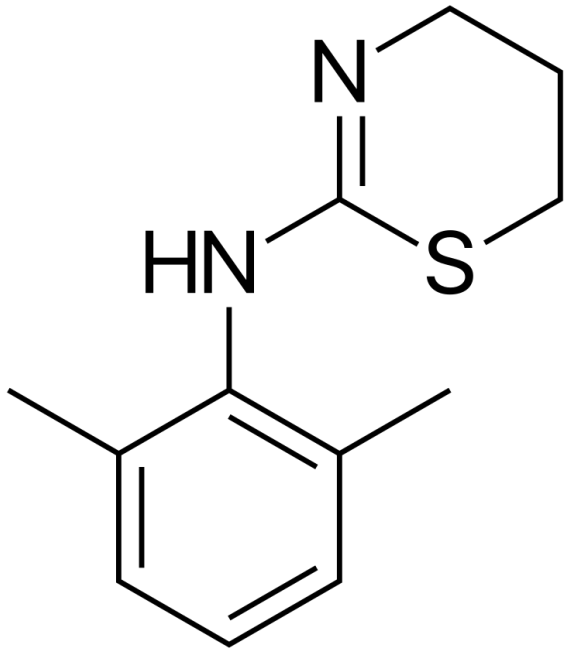
Legitimate

Uptick in fake tablets
M 30 containing fentanyl
Some obvious fakes, others more subtle
Fake alprazolam tablets

Counterfeit

Xylazine Overview

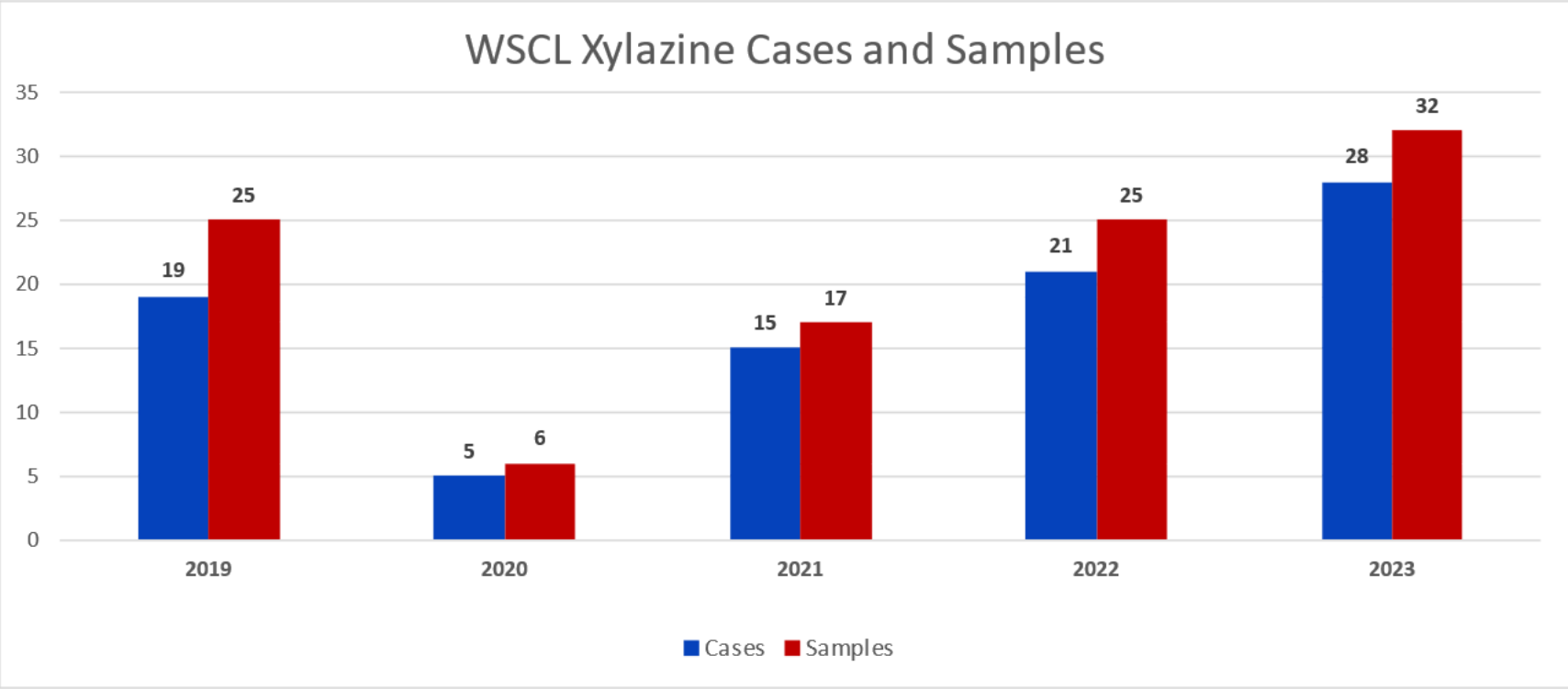
Veterinary applications
Mixture with opiates and concerns



Xylazine

Xylazine Trends

The chart below depicts Wisconsin State Crime Lab cases and samples which tested positive for xylazine. The distinction between a case and a sample is that one case can have multiple samples. Additionally, these counts may include residue samples.



*Note – 2023 does not represent a full calendar yet. Counts are based on WSCL complete date.


WISCONSIN STATE CRIME LABORATORY BUREAU
WAUSAU
MILWAUKEE
MADISON

Thank You!