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(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS

2011-12
(session year)

Assembly
(Assembly, Senate or Joint)

Committee on Health...

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
  (**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
  (**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

* Contents organized for archiving by: Stefanie Rose (LRB) (October 2013)

Assembly

Record of Committee Proceedings

Committee on Health

Clearinghouse Rule 12-009

Relating to the prescription drug monitoring program and affecting small business.
Submitted by Department of Safety and Professional Services.

March 28, 2012 Referred to Committee on Health.

May 23, 2012 **PUBLIC HEARING HELD**

Present:	(8)	Representatives Stone, Severson, Kaufert, Van Roy, Strachota, Petersen, Pasch and C. Taylor.
Absent:	(0)	None.
Excused:	(3)	Representatives Litjens, Richards and Seidel.

Appearances For

- Arthur Thexton, Madison — NADDI - Wisconsin

Appearances Against

- None.

Appearances for Information Only

- None.

Registrations For

- Ron Kuehn, Madison — WI Veterinary Medical Assn
- Jordan Lamb, Madison — WI Veterinary Medical Assn
- Robert Phillips, MD, Madison — Marshfield Clinic

Registrations Against

- Don Nelson, Madison — UW Madison

Registrations for Information Only

- Greg Gasper, Madison — Dept of Safety and Professional Services
- Chad Zadrazil, Madison — Dept of Safety and Professional Services

May 23, 2012 **EXECUTIVE SESSION HELD**

Present:	(8)	Representatives Stone, Severson, Kaufert, Van Roy, Strachota, Petersen, Pasch and C. Taylor.

Absent: (0) None.
Excused: (3) Representatives Litjens, Richards and Seidel.

Moved by Representative Stone, seconded by Representative Kaufert that **Clearinghouse Rule 12-009** be recommended for modifications requested.

Ayes: (8) Representatives Stone, Severson, Kaufert, Van Roy, Strachota, Petersen, Pasch and C. Taylor.
Noes: (0) None.
Absent: (3) Representatives Litjens, Richards and Seidel.

MODIFICATIONS REQUESTED RECOMMENDED, Ayes 8, Noes 0

June 14, 2012 No action taken.

Marsha Dake

Marsha Dake
Committee Clerk

Vote Record

Committee on Health

Date: 5-23-12

Bill Number: CHR 12-009

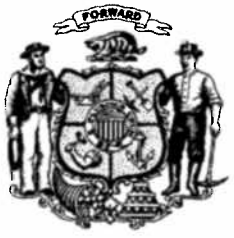
Moved by: Stone Seconded by: Kaufert

Motion: X Moved that the Assembly Health Committee requests PEB to modify CHR 12-009 as indicated in the text below; & if the Board does not provide written acceptance of prop. modif. delivered to Chrmn Stone's office by noon 5/31/12, that, pursuant to s. 227.19(4)(d)6., the Cmte objects to CHR 12-009 on the grounds the prop. rule is arbitrary & capricious and imposes undue hardship (see modif. by Legis Cncl.)

Committee Member	Aye	No	Absent	Not Voting
Representative Jeff Stone, Chair	X			
Representative Erik Severson	X			
Representative Dean Kaufert	X			
Representative Karl Van Roy	X			
Representative Patricia Strachota	X			
Representative Kevin Petersen	X			
Representative Michelle Litjens			X	
Representative Jon Richards			X	
Representative Sandy Pasch	X			
Representative Donna Seidel			X	
Representative Chris Taylor	X			
Totals:	8	0	3	

X Motion Carried ☐ Motion Failed

WISCONSIN STATE LEGISLATURE



Wisconsin Legislature

CR 12-009

AN ORDER to create ch. Phar 18, relating to the prescription drug monitoring program and affecting small business.
Submitted by Department of Safety and Professional Services

Register Entries

2/14/2012	674A: Rulemaking Notices
2/14/2012	674A: Rules Submitted to LC Clearinghouse
3/31/2012	675B: Rules Submitted to Legislature

History

1/27/2012	Received by Legislative Council.
2/21/2012	Report sent to Agency.

Assembly Actions

3/14/2012 Asm.	Report received from Agency
3/28/2012 Asm.	Referred to committee on Health
4/4/2012 Asm.	Germane amendment received
4/26/2012 Asm.	Public hearing scheduled
5/23/2012 Asm.	Public hearing held
5/23/2012 Asm.	Executive session held
5/23/2012 Asm.	Modifications requested, Ayes 8, Noes 0

Senate Actions

3/14/2012 Sen.	Report received from Agency
3/15/2012 Sen.	Referred to committee on Workforce Development, Small Business, and Tourism
4/4/2012 Sen.	Germane amendment received
4/16/2012 Sen.	No action taken
4/20/2012 Sen.	Referred to joint committee for review of Administrative Rules, pursuant to s. 227.19 (5) (a), Wisconsin Statutes

Motion: Moved, that the Assembly Health Committee requests the Pharmacy Examining Board to modify Clearinghouse Rule 12-009 as indicated in the text below; and, if the Board does not provide written acceptance of the proposed modifications, delivered to Chairperson Stone's office by noon on May 31, 2012, that, pursuant to s. 227.19(4)(d) 6., the Committee objects to Clearinghouse Rule 12-009 on the grounds the proposed rule is arbitrary and capricious, and imposes undue hardship:

Clearinghouse Rule 12-009
Proposed Modifications

(1) Create definition of "veterinary dispenser" in s. Phar 18.02(22):

- 18.02(22) "Veterinary dispenser" means a dispenser licensed in this state or licensed in another state and recognized by this state as a dispenser authorized to dispense monitored prescription drugs solely to animal patients.

2) Create s. Phar 18.04 (1) to be made up of definitions of terms that are only used in the data elements:

14 (Jauna)

- Renumber ss. Phar 18.02(6), DEA Registration Number, (4), NDC Number, and (15), NPI number, to ss. Phar 18.04 (1)(a), (c), and (d), respectively.

- Create ss. Phar 18.04(1)(b) and (e), definitions for "dispenser identifier" and "practitioner identifier":

18.04(1)(b) "Dispenser identifier" means the DEA registration number, NPI number or unique state-issued credential, permit or license number issued to a dispenser.

18.04(1)(e) "Practitioner identifier" means the DEA registration number, NPI number or unique state-issued credential, permit or license number issued to a practitioner.

3) Amend ss. Phar 18.04 (2) (b), (d), (i), (m) and (n) to read as follows:

- 18.04(2)(b) The dispenser~~'s NPI number or DEA registration number~~ identifier.
- 18.04(2)(d) The prescription number, if applicable.
- 18.04(2)(i) The practitioner~~'s NPI number or DEA registration number, if applicable~~ identifier.
- 18.04(2)(m) The patient's address, or if the patient is an animal, the owner of the patient's address, including street address, city, state and ZIP code.
- 18.04(2)(n) The patient's date of birth, or if the patient is an animal, the owner of the patient's date of birth.

4) Amend s. Phar 18.06 (1) to (3) to distinguish between "dispensers" and "veterinary dispensers":

-18.06(1) A dispenser, other than a veterinary dispenser, shall submit dispensing data to the board within 7 days of dispensing a monitored prescription drug.
- 18.06(2) If a dispenser, other than a veterinary dispenser, does not dispense a monitored prescription drug for 7 days, the dispenser shall submit a zero report to the board.
- 18.06(3) If a dispenser, other than a veterinary dispenser, is not able to submit dispensing data within 7 days of dispensing a monitored prescription drug as required by sub. (1), the board may grant an emergency waiver to a dispenser who satisfies all of the following conditions: . . .

5) Create new ss. Phar 18.06 (4), (5), and (6), unique requirements for veterinary dispensers:

- 18.06(4) A veterinary dispenser shall submit dispensing data to the board within 90 days of dispensing a monitored prescription drug.
- 18.06(5) If a veterinary dispenser does not dispense a monitored prescription drug for 90 days, the veterinary dispenser shall submit a zero report to the board.
- 18.06(6) If a veterinary dispenser is not able to submit dispensing data within 90 days of dispensing a monitored prescription drug as required by sub. (4), the board may grant an emergency waiver to a veterinary dispenser who satisfies all of the following conditions:

(a) The veterinary dispenser is not able to submit dispensing data because of circumstances beyond its control.
(b) The veterinary 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.

6) Renumber ss. Phar 18.06 (4) and (5) to ss. Phar 18.06 (7) and (8) and amend to read:

-18.06(7) Unless otherwise specified by the board, an emergency waiver granted under subs. (3) or (6) shall only be effective for 7 days.

-18.06(8) A dispenser who fails to submit dispensing data or a zero report as required by subs. (1) and (2), be granted an emergency waiver under sub. (3), or submits false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

7) Renumber s. Phar 18.07 to s. Phar 18.06(9) and amend to read:

~~**Phar 18.07 Veterinary dispensers.** (1) The board may grant a waiver from the requirements of s. Phar 18.06 to a~~ (9) A veterinary dispenser who ~~solely dispenses monitored prescription drugs to animal patients if the dispenser satisfies all of the following conditions:~~
~~(a) The dispenser submits dispensing data in accordance with the electronic reporting requirements of s. Phar 18.05, unless they have been separately waived by the board.~~
~~(b) The dispenser submits dispensing data compiled under s. Phar 18.04 to the board every 90 days.~~

~~(c) The dispenser submits a zero report to the board if he or she does not dispense a monitored prescription drug for 90 days.~~
~~(d) The dispenser files with the board a written application for a waiver on a form provided by the board.~~
~~(2) A dispenser granted a waiver under sub. (1) who~~ fails to submit dispensing data or a zero report as required by ~~sub. (1)~~ subs. (4) and (5), be granted an emergency waiver under sub. (6), or submits false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

~~**Note:** The application for a waiver 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 8935, Madison, WI 53708.~~

8) Delete the reference to 18.07 (1) in 18.11 (1) (c)

9) Renumber the sections and update the internal cross-references as indicated in the document entitled "Draft Modifications", dated May 18, 2012.


FORWARD
E PLURIBUS UNUM

DeWitt
Ross & Stevens s.c. Law Firm

Please respond to: Capitol Square Office
Email: jkl@dewittross.com
Direct: 608-252-9358

February 23, 2012

Mr. Chad Zadrazil
Department of Safety and Professional Services
Division of Board Services
P.O. Box 8935
Madison, WI 53708-8935

VIA U.S. MAIL AND EMAIL
chad.zadrazil@wisconsin.gov

RE: Wisconsin Veterinary Medical Association's Opposition to Proposed Phar 18 (Clearinghouse Rule 12-009), Relating to the Prescription Drug Monitoring Program

Dear Mr. Zadrizil:

I am writing on behalf of my client, the Wisconsin Veterinary Medical Association (WVMA), to express our opposition and concerns with the Department of Safety and Professional Services' (Department's) proposed Wis. Admin. Code § Phar 18, creating a prescription drug monitoring program (PDMP) in Wisconsin.

Our specific concerns are detailed below. But, in general, the legislation that directed the Department to create a PDMP in Wisconsin was aimed at requiring reporting from physicians to address drug abuse from ***human*** patients. The legislation did not target veterinarians reporting on ***animal*** patients. Many pharmaceuticals that are used in human medicine are ***not*** germane to veterinary medicine and vice-versa. In general, including veterinarians in the PDMP simply adds to the cost of the program and likely diminishes the value of the database.

Please be aware, veterinarians already report controlled substances to the Drug Enforcement Administration (DEA). They have exemplary compliance and they rarely require enforcement. As such, law enforcement has unrestricted access to all existing controlled substance reports currently required for veterinarians. The PDMP creates a whole new, duplicative reporting burden for veterinarians, which will likely provide no statistical benefit when it comes to tracking human drug misuse. The relatively small number of veterinarians, when compared to the number of human healthcare providers, clinics, hospitals, pharmacies, and other sources of drugs, bears out this statistical insignificance.

Finally, we note that the rule package provides the Pharmacy Examining Board with a comparison to laws in other states. However, what that comparison fails to point out is that veterinarians are exempt from a similar regulation in Minnesota and Illinois (*see* Minn. Stats. § 152.126(d) (2011) and 720 Ill. Comp. Stat. 570/302 (2011)).

Our strong preference is that veterinarians be exempt from this rule entirely for the reasons stated above. However, if that is deemed impossible, then we offer the following suggestions for amendments to this draft rule.

A. Need for Clarification of Definitions

Under the draft rule, the Department provides separate definitions of "dispenser" and "practitioner." *See* Phar 18.02(10) and (20). Under the rule, "dispenser" means a person licensed in this state to dispense drugs. Under the referenced statutory definition cited in the rule, "practitioner" means a person licensed in this state to prescribe or administer drugs. However, the rule requires separate entries for the "dispenser" and the "practitioner" to provide "NPI number or DEA registration number" under Phar 18.03(2), the compilation of dispensing data. Therefore, we ask whether the Department intends for dispenser and practitioner to mean the *person* who is licensed to prescribe, dispense or administer drugs? If so, what is the difference between a dispenser and a practitioner for purposes of § 18.03(2)? It seems that in all cases, a dispenser would have to be a practitioner and the two separate entries for the same information would be redundant. If, however, the dispenser is meant to refer to the *premises* from which the practitioners practice, then we suggest that is clarified.

Continually, it appears that throughout the rule, the terms "dispenser," "pharmacist" and "pharmacy" are used almost interchangeably. We ask for clarification as to what, if any, part of this rule applies to the premises, as opposed to the individual, from which drugs are dispensed.

B. Need for Flexibility in Electronic Reporting Platform for Veterinarians

According to our survey of the WVMA membership, only 38% of our members use any type of software or computer system in their practices. That means that 62% of our members keep their records by hand. Continually, of those who do use computer programs, less than 1% use a system that is compatible with the American Society for Automation in Pharmacy (ASAP) program. As a result, our members will either have to purchase expensive software updates or purchase completely new software programs (and new hardware) to comply with this rule as it is drafted. In addition, a majority of these veterinary practices will have to add human resources to manage and comply with PDMP reporting requirements.

Acquiring computer hardware, software, relevant technology upgrades and hiring additional manpower will drive up the cost of veterinary care in Wisconsin. Veterinary practice owners are solely responsible for all of their overhead. This rule will impact pet owners and farmers who are already struggling in our challenged state economy to pay for care for their animals.

Accordingly, we ask for additional reporting flexibility in this rule specifically for veterinarians. We suggest the following amendment to Phar 18.04(2), which would allow for alternative electronic methods to be used for veterinarians:

> "(2) Subject to s. 18.06 and sub. (5), a dispenser shall submit dispensing data to the board electronically in the format identified in the American society for automation in pharmacy (ASAP) implementation guide for prescription monitoring programs. A dispenser who is a veterinarian may use any electronic format to submit dispensing data to the board electronically."

In addition, the following fields required as a part of the "dispensing data" under 18.03(2) are not applicable or are irrelevant for veterinary medical practices: dispenser's NPI number; prescription number; NDC number; estimated number of days of drug therapy; patient's full name; patient's address; patient's date of birth; and patient's gender. Similarly, the field requiring a "DEA registration number" may be used for controlled substances, but this proposed rule does also applies to drugs that are not controlled substances. For those drugs, there is no applicable DEA registration number. Accordingly, we ask that the following amendment be adopted to § 18.03(2) and that a new section (4) be created to remove these fields for veterinarian dispensers:

> "(2) Except as provided in (4), the dispensing data shall contain the following information:"
>
> "(4) If the dispenser is a licensed veterinarian, then the dispensing data need only contain information in sub. (2) (a), (c), (e), (g), (i), (k) and (L)."

C. Request for Exemption for Post-Operative Reporting

Frequently, veterinarians will write one-time, non-refillable prescriptions for medications for animals post-surgery. These post-operative medications are intended to provide limited, one-time pain management relief for animals that are healing.

Because there is no risk of these prescriptions being renewed or refilled, we request the following exemption be created under § 18.06 for these limited circumstances for animal patients only:

"(3) A dispenser is not required to compile or submit dispensing data for a patient who is an animal when that prescription drug is dispensed immediately after surgery and the prescription is limited to a maximum of 10 days of dosage and cannot be refilled or renewed."

D. Submission of Additional Economic Data

In the Economic Impact Analysis that is a part of this administrative rule package, the Department notes that it received two comments pertaining to the economic impact that this rule could have on Wisconsin veterinarians. The WVMA submitted one of the two received comments as a part of their January 13, 2012, "Comments & Recommendations on the Draft Prescription Drug Monitoring Program Rules." And, in contrast to the assertion in the Economic Impact Analysis that no follow-up data was provided by WVMA, Kim Brown Pokorny, Executive Director of the WVMA, emailed additional information to the department in an email dated January 27, 2012. This additional information is also summarized below.

The frustration expressed by the Department in the Economic Impact Analysis with regard to not having enough information about Wisconsin veterinarians' prescribing practices is an excellent illustration of the issues that our members will face when complying with this rule. As Mr. Zadrizil notes in the analysis, "Without having information regarding the number of times veterinarians dispense the monitored prescription drugs, the Department has no way to validate or calculate Dr. Spencer's or the WVMA's estimate[d] economic impact report." Correct. This information is lacking because Wisconsin veterinarians do not have a consistently used electronic system that tracks their dispensing practices. Accordingly, we can only estimate this data.

The question, "How many times per week, on average, do veterinarians dispense controlled substances or Tramadol from their clinic?" assumes that there is software available that can track this information. It is important to understand that most veterinarians do not have electronic records. Therefore, to comply with this rule as it is proposed, they will retype the information requested into a reportable form to send it to the Department. The WVMA is trying to account for the time required to retype the information into one report.

Based on our records, there are 719 veterinary clinics in Wisconsin. The Department's records indicate that there are 3,000 licensed veterinarians in Wisconsin. Therefore, the average number of veterinarians per clinic is 4.17. We interviewed a representative clinic with 6 veterinarians and a representative clinic with 3 veterinarians – both using veterinary recordkeeping software, but different software in each clinic. We asked them to pull out the information listed in the rule from their records. They supplied the WVMA with the hours it

took them to pull the information required and the average time was 4.5 hours for a week's worth of records. Please note that this estimate assumes that a clinic has some kind of electronic records management tool. If a clinic lacks electronic records software, then these estimates would rise. In addition, this also was based on a clinic reporting as a unit and not on each individual dispenser reporting. Finally, this estimate does not include the time or costs associated with securing the state vendor's platform software or any additional software/hardware purchase.

E. Concern Regarding Potential Increase in Fees

In the prepared Economic Impact Analysis that is a part of this administrative rule package, the Department estimates that this program will cost $210,000 annually to administer. However, we question whether that estimate takes into account the likelihood that Wisconsin veterinarians will all be requesting waivers to file paper records.

In addition, there is no indication in the analysis of how the Department will cover those costs, whether it be from General Purpose Revenue or some increased Program Revenue. The WVMA respectfully requests that the Department refrain from increasing licensing or other fees on Wisconsin veterinarians to pay for this program. As discussed in detail in D above, our members will already face significant additional costs simply to comply with this program. To then impose increased fees to pay for the Department's monitoring and administering costs would be inappropriate. Accordingly, we specifically request that no fee increases be levied to pay for this new program.

F. Request for Enforcement Authority over Veterinarians be Grants to the Veterinary Examining Board

We understand that the enforcement authority for violations of proposed Phar 18 lies with the Pharmacy Examining Board by virtue of Wis. Stat. § 450.17. However, as the Department considers future statutory changes to this program, we ask that you consider placing the enforcement authority for this program with regard to veterinarians with the Veterinary Examining Board (VEB). The VEB is well-positioned to understand the prescription dispensing practices and issues related to veterinary medicine. As such, it would be appropriate for the VEB to have enforcement authority over veterinarians who are complying with this rule.

G. Potential Animal Welfare Issues

The WVMA is concerned that this proposal could impact animal welfare. Please be aware that some veterinary prescription drugs are not carried by most commercial pharmacies. Specifically, Buprenex (brand name) or buprenorphine (generic) is a pain medication that is commonly used in treating cats, and is never carried by pharmacies.

Similarly, it is our understanding that human patient pharmacies in Wisconsin do not carry Buprenorphine. However, human patient pharmacies do carry a drug called Suboxone in 2 mg and 8 mg tablets by special order. Although the three pharmacists we spoke to about this drug assured us that Suboxone and Buprenorphine are interchangeable, they are not. Suboxone is a combination of Buprenorphene and Naloxone that is not used in veterinary medicine. The average dose dispensed of Buprenorphine is liquid 0.1 to 0.15 mg per dose. Therefore, even if a 2 mg tablet of Suboxone were an equivalent drug, it would have to be split into 10 pieces to be safe try giving that to a cat. This illustrates a situation in which human patient pharmacists can mistakenly try to substitute something that could be harmful to our animal patients.

If veterinarians avoid certain pain treatments because of the cost and burden of additional reporting requirements, then animals will suffer. The WVMA is concerned that animal welfare and pain control may ultimately be compromised if there are not accommodations made in this rule to recognize the differences with between veterinary medicine and human medical practices.

If you have any questions about these comments, please do not hesitate to contact me directly at (608) 252-9358 or jkl@dewittross.com.

Very truly yours,

DeWitt Ross & Stevens s.c.

Jordan K. Lamb

JKL:jkl

cc. Kim Brown Pokorny, Wisconsin Veterinary Medical Association

DeWitt
Ross & Stevens

Jordan K. Lamb
Attorney
jkl@dewittross.com

Ph: 608.252.9358
Fax: 608.252.9243

Two East Mifflin Street, Suite 600, Madison, WI 53703-2865

Wis. Veterinary Medical Assn. Concerns

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD (CLEARINGHOUSE RULE 12-009)

PROPOSED ORDER

An order of the Pharmacy Examining Board to create ch. Phar 18, relating to the prescription drug monitoring program and affecting small business.

This rule is not subject to ss. 227.135 (2) or 227.185, Stats., as affected by 2011 Wis. Act 21. The scope statement for this rule, published in Register No. 660, on December 14, 2010, was sent to LRB prior to June 8, 2011 (the effective date of 2011 Wisconsin Act 21).

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted:

Subchapter II of s. 961 and ss. 19.35, 146.82, 450.01 to 065, 09 and 19 and 453.02, Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) (a), 450.19 (2) and (5), 961.31, Stats.

Explanation of agency authority:

In s. 450.19 (2), Stats., the legislature directs the Pharmacy Examining Board (Board) to establish by rule a prescription drug monitoring program. In s. 961.31, Stats., the legislature authorizes the Board to promulgate rules relating to the dispensing of controlled substances. Finally, in ss. 15.08 (5) (b), and 227.11 (2) (a), Stats., the legislature confers to the Board the powers to promulgate rules for the guidance of the profession and to interpret the provisions of statutes it enforces.

Related statute or rule:

Section 146.82, chs. 450 and 961, Stats., and chs. Phar 1 and 8 and CSB 2.

Plain language analysis:

The proposed rule creates a prescription drug monitoring program (PDMP) to collect and maintain data regarding the prescribing and dispensing of monitored prescription drugs. The monitored prescription drugs are federally controlled substances in Schedules II-V, as changed

by 21 CFR 1308, state controlled substances in Schedules II-V, as amended by the Controlled Substances Board, and Tramadol, a drug identified by the Board as having a substantial potential for abuse. A controlled substance that can be legally dispensed without a prescription order is not a monitored prescription drug under the proposed rule.

In general, the proposed rule requires dispensers to compile and submit to the Board data about each time they dispense a monitored prescription drug within 7 days. The proposed rule also requires dispensers to submit reports to the Board for each 7-day period during which he or she does not dispense a monitored prescription drug. For each dispensing of a monitored prescription drug, dispensers must compile and submit the following data to the Board:

- dispenser's full name;
- dispenser's NPI number or DEA registration number;
- date dispensed;
- prescription number;
- NDC number or the name and strength of the monitored prescription drug;.
- quantity dispensed;
- estimated number of days of drug therapy;
- practitioner's full name;
- practitioner's NPI number or DEA registration number, if applicable;
- date prescribed;
- quantity prescribed;
- patient's full name;
- patient's address, including street address, city, state and ZIP code;
- patient's date of birth; and
- patient's gender.

Under the proposed rule, the Board may waive the 7-day reporting requirements for dispensers who only dispense monitored prescription drugs to non-human animal patients. Instead, the dispensers would be required to submit the required data or report indicating that they have not dispensed a monitored prescription drug every 90 days.

The proposed rule requires dispensers to create accounts with the Board and electronically submit the data to the Board in the format established by the version and release of the American Society for Automation in Pharmacy's Implementation Guide for Prescription Monitoring Programs identified by the Board or other electronic format identified by the Board.

Under the proposed rule, the Board may grant a waiver to a dispenser who is not able to comply with the electronic data submission requirements. The Board may also grant an emergency waiver to a dispenser who is unable to submit data to the Board within 7 days of dispensing a monitored prescription drug. Therefore, dispensers who are not able to comply with one or both of the reporting or submission requirements may submit to the Board applications for a waiver or an emergency waiver.

The proposed rule requires the Board to develop and maintain a database to store all of the data submitted to it as part of the PDMP. Practitioners, dispensers and their delegates are able create

accounts with the Board to access the database and view information that may be helpful in determining whether a patient is using monitored prescription drugs illicitly. The Board may limit a practitioner's, dispenser's or their delegate's access to the information based upon wrongful use of the information, issued disciplinary action or other adverse action taken against a practitioner, dispenser or their delegates.

Further, under the proposed rule, other entities, such as law enforcement authorities, patients and staff of the Department of Safety and Professional Services, may obtain data from the Board as permitted under s. 146.82, Stats.

Dispensers, practitioners and their delegates are able to request that the Board review a denial of a request for a waiver, emergency waiver or limitation imposed upon their access to information. The Board will conduct the review at a regularly scheduled meeting and allow the practitioner, dispenser or delegate to address the Board.

The proposed rule states that the data compiled and stored by the Board under the proposed rules is confidential and not subject to inspection or copying under the state's open records laws.

Under the proposed rule, the Board may exchange data obtained through the PDMP with relevant agencies and prescription monitoring programs in other states.

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

There is no existing or proposed federal regulation.

Comparison with rules in adjacent states:

Illinois: The statutes and administrative rules governing the Illinois Prescription Monitoring Program require dispensers to submit to a database similar information regarding the prescribing and dispensing of controlled substances (Schedules II-V) within 7 days of the dispensing. *See* 720 Illinois Compiled Statutes 570/316-21 and Illinois Administrative Code Title 77, Chapter X, Subchapter e, Part 2080.

Iowa: The statutes and administrative rules governing the Iowa Prescription Monitoring Program require dispensers to submit to a database similar information regarding the prescribing and dispensing of controlled substances (Schedules II-IV) two times per month. *See* Iowa Code § 124.551-58 and Iowa Administrative Code Title 657, Chapter 37.

Michigan: The statutes and administrative rules governing the Michigan Automated Prescription System require dispensers to submit to a database similar information regarding the prescribing and dispensing of controlled substances (Schedules II-V) two times per month. *See* Michigan Public Health Code § 333.7333a and Michigan Administrative Code R. 338.471.

Minnesota: The statutes governing the Minnesota Prescription Monitoring Program require dispensers to submit to a database similar information regarding the prescribing and dispensing of controlled substances (Schedules II-IV) on a daily basis. *See* Minnesota Statute 152.126.

Summary of factual data and analytical methodologies:

The Board created a Work Group to develop the proposed rule. The Work Group analyzed information from national non-profit organizations that compiled information about other states' prescription monitoring programs. Further, the organizations provided analysis regarding the effectiveness of differing prescription drug monitoring models and processes.

The Board also solicited feedback from approximately fifty stakeholders that represent health care practitioners, pharmacists, pharmacies, hospitals, public health agencies and law enforcement agencies. The Board solicited comments from the stakeholders throughout the development of the proposed rule and many stakeholders submitted comments to the Board. The Board will consult with the stakeholders and other interested individuals as implementation of the PDMP continues.

Further, as of February 2012, there are forty operational state prescription monitoring programs in the United States, including programs in all four states neighboring Wisconsin. The Work Group solicited and compiled information from states' operational prescription monitoring programs regarding best practices and techniques to minimize the burden on practitioners and dispensers. Importantly, the Work Group used the information to ensure the compatibility of the PDMP with prescription monitoring programs in other states and better situate itself for future federal grant funding as required by 2009 Wis. Act 362. The Work Group also identified criteria required to apply for other grants in an effort to maximize the possibility of obtaining future federal grant funding for the PDMP.

Finally, the Work Group relied on the requirements and guidelines of the Harold Rogers Prescription Drug Monitoring Implementation Grant that the federal Department of Justice awarded to the Department to implement the PDMP. The federal grant requirements provide relevant information because they are based on best practices of operational PDMP and the previous experiences of grantees implementing prescription monitoring programs.

Analysis and supporting documents used to determine effect on small business or in preparation of Economic Impact Analysis:

To prepare the Economic Impact Analysis and regulatory flexibility reports for the proposed rule, the Department actively solicited comments from the public and stakeholders representing pharmacies; pharmacists; health care practitioners, including physicians, dentists and veterinarians; hospitals; clinics and law enforcement officials since November 2011. Further, the Department posted notice to solicit comments on the economic impact of the proposed rule on its website for more than 30 days, from December 16, 2011 to January 19, 2012. The Department also held a roundtable discussion about the proposed rule on January 17, 2012 to solicit feedback about the proposed rule from stakeholders and members of the public who expressed interest in the PDMP.

During the solicitation period for comments regarding the economic impact of the proposed rule, the Department received four comments that referred to the economic impact or funding of the

PDMP. Of the four comments, two provide specific estimates regarding the economic impact of the proposed rule on veterinarians in Wisconsin and two present general concerns regarding the ongoing funding of the PDMP beyond the federal grant.

For a complete analysis of the received comments, see the Fiscal Estimate, Economic Impact Analysis and Final Regulatory Flexibility Analysis.

Anticipated costs incurred by the private sector:

As described in the Economic Impact Analysis and Final Regulatory Flexibility Analysis, the Department anticipates that specific segments of the private sector may incur moderate costs to comply with the requirements of the proposed rule. However, while the health care sector may incur moderate costs to comply with the requirements of the proposed rule, the Department does not find that the proposed rule would adversely affect in any material way the economy, any sector of the economy, productivity, jobs or the overall economic competitiveness of this state. Similarly, the Department does not find that the proposed rule will have any economic effect on public utilities or their rate payers.

Fiscal Estimate:

The Fiscal Estimate and Economic Impact Analysis are attached.

Effect on small business:

The Final Regulatory Flexibility Analysis is attached.

Changes to the analysis prepared under s. 227.14 (2), Stats.:

The statutes interpreted are more specific per the Clearinghouse Report.

In the explanation of agency authority, the language "as amended by 2009 Act 362" has been deleted per the Clearinghouse Report.

The plain language analysis has been changed to reflect modifications made to the text of the proposed rule.

Copies of the Proposed Rule, Fiscal Estimate, Economic Impact Analysis or Final Regulatory Flexibility Analysis:

Copies are available upon request to Chad Zadrazil, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708 or by email at chad.zadrazil@wisconsin.gov.

Agency contact person:

Chad Zadrazil, Program and Policy Analyst – Advanced, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8935, Madison, Wisconsin 53708; telephone 608-266-0011; email at chad.zadrazil@wisconsin.gov.

TEXT OF RULE

SECTION 1. Ch. Phar 18 is created to read:

CHAPTER PHAR 18

PRESCRIPTION DRUG MONITORING PROGRAM

Phar 18.01 Authority and scope. The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a), 961.31, 450.02 (3) (a) and 450.19, Stats., for the purpose of creating a prescription drug monitoring program to collect and maintain information relating to the prescribing and dispensing of prescription drugs.

Phar 18.02 Definitions. As used in this chapter:

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

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

(3) "Animal" has the meaning given in s. 453.02 (1m), Stats.

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

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

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

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

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

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

(8) "Dispense" has the meaning given in s. 450.01 (7), Stats.

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

(a) a pharmacy from where a pharmacist dispenses a monitored prescription drug.

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

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

(10) "Dispenser delegate" means an agent or employee of a dispenser to whom the task of inputting or accessing PDMP information has been delegated.

(11) "Dispensing data" means data compiled pursuant to s. Phar 18.04.

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

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

1. A controlled substance included in s. 450.19 (1), Stats.

2. A drug identified by the board as having a substantial potential for abuse in s. Phar 18.03.

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

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

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

(16) "Patient" has the meaning given in s. 450.01 (14), Stats.

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

(18) "PDMP information" means all of the following:

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

(b) The information created by the board to satisfy the requirements in s. Phar 18.13.

(19) "Pharmacy" means any place of practice licensed by the board under ss. 450.06 or 450.065, Stats.

(20) "Practitioner" has the meaning given in s. 450.01 (17), Stats.

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

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

(23) "Prescription order" has the meaning given in s. 450.01 (21), Stats.

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

(25) "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.

Phar 18.03 Drugs that have a substantial potential for abuse. Pursuant to s. 450.19 (1), Stats., the board has identified all of the following drugs as having a substantial potential for abuse:

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

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

(3) Tramadol.

Phar 18.04 Dispensing data. (1) Subject to s. Phar 18.09, a dispenser shall compile dispensing data that contains information about each time he or she dispenses a monitored prescription drug to a patient.

(2) The dispensing data shall contain all of the following information:

(a) The dispenser's full name.

(b) The dispenser's NPI number or DEA registration number.

(c) The date dispensed.

(d) The prescription number.

(e) The NDC number or the name and strength of the monitored prescription drug.

(f) The quantity dispensed.

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

(h) The practitioner's full name.

(i) The practitioner's NPI number or DEA registration number, if applicable.

(j) The date prescribed.

(k) The quantity prescribed.

(L) The patient's full name.

(m) The patient's address, including street address, city, state and ZIP code.

(n) The patient's date of birth.

(o) The patient's gender.

(3) A dispenser who fails to compile dispensing data as required by subs. (1) and (2) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

Phar 18.05 Electronic submission of dispensing data. (1) A dispenser shall create an account with the board through which the dispenser shall submit dispensing data to the board.

Note: The application to create an account may be completed 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 8935, Madison, WI 53708.

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

Note: The guide for dispensers which specifies the data standards in the version and release of the ASAP implementation guide for prescription monitoring programs identified by the board and other electronic formats identified by the board may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

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

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

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

Note: The application for a waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

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

Phar 18.06 Frequency of submissions. (1) A dispenser shall submit dispensing data to the board within 7 days of dispensing a monitored prescription drug.

(2) If a dispenser does not dispense a monitored prescription drug for 7 days, the dispenser shall submit a zero report to the board.

(3) If a dispenser is not able to submit dispensing data within 7 days of dispensing a monitored prescription drug as required by sub. (1), the board may grant an emergency waiver to a dispenser who satisfies all of the following conditions:

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

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

Note: The application for an emergency waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

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

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

Phar 18.07 Veterinary dispensers. (1) The board may grant a waiver from the requirements of s. Phar 18.06 to a dispenser who solely dispenses monitored prescription drugs to animal patients if the dispenser satisfies all of the following conditions:

(a) The dispenser submits dispensing data in accordance with the electronic reporting requirements of s. Phar 18.05, unless they have been separately waived by the board.

(b) The dispenser submits dispensing data compiled under s. Phar 18.04 to the board every 90 days.

(c) The dispenser submits a zero report to the board if he or she does not dispense a monitored prescription drug for 90 days.

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

Note: The application for a waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(2) A dispenser granted a waiver under sub. (1) who fails to submit dispensing data as required by sub. (1) or submits false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

Phar 18.08 Correction of dispensing data. If a dispenser discovers omissions or inaccuracies in previously submitted dispensing data or other PDMP information, the dispenser shall notify the board in writing within 7 days and submit documentation that identifies the erroneous information and includes the correct information.

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 8935, Madison, WI 53708.

Phar 18.09 Exemptions from compiling and submitting dispensing data. (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew his or her license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

(a) The dispenser provides evidence sufficient to the board that he or she 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 8935, 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 prescription drug is administered directly to a patient.

Phar 18.10 Direct access to PDMP information. (1) Dispensers, practitioners, dispenser delegates and practitioner delegates may access PDMP information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records.

(2) To obtain access to PDMP information, dispensers, practitioners, dispenser delegates and practitioner delegates shall create an account with the board on a form provided by the board.

Note: The application to create an account may be completed 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 8935, Madison, WI 53708.

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

(a) The dispenser, dispenser delegate, practitioner or practitioner delegate uses PDMP information in violation of ss. 146.82, 450.19, Stats., this chapter or other state or federal laws or regulations relating to the privacy of patient health care records.

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

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

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

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

(f) The dispenser, dispenser delegate, practitioner or practitioner delegate is convicted of a crime substantially related to the prescribing or dispensing of a monitored prescription drug.

(g) The dispenser delegate or practitioner delegate is no longer delegated the task of inputting or accessing PDMP information.

Phar 18.11 Requests for review. (1) A dispenser, dispenser delegate, practitioner or practitioner delegate may request that the board review any of the following:

(a) The denial of a waiver requested pursuant to s. Phar 18.05 (3).

(b) The denial of an emergency waiver requested pursuant to s. Phar 18.06 (3).

(c) The denial of a waiver requested pursuant to s. Phar 18.07 (1).

(d) The denial, suspension, revocation or other restriction or limitation imposed on the dispenser's, dispenser delegate's, practitioner's or practitioner delegate's account pursuant 18.10 (3).

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

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

(b) The reason for requesting a review.

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

(4) No discovery is permitted.

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

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

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

Phar 18.12 Methods of obtaining PDMP information. (1)The board shall disclose PDMP information about a patient to the patient if he or she does all of the following:

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

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

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

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

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

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

(3) The board shall disclose the minimum amount of PDMP information necessary to designated staff of a relevant agency in another state 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 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

(b) Provides proof sufficient to the board that the relevant agency in another state is entitled to the information under ss. 146.82 and 450.19 (2) (c), Stats.

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

(4) The board shall disclose the minimum amount of PDMP information necessary to a health care facility staff committee, or accreditation or health care services review organization 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 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

(b) Provides proof sufficient to the board that the health care facility staff committee, or accreditation or health care services review organization is entitled to the information under s. 146.82 (2) (a) 1., Stats.

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

(5) The board shall disclose the minimum amount of PDMP information necessary to designated staff of a federal or state governmental agency in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

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

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

(6) The board shall disclose the minimum amount of PDMP information necessary to designated staff of the department who is charged with investigating dispensers, dispenser delegates, 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 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

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

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

(7) The board shall disclose the minimum amount of PDMP information necessary to a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

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

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

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

(8) The board shall disclose the minimum amount of PDMP information necessary to a coroner, deputy coroner, medical examiner or medical examiner's assistant following the death of a patient in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

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

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

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

(9) The board shall disclose the minimum amount of PDMP information necessary to a researcher 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 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

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

(b) Provides proof sufficient to the board that the person is entitled to the information under s. ss. 146.82 (2) (a) 6. or 20., Stats.

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

(10) The board shall disclose the minimum amount of PDMP information to designated staff of a law enforcement authority in the same or similar manner, and the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

(b) Provides a lawful order of a court of record under s. 146.82 (2) (a) 4., Stats., or provides evidence satisfactory to the board that the law enforcement agency is entitled to the information under s. 146.82 (a) 11., Stats.

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

Note: The application to create an account and form to request PDMP information may be completed online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

Phar 18.13 Use of PDMP information by the board and department. (1) The board shall develop and maintain a PDMP database to store PDMP information.

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

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

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

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

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

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

(b) The collection of prescription drug information as part of the assigned duties and responsibilities under s. 450.19, Stats., and this chapter.

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

(d) Other legally authorized purposes.

Phar 18.14 Confidentiality of PDMP information. (1) The PDMP information maintained by the board, department or a vendor contracting with the department which is submitted to, maintained, or stored as a part of the program is not subject to inspection or copying under s. 19.35, Stats.

(2) A person who discloses PDMP information in violation of ss. 146.82, 450.19, Stats., this chapter or other state or federal laws or regulations relating to the privacy of patient health care records, may be subject to disciplinary action by the licensing board that issued the license under which the person is authorized to prescribe or dispense monitored prescription drugs and all appropriate civil and criminal penalties.

Phar 18.15 Exchange of PDMP information. (1) The board may exchange PDMP information with a prescription monitoring program operated by a relevant agency in another 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 drug 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 drug 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 drug monitoring program's continued compatibility with the program at any time.

(END OF TEXT OF RULE)

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.

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board


FORWARD
E PLURIBUS UNUM

DeWitt
Ross & Stevens s.c. Law Firm

Please respond to: Capitol Square Office
Email: jkl@dewittross.com
Direct: 608-252-9358

February 28, 2012

Mr. Gregory Weber and Members of the
Wisconsin Pharmacy Examining Board
c/o Chad Zadrazil, DSPS
Division of Board Services
P.O. Box 8953
Madison, WI 53708-8935

VIA EMAIL ONLY
chad.zadrazil@wisconsin.gov

RE: WVMA Post-Hearing Comments on Proposed Phar 18, PDMP

Dear Mr. Weber:

After listening to the discussion of the Pharmacy Examining Board (Board) following the close of the public hearing on Monday, February 27, 2012 on proposed Phar 18, the creation of a Prescription Drug Monitoring Program (PDMP) in Wisconsin, I thought it might be helpful if I write to clarify the comments submitted by my client, the Wisconsin Veterinary Medical Association (WVMA).

I heard the Board discuss and ask legal counsel about whether veterinarians can be *exempted* from this rule in Wisconsin. The response that was given was that the statute would not allow such an exemption and that answer appeared to end the Board's consideration of the issues raised by the WVMA, the Veterinary Examining Board and the veterinarians who testified. I respectfully request that you consider adopting *another alternative* (other than exemption) for veterinarians in this rule, which will allow for a flexible reporting system that is responsive to the needs and limitations of veterinary medical practice in Wisconsin.

The statute that directs the Board to create the PDMP says that the established prescription drug monitoring program must, "Require a pharmacist or practitioner to generate a record documenting each dispensing of a prescription drug and to deliver the record to the board, except that the program may not required the generation of a record when a drug is administered directly to a patient." Wis. Stat. § 450.19 (2) (a).

The law further states that the program must, "Specify a secure electronic format for delivery of a record generated under the program and authorize the board to grant a pharmacist or a practitioner a waiver of the specified format." Wis. Stat. § 450.19 (2) (d) (*emphasis added*).

This statutory language is broad enough, in my opinion, to allow the Board to create a program that will allow Wisconsin veterinarians the flexibility to provide electronic records to the Board in a way that both meets the requirements of the statute and that will not impose undue hardship on their businesses.

As you heard, most veterinarians do not currently use electronic records systems and, when they do, they are not consistent with the ASAP standards. In the formal comments that I submitted to the Board in advance of the hearing, I requested that the Board consider the following amendment to Phar 18.04 (2), which would allow for alternative electronic methods to be used for veterinarians to submit records to the Board:

> "(2) Subject to s. 18.06 and sub. (5), a dispenser shall submit dispensing data to the board electronically in the format identified in the American society for automation in pharmacy (ASAP) implementation guide for prescription monitoring programs. A dispenser who is a veterinarian may use any electronic format to submit dispensing data to the board electronically."

This change would allow for veterinarians to upload scanned paper documents or use other web interface tools that may not be identified in the ASAP manual, but that may be ultimately available from the vendor chosen to provide the system. It also would allow flexibility among veterinarians, such that not all offices may use the same electronic system to comply with the reporting requirement.

Our written comments also provided details on the problems veterinarians will face if the fields specifying dispenser data are not reflective of the differences between veterinary medicine and human medicine. In order to account for the issues related to the request for dispensing data that is not applicable to animal patients, we requested the following amendment to § 18.03(2) and that a new section (4) be created to remove these fields for veterinarian dispensers:

> "(2) Except as provided in (4), the dispensing data shall contain the following information:"
>
> "(4) If the dispenser is a licensed veterinarian, then the dispensing data need only contain information in sub. (2) (a), (c), (e), (g), (i), (k) and (L)."

I draw this to your attention again because I feel that there is another option that can address the concerns raised by the veterinarians that also meets the requirements of the statute. I respectfully request that you utilize the "waiver" authority that was granted to you under the

statute and that you use that authority to provide flexibility for Wisconsin veterinarians to comply with this rule.

Finally, the WVMA has surveyed all of the thirty-seven (37) states that currently have an operational PMP and have found that the following twenty-~~four~~ three (23) states, which all have an operational PMP, also all exempt veterinarians from the program: Colorado; Connecticut; Florida; Hawaii; Idaho; Illinois; Iowa; Louisiana; Maine; Massachusetts; Mississippi; Nevada; New Mexico; North Carolina; North Dakota; Ohio; Oregon; Pennsylvania; Texas; Utah; Vermont; Virginia; and Wyoming. I offer this information because it appeared that the Board was relying on an inaccurate chart during its discussion of the issue on Monday.

If you have any questions about these comments, please do not hesitate to contact me at (608) 252-9358 or jkl@dewittross.com.

Very truly yours,

DeWitt Ross & Stevens s.c.

Jordan Lamb

Jordan K. Lamb

JKL:jkl

cc. Kim Pokorny, WVMA Executive Director (*via email only*)
Members of the Veterinary Examining Board (*via email only c/o Tom Ryan* Thomas.Ryan@wisconsin.gov)
Chad Zadrazil, DSPS Division of Board Services (*via email only*)


FORWARD
E PLURIBUS UNUM

DATE: March 28, 2012

TO: Marsha Dake

Committee on Health

FROM: Patrick E. Fuller, Assembly Chief Clerk

RE: Clearinghouse Rules Referral

The following Clearinghouse Rule has been referred to your committee.

CLEARINGHOUSE RULE 12–009

AN ORDER to create ch. Phar 18, relating to the prescription drug monitoring program and affecting small business.

Submitted by **Department of Safety and Professional Services.**

Report received from Agency on **March 14, 2012.**

To committee on **Health.**

Referred on **Wednesday, March 28, 2012.**

Last day for action - **Friday, April 27, 2012.**

Under section 227.19 (4) of the Wisconsin Statutes, your committee has 30 days to take action or get an extension. The day **after** the official referral date is day one of your review period. Therefore, the 30th day should fall four weeks and two days after the referral date. For example, for Clearinghouse Rules referred on a Monday, a Wednesday would be your 30th day. For Clearinghouse Rules referred on a Thursday or Friday, your 30th day would fall on a weekend. Therefore, your time would expire on the next working day (Monday) as provided for in s. 990.001 of the Wisconsin Statutes. Also, if the 30th day falls on a legal holiday, time would expire on the next working day.

To extend your review period for an additional 30 days, your committee has one of two options. Section 227.19(4)(b) states that you can request in writing that the agency meet with the committee to review the proposed rule. Another option is to publish or post notice that the committee will hold a meeting or hearing to review the proposed rule and immediately send a copy of the notice to the agency.

Section 227.19 **requires** you to notify each member of your committee that you have received this Clearinghouse Rule. Although some committee chairs choose to do so, you are not required by law or rule to send a copy of the text of the rule to each member at this time. Instead, your notice could state that members should contact you if they wish to receive a hard copy of the rule. Another option would be to email the rule to members. Please put a copy of your official notification memo in the rule jacket.

Three copies of the Clearinghouse Rule and its accompanying documents are contained in the jacket. If you wish to have your Legislative Council attorney review the Clearinghouse Rule, send him/her a copy. I only need one copy remaining in the jacket when you report it out of committee at the end of the review period.

The identical process is happening simultaneously in the Senate. Keep track of their action on the rule.

For assistance with the Clearinghouse Rule process, please consult Kay Inabnet (6–5550) or your Legislative Council attorney. If you wish to learn more on this subject, read *Review of Administrative Rules* which is part of the Legislative Council's Wisconsin Legislator Briefing Book series, section 227.19 of the Wisconsin Statutes or part 2 of the *Administrative Rules Procedures Manual* written by the Revisor of Statutes Bureau and the Wisconsin Legislative Council staff.


FORWARD
E PLURIBUS UNUM

Dake, Marsha

From: Dake, Marsha

Sent: Thursday, March 29, 2012 1:34 PM

To: Bowers, Jim; Dake, Marsha; Field, Adam; Handrick, Diane; Hein, Tanya; Larson, Brian; Ludwig, Frederic; Moore, Heather; Moran, Christian; Rep.Kaufert; Rep.Litjens; Rep.Pasch; Rep.Petersen; Rep.Richards; Rep.Seidel; Rep.Severson; Rep.Stone; Rep.Strachota; Rep.Taylor; Rep.Van Roy; Scholz, AJ; Turke, Jon; Walsh, Patrick; Whittlef, Holly

Subject: FW: CR 12-009 Documents

Attachments: 165-Phar 18- Prescription Drug Monitoring Program-Proposed Order.pdf; 165-Phar 18- Prescription Drug Monitoring Program-Report to the Legislature.pdf; 165-Phar 18- Prescription Drug Monitoring Program-Fiscal Estimate and Economic Impact Analysis (Updated).pdf; 165-Phar 18- Prescription Drug Monitoring Program-Fiscal Estimate and Economic Impact Analysis (Original).pdf; 165-Phar 18- Prescription Drug Monitoring Program-Final Regulatory Flexibility Analysis.pdf

Members:

The following Clearinghouse Rule has been referred to the Assembly Committee on Health:

12-009 Relating to the prescription drug monitoring program and affecting small business.

Please see the attached documents for further information about this rule.

The last day for committee action is April 27, 2012. If you have any questions or would like to request action on any of these rules, please contact our office no later than April 20, 2012.

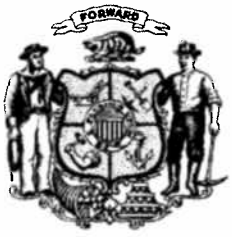
Thank you.

Marsha Dake

Committee Clerk

6-8590

WISCONSIN STATE LEGISLATURE



TEXT OF RULE

SECTION 1. Ch. Phar 18 is created to read:

CHAPTER PHAR 18

PRESCRIPTION DRUG MONITORING PROGRAM

Phar 18.01 Authority and scope. The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a), 961.31, 450.02 (3) (a) and 450.19, Stats., for the purpose of creating a prescription drug monitoring program to collect and maintain information relating to the prescribing and dispensing of prescription drugs.

Phar 18.02 Definitions. As used in this chapter:

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

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

(3) "Animal" has the meaning given in s. 453.02 (1m), Stats.

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

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

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

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

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

Comment [CZ1]: Changed for clarity.

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

(8) "Dispense" has the meaning given in s. 450.01 (7), Stats.

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

(a) a pharmacy from where a pharmacist dispenses a monitored prescription drug.

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

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

(10) "Dispenser delegate" means an agent or employee of a dispenser to whom the task of inputting or accessing PDMP information has been delegated.

(11) "Dispensing data" means data compiled pursuant to s. Phar 18.04.

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

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

1. A controlled substance included in s. 450.19 (1), Stats.

2. A drug identified by the board as having a substantial potential for abuse in s. Phar 18.03.

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

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

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

Comment [CZ2]: Changed "pharmacy" to "dispenser" and rearrange to make the order of words consistent with the other sections.

(16) "Patient" has the meaning given in s. 450.01 (14), Stats.

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

(18) "PDMP information" means all of the following:

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

(b) The information created by the board to satisfy the requirements in s. Phar 18.13.

(19) "Pharmacy" means any place of practice licensed by the board under ss. 450.06 or 450.065, Stats.

(20) "Practitioner" has the meaning given in s. 450.01 (17), Stats.

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

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

(23) "Prescription order" has the meaning given in s. 450.01 (21), Stats.

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

(25) "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.

Phar 18.03 Drugs that have a substantial potential for abuse. Pursuant to s. 450.19 (1), Stats., the board has identified all of the following drugs as having a substantial potential for abuse:

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

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

(3) Tramadol.

Phar 18.04 Dispensing data. (1) Subject to s. Phar 18.09, a dispenser shall compile dispensing data that contains information about each time he or she dispenses a monitored prescription drug to a patient.

(2) The dispensing data shall contain all of the following information:

(a) The dispenser's full name.

waive?

(b) The dispenser's NPI number or DEA registration number.

(c) The date dispensed.

(d) The prescription number.

(e) The NDC number or the name and strength of the monitored prescription drug.

(f) The quantity dispensed.

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

(h) The practitioner's full name.

(i) The practitioner's NPI number or DEA registration number, if applicable.

(j) The date prescribed.

(k) The quantity prescribed.

(L) The patient's full name.

(m) The patient's address, including street address, city, state and ZIP code.

(n) The patient's date of birth.

(o) The patient's gender.

(3) A dispenser who fails to compile dispensing data as required by subs. (1) and (2) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

Phar 18.05 Electronic submission of dispensing data. (1) A dispenser shall create an account with the board through which the dispenser shall submit dispensing data to the board.

Note: The application to create an account may be completed 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 8935, Madison, WI 53708.

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

Note: The guide for dispensers which specifies the data standards in the version and release of the ASAP implementation guide for prescription monitoring programs identified by the board and other electronic formats identified by the board may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

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

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

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

Note: The application for a waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(4) A dispenser who fails to create an account with the board and submit dispensing data as required by subs. (1) and (2) or be granted a waiver under sub. (3) may be subject to

disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

Phar 18.06 Frequency of submissions. (1) A dispenser shall submit dispensing data to the board within 7 days of dispensing a monitored prescription drug.

(2) If a dispenser does not dispense a monitored prescription drug for 7 days, the dispenser shall submit a zero report to the board.

(3) If a dispenser is not able to submit dispensing data within 7 days of dispensing a monitored prescription drug as required by sub. (1), the board may grant an emergency waiver to a dispenser who satisfies all of the following conditions:

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

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

Note: The application for an emergency waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

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

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

Phar 18.07 Veterinary dispensers. (1) The board may grant a waiver from the requirements of s. Phar 18.06 to a dispenser who solely dispenses monitored prescription drugs to animal patients if the dispenser satisfies all of the following conditions:

(a) The dispenser submits dispensing data in accordance with the electronic reporting requirements of s. Phar 18.05, unless they have been separately waived by the board.

(b) The dispenser submits dispensing data compiled under s. Phar 18.04 to the board every 90 days.

(c) The dispenser submits a zero report to the board if he or she does not dispense a monitored prescription drug for 90 days.

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

Note: The application for a waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(2) A dispenser granted a waiver under sub. (1) who fails to submit dispensing data or a zero report as required by sub. (1) or submits false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

Comment [CZ3]: Added for clarity.

Phar 18.08 Correction of dispensing data. If a dispenser discovers omissions or inaccuracies in previously submitted dispensing data or other PDMP information, the dispenser shall notify the board in writing within 7 days and submit documentation that identifies the erroneous information and includes the correct information.

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 8935, Madison, WI 53708.

Phar 18.09 Exemptions from compiling and submitting dispensing data. (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew his or her license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

(a) The dispenser provides evidence sufficient to the board that he or she 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 8935, 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.

Comment [CZ4]: Added for clarity.

Phar 18.10 Direct access to PDMP information. (1) Dispensers, practitioners, dispenser delegates and practitioner delegates may access PDMP information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records.

(2) To obtain access to PDMP information, dispensers, practitioners, dispenser delegates and practitioner delegates shall create an account with the board on a form provided by the board.

Note: The application to create an account may be completed 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 8935, Madison, WI 53708.

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

(a) The dispenser, dispenser delegate, practitioner or practitioner delegate uses PDMP information in violation of ss. 146.82, 450.19, Stats., this chapter or other state or federal laws or regulations relating to the privacy of patient health care records.

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

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

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

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

(f) The dispenser, dispenser delegate, practitioner or practitioner delegate is convicted of a crime substantially related to the prescribing or dispensing of a monitored prescription drug.

(g) The dispenser delegate or practitioner delegate is no longer delegated the task of inputting or accessing PDMP information.

Phar 18.11 Requests for review. (1) A dispenser, dispenser delegate, practitioner or practitioner delegate may request that the board review any of the following:

(a) The denial of a waiver requested pursuant to s. Phar 18.05 (3).

(b) The denial of an emergency waiver requested pursuant to s. Phar 18.06 (3).

(c) The denial of a waiver requested pursuant to s. Phar 18.07 (1).

(d) The denial, suspension, revocation or other restriction or limitation imposed on the dispenser's, dispenser delegate's, practitioner's or practitioner delegate's account pursuant to s. Phar 18.10 (3).

Comment [CZ5]: Added to correct citation format

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

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

(b) The reason for requesting a review.

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

(4) No discovery is permitted.

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

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

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

Phar 18.12 Methods of obtaining PDMP information. (1)The board shall disclose PDMP information about a patient to the patient if he or she does all of the following:

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

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

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

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

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

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

(3) The board shall disclose the minimum amount of PDMP information necessary to designated staff of a relevant agency in another state 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 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

(b) Provides proof sufficient to the board that the relevant agency in another state is entitled to the information under ss. 146.82 and 450.19 (2) (c), Stats.

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

(4) The board shall disclose the minimum amount of PDMP information necessary to a health care facility staff committee, or accreditation or health care services review organization 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 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

(b) Provides proof sufficient to the board that the health care facility staff committee, or accreditation or health care services review organization is entitled to the information under s. 146.82 (2) (a) 1., Stats.

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

(5) The board shall disclose the minimum amount of PDMP information necessary to designated staff of a federal or state governmental agency in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

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

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

(6) The board shall disclose the minimum amount of PDMP information necessary to designated staff of the department who is charged with investigating dispensers, dispenser

delegates, 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 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

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

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

(7) The board shall disclose the minimum amount of PDMP information necessary to a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

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

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

Comment [CZ6]: Correction.

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

(8) The board shall disclose the minimum amount of PDMP information necessary to a coroner, deputy coroner, medical examiner or medical examiner's assistant following the death of a patient in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

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

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

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

(9) The board shall disclose the minimum amount of PDMP information necessary to a researcher 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 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

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

(b) Provides proof sufficient to the board that the person is entitled to the information under ~~s.~~ ss. 146.82 (2) (a) 6. or 20., Stats.

Comment [CZ7]: Correction.

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

(10) The board shall disclose the minimum amount of PDMP information to designated staff of a law enforcement authority in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, 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:

Comment [CZ8]: Correction.

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

(b) Provides a lawful order of a court of record under s. 146.82 (2) (a) 4., Stats., or provides evidence satisfactory to the board that the law enforcement agency is entitled to the information under s. 146.82 (2) (a) 11., Stats.

Comment [CZ9]: Added to correct citation.

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

Note: The application to create an account and form to request PDMP information may be completed online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

Phar 18.13 Use of PDMP information by the board and department. (1) The board shall develop and maintain a PDMP database to store PDMP information.

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

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

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

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

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

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

(b) The collection of ~~prescription drug information~~ dispensing data as part of the assigned duties and responsibilities under s. 450.19, Stats., and this chapter.

Comment [CZ10]: Changed for clarity.

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

(d) Other legally authorized purposes.

Phar 18.14 Confidentiality of PDMP information. (1) The PDMP information maintained by the board, department or a vendor contracting with the department which is submitted to, maintained, or stored as a part of the program is not subject to inspection or copying under s. 19.35, Stats.

(2) A person who discloses PDMP information in violation of ss. 146.82, 450.19, Stats., this chapter or other state or federal laws or regulations relating to the privacy of patient health care records, may be subject to disciplinary action by the licensing board that issued the license under which the person is authorized to prescribe or dispense monitored prescription drugs and all appropriate civil and criminal penalties.

Phar 18.15 Exchange of PDMP information. (1) The board may exchange PDMP information with a prescription monitoring program operated by a relevant agency in another 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 ~~drug~~ monitoring program to the program, the board may consider any of the following:

Comment [CZ11]: Deleted to be consistent throughout the section.

(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 ~~drug~~ monitoring program.

Comment [CZ12]: Deleted to be consistent throughout the section.

(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 ~~drug~~ monitoring program's continued compatibility with the program at any time.

Comment [CZ13]: Deleted to be consistent throughout the section.