



**VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD**

**Contact: Chad Zadrazil (608) 266-2112
Room 121A, 1400 East Washington Avenue, Madison
February 5, 2016**

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

AGENDA

9:30 A.M.

OPEN SESSION - CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1-2)**
- B. Approval of Minutes of December 1, 2015 (3-4)**
- C. Administrative Matters**
 - 1) Staff Updates
 - 2) Board Members
 - a. Yvonne Bellay – Dept. of Agriculture, Trade, and Consumer Protection Designee
 - b. Alan Bloom – Pharmacologist
 - c. Doug Englebert – Dept. of Health Services Designee
 - d. Franklin LaDien – Pharmacy Examining Board Designee
 - e. Gunnar Larson – Psychiatrist
 - f. Jeffrey Miller – Board of Nursing Designee
 - g. Tina Virgil – Attorney General Designee
 - h. Wendy Pietz – Dentistry Examining Board Designee
 - i. Timothy Westlake – Medical Examining Board Designee
- D. 9:30 A.M. PUBLIC HEARING: Clearinghouse Rule 15-101 Relating to Operation of Prescription Drug Monitoring Program (PDMP) (5-20)**
 - 1) Review and Respond to Clearinghouse Report and Public Hearing Comments
- E. Discussion and Consideration of Items Received After Preparation of the Agenda:**
 - 1) Introductions, Announcements, and Recognition
 - 2) Presentations of Petition(s) for Summary Suspension
 - 3) Presentation of Proposed Stipulation(s), Final Decision(s) and Order(s)
 - 4) Presentation of Final Decision and Order(s)
 - 5) Informational Item(s)

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

F. Public Comments

ADJOURNMENT

The next scheduled meeting is March 15, 2016.

**CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
December 1, 2015**

PRESENT: Alan Bloom, Yvonne Bellay, Doug Englebert, Franklin LaDien, Gunnar Larson, Timothy Westlake

EXCUSED: Jeffrey Miller, Patrick Mitchell, Wendy Pietz

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

CALL TO ORDER

Doug Englebert called the meeting to order at 9:32 a.m. A quorum of six (6) members was confirmed.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES OF OCTOBER 6, 2015

MOTION: Franklin LaDien moved, seconded by Timothy Westlake, to adopt the minutes of October 6, 2015 as published. Motion carried unanimously.

2016 MEETING DATES

MOTION: Alan Bloom moved, seconded by Timothy Westlake, to approve the meeting dates for 2016 with the change of moving the January 19, 2016 meeting to February 5, 2016. Motion carried unanimously.

**PUBLIC HEARING: CLEARINGHOUSE RULE 15-083 RELATING TO MEASUREMENT
OF CONTROLLED SUBSTANCES FOR PURPOSES OF SPECIAL USE
AUTHORIZATIONS**

Review and Respond to Clearinghouse Report and Public Hearing Comments

MOTION: Timothy Westlake moved, seconded by Alan Bloom, to accept all Clearinghouse comments for CR 15-083 relating to Measurement of Controlled Substances for Purposes of Special Use Authorizations. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule 15-083 relating to Measurement of Controlled Substances for Purposes of Special Use Authorizations for submission to the Governor's Office and Legislature. Motion carried unanimously.

LEGISLATION AND RULE MATTERS

CSB 4 Relating to Date for Submission of PDMP Data (Act 199)

MOTION: Timothy Westlake moved, seconded by Gunnar Larson, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule 15-070 relating to Date for Submission of PDMP Data (Act 199) for submission to the Governor's Office and Legislature. Motion carried unanimously.

CSB 4 Relating to Prescription Drug Monitoring Program Operations

MOTION: Timothy Westlake moved, seconded by Franklin LaDien, to designate the Chair to approve the preliminary rule draft of CSB 4 relating to Prescription Drug Monitoring Program Operations for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

KRATOM (MITRAGYNINE) SCHEDULING

MOTION: Franklin LaDien moved, seconded by Alan Bloom, to request DSPS staff investigate the current history of the scheduling of mitragynine and 7-hydroxymitragynine. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 12:42 p.m.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 26 January 2016 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date:	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Public Hearing on Clearinghouse Rule 15-101 relating to operation of prescription drug monitoring program Review and respond to Clearinghouse Report and Public Hearing comments	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Hold Public Hearing at 9:30 Discuss any public hearing comments. Review, discuss and respond to any Clearinghouse comments.			
11) Authorization			
<i>Sharon Henes</i>		<i>26 January 2016</i>	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to repeal 4.03 (3); to amend CSB 4.02 (4), 4.08 (1), 4.10 (1) (c), 4.10 (2) (a), 4.11 (1), 4.11 (1) (b), 4.11 (2), 4.11 (2) (c), 4.11 (7), 4.11 (7) (c), 4.11 (8) and 4.11 (8) (c); to create 4.15 relating to the operation of the prescription drug monitoring program.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.385, Stats.

Statutory authority: ss. 961.385 (2)

Explanation of agency authority:

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

Related statute or rule:

Plain language analysis:

Section 1 indicates Board means the Controlled Substances Board. 2015 Act 55 changed the jurisdiction of the prescription drug monitoring program from the Pharmacy Examining Board to the Controlled Substances Board.

Section 2 repeals Tramadol from the list of monitored prescription drugs, because Tramadol is now identified as a controlled substance by both federal and Wisconsin law.

Section 3 changes the “his or her” to its to be consistent with the language throughout this chapter.

Sections 4 and 5 update dispenser and dispenser delegate to pharmacist and pharmacist delegate. This change was done for clarity in CR 14-003, and there were two instances of these words that were inadvertently missed.

Sections 6, 7, 8, 9, 10, 11, 12 and 13 replace the references to PDMP information with references to dispensing data. This change is to create clarity between the situations in which the Board may disclose dispensing data and when the Board may disclose other PDMP information. There are situations in which it may be inappropriate and contradictory to the purpose of the program to disclose PDMP information when dispensing data would be more appropriate. The change clearly delineates when the Board may release dispensing data and PDMP information.

Section 14 creates a section on disclosure of PDMP information when the Board identifies suspicious or critically dangerous conduct or practices in PDMP data. 2015 Act 55 directs the board to include provisions in the rules governing the Board's disclosure of PDMP information that allow the Board to disclose information to relevant state boards and agencies, agencies of other states and law enforcement agencies under circumstances that indicate suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner or patient. This rule defines the factors that the Board will use to determine whether the conduct or practices of a pharmacy, pharmacist, practitioner or patient are suspicious or critically dangerous.

When looking at the pharmacist's or pharmacy's practice, the factors will include: practice which deviates from accepted practice, unusual patterns in payment, history of actions taken against the pharmacist or pharmacy, type and number of monitored prescription drugs dispensed, forged prescription orders for a monitored prescription that have been dispensed, the distance patients travel to have monitored prescription drugs dispensed and the number of patients dispensed monitored prescription drugs who meet the criteria of patients engaging in suspicious or critically dangerous conduct.

When looking at the practitioner's practice, the factors will include: prescribing practices which deviate from accepted prescribing practices, prescribing potentially dangerous combinations of monitored prescription drugs to the same patient, the type and number of monitored prescription drugs prescribed by the practitioner, history of actions taken against the practitioner, the distance patients travel to obtain monitored prescription drug prescriptions and the number of patients to whom the practitioner prescribes monitored prescriptions who meet the criteria of patients engaging in suspicious or critically dangerous conduct.

When looking at a patient, the factors will include: the number of practitioners from whom the patient has obtained a prescription for a monitored prescription drug, number of pharmacies from where the patient was dispensed a monitored prescription drug, the number of prescriptions for monitored drug obtained by the patient, the number of monitored prescription drug doses dispensed to the patient, the monitored prescription drugs dispensed to a patient which include dangerous levels of any drug, the number of times the patient is prescribed or dispensed a monitored drug before the previously dispensed amount of the same or a similar monitored prescription drug would be expected to end and the payment methodology used by the patient to obtain controlled substances.

Upon determining that there are circumstances indicating suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner or patient, the Board may disclose PDMP information to a relevant patient, pharmacist, practitioner, state board or agency, agency of another state or law enforcement agency.

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

Comparison with rules in adjacent states:

Illinois: Illinois' prescription monitoring program does not address proactive disclosure of suspicious or critically dangerous conduct or practices.

Iowa: Iowa does not have rules which allow for disclosure to regulatory agencies or law enforcement without an order, subpoena or other means of legal compulsion relating to a specific investigation of a specific individual and supported by a determination of probable cause.

Michigan: Michigan's prescription monitoring program does not address proactive disclosure of suspicious or critically dangerous conduct or practices to entities.

Minnesota: The Minnesota Board of Pharmacy is required by statute to review the data submitted to the prescription monitoring program on at least a quarterly basis to determine if a patient meets criteria defined by the Board in consultation with an advisory task force. If the Board determines that a patient meets the criteria, the Board may disclose information about the patient to prescribers and pharmacists who have treated the patient. The prescription monitoring program may be used by permissible users for the identification of individuals receiving prescriptions for controlled substances from prescribers who subsequently obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards of use for those controlled substances and individuals presenting forged or otherwise false or altered prescriptions for controlled substances to dispensers. Minnesota does not allow accessing the database for the sole purpose of identifying prescribers of controlled substances for unusual or excessive prescribing patterns without a valid search warrant or court order. No licensing board or agency may access the database for the purpose of obtaining information to be used to initiate or substantiate a disciplinary action against a prescriber.

Summary of factual data and analytical methodologies:

In order to define what factors to evaluate to determine what constitutes suspicious or critically dangerous conduct or practices the Board consulted the following sources:

Prescription Drug Monitoring Program Center of Excellence at Brandeis University, *Using PDMP Data to Guide Interventions with Possible At-Risk Prescribers*, Oct. 2014.

Prescription Drug Monitoring Program Center of Excellence at Brandeis University, *Guidance on PDMP Best Practices: Options for Unsolicited Reporting*, Jan. 2014.

Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach*, Nov. 2015.

Haegerich, et al., *What We Know, and Don't Know, About the Impact of State Policy and Systems-Level Interventions on Prescriptions Drug Overdose, Drug and Alcohol Dependence: An International Journal on Biomedical and Psychosocial Approaches*, Oct. 2014.
WCMR 14-118-011 Rules Governing The Controlled Substances Prescription Monitoring Program.

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

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to Sharon.Henes@wisconsin.gov. Comments must be received at or before the public hearing at 9:30 a.m. on February 5, 2016 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 4.02 (4) is amended to read:

CSB 4.02 (4) "Board" ~~has the meaning given in s. 450.01 (2), Stats.~~ means Controlled Substances Board.

SECTION 2. CSB 4.03 (3) is repealed.

SECTION 3. CSB 4.08 (1) is amended to read:

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

SECTION 4. CSB 4.10 (1) (c) is amended to read:

CSB 4.10 (1) (c) The denial, suspension, revocation or other restriction or limitation imposed on the ~~dispenser's, dispenser pharmacist's, pharmacist~~ delegate's, practitioner's, or practitioner delegate's account pursuant to s. CSB 18.09 (3).

SECTION 5. CSB 4.10 (2) (a) is amended to read:

CSB 4.10 (2) (a) The ~~dispenser's, dispenser pharmacist's, pharmacist~~ delegate's, practitioner's, or practitioner delegate's name and address, including street address, city, state and ZIP code.

SECTION 6. CSB 4.11 (1) is amended to read:

CSB 4.11 (1) The board shall disclose ~~PDMP information~~ dispensing data about a patient to the patient if he or she does all of the following:

SECTION 7. CSB 4.11 (1) (b) is amended to read:

CSB 4.11 (1) (b) Makes a request for the ~~PDMP information~~ dispensing data on a form provided by the board.

SECTION 8. CSB 4.11 (2) is amended to read:

CSB 4.11 (2) The board shall disclose ~~PDMP information~~ dispensing data about a patient to a person authorized by the patient if the person authorized by the patient does all of the following:

SECTION 9. CSB 4.11 (2) (c) is amended to read:

CSB 4.11 (2) (c) Makes a request for the ~~PDMP information~~ dispensing data on a form provided by the board.

SECTION 10. CSB 4.11 (7) is amended to read:

CSB 4.11 (7) The board shall disclose the minimum amount of ~~PDMP information~~ dispensing data necessary to a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health

care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

SECTION 11. CSB 4.11 (7) (c) is amended to read:

CSB 4.11 (7) (c) Makes a request for the ~~PDMP information~~ dispensing data through its account with the board.

SECTION 12. CSB 4.11 (8) is amended to read:

CSB 4.11 (8) The board shall disclose the minimum amount of ~~PDMP information~~ dispensing data necessary to a coroner, deputy coroner, medical examiner, or medical examiner's assistant following the death of a patient in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

SECTION 13. CSB 4.11 (8) (c) is amended to read:

CSB 4.11 (8) (c) Makes a request for the ~~PDMP information~~ dispensing data through its account with the board.

SECTION 14. CSB 4.15 is created to read:

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

(1) The board may review PDMP information to determine whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist, pharmacy, practitioner, or patient.

(a) 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:

1. The pharmacist or pharmacy's monitored prescription drug dispensing practices deviate from accepted pharmacist or pharmacy practices.
2. There are unusual patterns in the payment methodology used by patients to whom monitored prescription drugs are dispensed by the pharmacist or pharmacy.
3. The history of actions taken against the pharmacist or pharmacy by other state agencies, agencies of another state, or law enforcement.
4. The type and number of monitored prescription drugs dispensed by the pharmacist or at the pharmacy.
5. The pharmacist or pharmacy has dispensed forged prescription orders for a monitored prescription drug.
6. The distance patients travel to have monitored prescription drugs dispensed at the pharmacy.

7. The number of patients dispensed monitored prescription drugs at the pharmacy or by the pharmacist who satisfy any of the criteria identified in par. (c).

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

1. The practitioner's monitored prescription drug prescribing practices deviate from accepted prescribing practices.
2. The practitioner prescribes potentially dangerous combinations of monitored prescription drugs to the same patient.
3. The type and number of monitored prescription drugs prescribed by the practitioner.
4. The history of actions taken against the practitioner by other state agencies, agencies of another state, or law enforcement.
5. The distance patients travel to obtain monitored prescription drug prescriptions from the practitioner.
6. The number of patients to whom the practitioner prescribed a monitored prescription who satisfy any of the criteria identified in par. (c).

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

1. The number of practitioners from whom the patient has obtained a prescription for a monitored prescription drug.
2. The number of pharmacies from where the patient was dispensed a monitored prescription drug.
3. The number of prescriptions for a monitored prescription drug obtained by the patient.
4. The number of monitored prescription drug doses dispensed to the patient.
5. Whether the monitored prescription drugs dispensed to the patient include dangerous levels of any drug.
6. 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.
7. The payment methodology used by the patient to obtain controlled substances at a pharmacy.

(d) Upon determining that circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacy, practitioner, or patient, the Board may disclose PDMP information to any of the following:

1. A relevant patient.
2. A relevant pharmacist or practitioner.
3. A relevant state board or agency.
4. A relevant agency of another state.
5. A relevant law enforcement agency.

SECTION 15. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____

Agency _____
(Member of the Board or Secretary)
(board or department name)

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Original Updated Corrected

2. Administrative Rule Chapter, Title and Number

CSB 4

3. Subject

Operation of the prescription drug monitoring program

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected

6. Fiscal Effect of Implementing the Rule

No Fiscal Effect Increase Existing Revenues Increase Costs
 Indeterminate Decrease Existing Revenues Could Absorb Within Agency's Budget
 Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

State's Economy Specific Businesses/Sectors
 Local Government Units Public Utility Rate Payers
 Small Businesses (if checked, complete Attachment A)

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes No

9. Policy Problem Addressed by the Rule

2015 Act 55 requires rules defining what constitutes suspicious or critically dangerous conduct or practices for purposes of disclosure to relevant state boards and agencies, relevant agencies of other states and relevant law enforcement agencies under circumstances indicating suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner or patient. In addition, this rule makes minor clean-up changes.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

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

11. Identify the local governmental units that participated in the development of this EIA.

None. This does not affect local governmental units.

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

This rule does not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit to implement the rule is to provide notice to pharmacists, pharmacies, practitioners and patients as to the factors the board will consider in making determinations related to suspicious or critically dangerous conduct or practices. In addition, the clean-up revisions will create continuity and clarity throughout the rule.

14. Long Range Implications of Implementing the Rule

The long range implication is clarity.

15. Compare With Approaches Being Used by Federal Government

None

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

Illinois and Michigan do not address proactive disclosure of suspicious or critically dangerous conduct or practices.

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

Iowa does not allow for disclosure to regulatory agencies or law enforcement without and order, subpoena or other means of legal compulsion relating to a specific individual and supported by a determination of probable cause. The Minnesota Board of Pharmacy is required by statute to review the data submitted on at least a quarterly basis to determine if a patient meets criteria defined by the Board in consultation with an advisory task force. If a patient meets the criteria, the Board may disclose information about the patient to prescribers and pharmacists. Minnesota does not allow accessing the database for the sole purpose of identifying prescribers of controlled substances for unusual or excessive prescribing patterns without a valid search warrant or court order. No licensing board or agency may access the database for the purpose of obtaining information to be used to initiate or substantiate a disciplinary action against a prescriber.

17. Contact Name

Sharon Henes

18. Contact Phone Number

(608) 261-2377

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
 - Less Stringent Schedules or Deadlines for Compliance or Reporting
 - Consolidation or Simplification of Reporting Requirements
 - Establishment of performance standards in lieu of Design or Operational Standards
 - Exemption of Small Businesses from some or all requirements
 - Other, describe:
-

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

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
-



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Terry C. Anderson
Legislative Council Director

Margit S. Kelley
Clearinghouse Assistant Director

Jessica Karls-Ruplinger
Legislative Council Deputy Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **15-101**

AN ORDER to repeal CSB 4.03 (3); to amend CSB 4.02 (4), 4.08 (1), 4.10 (1) (c) and (2) (a), and 4.11 (1), (1) (b), (2), (2) (c), (7), (7) (c), (8), and (8) (c); and to create CSB 4.15, relating to the operation of the prescription drug monitoring program.

Submitted by **CONTROLLED SUBSTANCES BOARD**

12-29-2015 RECEIVED BY LEGISLATIVE COUNCIL.

01-25-2016 REPORT SENT TO AGENCY.

SG:BL

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]
Comment Attached YES NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]
Comment Attached YES NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]
Comment Attached YES NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]
Comment Attached YES NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]
Comment Attached YES NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]
Comment Attached YES NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]
Comment Attached YES NO



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Terry C. Anderson
Legislative Council Director

Margit S. Kelley
Clearinghouse Assistant Director

Jessica Karls-Ruplinger
Legislative Council Deputy Director

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1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]

Comment Attached YES NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached YES NO