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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)

STATE OF WISCONSIN
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Governor Scott Walker **Secretary Dave Ross**

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April 4, 2012

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COMMITTEE ON WORKFORCE DEVELOPMENT,
SMALL BUSINESS, AND TOURISM
ROOM 306 SOUTH
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MADISON, WI 53707

REPRESENTATIVE JEFF STONE
COMMITTEE ON HEALTH
ROOM 314 NORTH
STATE CAPITOL
P.O. BOX 8953
MADISON, WI 53708

RE: Germane Modification to Clearinghouse Rule 12-009

Dear Senator Moulton and Representative Stone:

Pursuant to s. 227.19(4)(b)3., Stats., the Pharmacy Examining Board (Board) is submitting a germane modification to Clearinghouse Rule 12-009, relating to the prescription drug monitoring program and affecting small business. The Board's modification affects the proposed rule as follows:

In SECTION 1, amend Phar 18.02 (6) to read:

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

In SECTION 1, amend Phar 18.02 (15) to read:

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

In SECTION 1, amend Phar 18.07 (2) to read:

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.

In SECTION 1, amend Phar 18.09 (2) to read:

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

In SECTION 1, amend Phar 18.11 (1) (d) to read:

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).

In SECTION 1, amend Phar 18.12 (7) (b) to read:

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

In SECTION 1, amend Phar 18.12 (9) (b) to read:

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.

In SECTION 1, amend Phar 18.12 (10) (intro.) to read:

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:

In SECTION 1, amend Phar 18.12 (10) (b) to read:

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.

In SECTION 1, amend Phar 18.13 (6) (b) to read:

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

In SECTION 1, amend Phar 18.15 (2) to (3) to read:

(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.

I understand that the submission of this germane modification will extend both Committee's review period for ten working days pursuant to s. 227.19(4)(b)3., Stats.

Please contact me at 608-266-0011 or chad.zadrazil@wisconsin.gov if you have any questions regarding this germane modification.

Sincerely,

Chad Zadrazil
Program and Policy Analyst – Advanced
Department of Safety and Professional Services


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DeWitt
Ross & Stevens s.c. Law Firm

MEMORANDUM

TO: Representative Stone

FROM: Jordan Lamb and Ron Kuehn, on behalf of the Wisconsin Veterinary Medical Association (WVMA)

Jordan Lamb

DATE: May 3, 2012

RE: Request for Changes to Proposed Wis. Admin. Code § Phar 18, Prescription Drug Monitoring Rule

The Wisconsin Pharmacy Examining Board (PEB), housed at the Department of Safety and Professional Services (DSPS), has proposed new Wis. Admin. Code § Phar 18, which creates a statewide Prescription Drug Monitoring Program (PDMP) that applies to health care practitioners, pharmacists *and veterinarians*.

On behalf of the Wisconsin Veterinary Medical Association (WVMA), we ask that the Assembly Committee on Health request that the following three (3) changes be made to proposed Phar 18 to address concerns raised by Wisconsin's veterinarians:

Amendment #1: Waive the requirement that data in fields § 18.04 (b), (d), (g), (i), (L), (m), (n), and (o) be collected for animal patients as this information is not applicable to the practice of veterinary medicine and/or adds no value to the information collected by the PDMP.

Amendment #2: Grant the Veterinary Examining Board, not the PEB, the authority under § 18.05 to specify the alternative electronic format used by veterinarians to collect information on monitored drugs dispensed to animal patients.

Amendment #3: Automatically apply the 90-day reporting requirement under § 18.07 to veterinarians so that no written request for a waiver is required.

Each amendment requested above is explained in detail in the memo that follows.

MEMORANDUM

TO: Representative Stone
FROM: Jordan Lamb and Ron Kuehn (WVMA)
DATE: May 3, 2012
PAGE: 2

A. Background – PDMP Rule Required by 2009 Act 362

The proposed PDMP rule was created by the PEB under the supervision of the DSPS (formerly the Department of Regulation and Licensing) as directed by the Wisconsin Legislature in 2009 Wisconsin Act 362. Act 362 directed the Board to create a PDMP that requires "...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 require the generation of a record when a drug is administered directly to a patient." Wis. Stat. § 450.19(2)(a) (2011) (*emphasis added*). The inclusion of the word "practitioner" in the statute applies the monitoring rule to veterinarians.

The WVMA took a very active role as the draft PDMP rule was developed this winter by the Board. The goal was to try to make the rule as workable as possible for Wisconsin veterinarians. Importantly, critical changes were made at our request by the Board. However, in our opinion, the rule still needs improvement and we plan to continue our work with the Legislature this spring.

B. PDMP Applies to Controlled Substances and Tramadol

The PDMP collects and maintains data regarding the prescribing and dispensing of monitored prescription drugs. "Monitored prescription drugs" include federally controlled substances in Schedules II-V, state controlled substances in Schedules II-V 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.

C. Rule Requires Submission of Dispensing Data

1. Required Data for Each Monitored Prescription Drug. Each time a monitored prescription drug is dispensed, 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. *Proposed* Wis. Admin. Code § Phar 18.04.

The WMVA provided comments to the Board at several points during the rule development process to ask for additional flexibility in this rule with regard to the submission of dispensing data from veterinarians because some of the above-listed fields do not lend themselves well to the practice of veterinary medicine. However, the Board declined to make any modifications to this section of the rule. Rather, the rule requires

the submission of *all* of the data fields listed above for each dispensing record for a monitored prescription drug. "A dispenser who fails to compile dispensing data as required by [the list above] 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." *Proposed* Wis. Admin. Code § Phar 18.04 (3).

Requested Amendment #1: Waive the requirement that data in fields § 18.04 (b), (d), (g), (i), (L), (m), (n), and (o) be collected for animal patients as this information is not applicable to the practice of veterinary medicine and/or adds no value to the information collected by the PDMP.

(b) The dispenser's NPI number[1] or DEA registration number. *Veterinarians do not have NPI numbers. The DEA number would work for all substances except Tramadol, which is not a controlled substance. What number should be recorded for Tramadol dispensed by veterinarians?*

(d) The prescription number. *Veterinarians do not use prescription numbers.*

(g) The estimated number of days of drug therapy. *This is not applicable to drugs dispensed to animal patients.*

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

(L) The patient's full name. *This field serves no meaningful purpose when applied to animal patients.*

(m) The patient's address, including street address, city, state and ZIP code. *This field is not applicable animal patients.*

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[1] NPI or National Provider Identification number is a unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services (CMS). Covered health care providers and all health plans and health care clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA. Individual HIPAA covered healthcare providers include: physicians, physician assistants, nurse practitioners, dentists, chiropractors, physical therapists and athletic trainers. NPI is also required for organizations such as hospitals, home health care agencies, nursing homes, residential treatment centers, group practices, laboratories, pharmacies and medical equipment companies. Use of the NPI was mandated as part of the Administrative Simplifications portion of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and CMS began issuing NPIs in October 2006. When HIPAA was established, the American Veterinary Medical Association (AVMA) asked the U.S. Department of Health and Human Services if veterinarians were covered under the Act, and were told they were not. Consequently, veterinarians have not generally obtained NPIs. There is no category for veterinarians under the NPI system.

(n) The patient's date of birth. *This information is unknown for animal patients.*

(o) The patient's gender. *This information is not applicable to animal patients. Veterinarians use categories based on other characteristics (i.e., spayed, neutered, etc.)*

2. Electronic Reporting is Required. Dispensers are required 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 (ASAP's) Implementation Guide for Prescription Monitoring Programs "or other electronic format identified by the Board." *Proposed* Wis. Admin. Code § Phar 18.05.

The WVMA worked extensively with the Board to get the language added to the rule that would allow an electronic format *other than* an ASAP format. We believe that veterinarians will have to use an alternative method for the electronic submission of data to the Board because very few have, or will have, access to an ASAP compatible format.

Requested Amendment #2: Grant the Veterinary Examining Board, not the PEB, the authority under § 18.05 to specify the alternative electronic format used by veterinarians to collect information on monitored drugs dispensed to animal patients. While the WVMA appreciates that the Board included flexibility in this area of the rule, it has become increasingly clear that the PEB lacks the knowledge and background to adequately assess the application of a prescription drug monitoring program to veterinary medical practice. In addition, the enforcement for failure to submit dispensing data under this rule is granted to "the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs." *See Proposed* Wis. Admin. Code § Phar 18.04(3). Accordingly, it only make sense to empower the Veterinary Examining Board with the authority to approve the e-record system applicable to veterinarians.

3. Timing for Submission of Data. The proposed rule generally requires dispensers to compile and submit data to the Board within 7 days of dispensing a monitored drug. However, the Board included a specific waiver provision for veterinarians. The Board "may" waive the 7-day reporting requirements for dispensers who only dispense monitored prescription drugs to non-human animal patients (*i.e.*, veterinarians) and instead allow them to report every 90 days. *Proposed* Wis. Admin. Code § Phar 18.07.

Requested Amendment #3: Automatically apply the 90-day reporting requirement under § 18.07 to veterinarians so that no written request for a waiver is required. The WVMA anticipates that most, if not all, of Wisconsin's 2,381 veterinarians would request this waiver. That means that the PEB would receive more

than 2,000 written requests that would have to be reviewed and acted upon. Rather, we believe it would be simpler, lessen this administrative burden and have no substantive effect on this rule if these waivers for additional reporting time were simply granted.

D. Note about the Estimated Economic Impact on Wisconsin Veterinarians

As noted in the materials sent to the committee by DSPS, the WVMA submitted information to the Board on two occasions during the rule-development process about the potential financial impacts that Phar 18 might have on the WVMA membership. Based on our estimations, it could be quite time-intensive and costly for veterinarians and their staff to manually record, track and record the required PDMP information into the selected electronic system because most vet clinics lack any electronic system for tracking this information.

However, we have been criticized by the PEB and the DSPS because our financial estimates were based on having staff from selected clinics *go back* and retroactively compile the required information. The Board and the DSPS believe that collecting the required information on a going-forward basis (*i.e.*, collecting the information as we go) will significantly reduce our costs and our projected financial impacts on our membership.

Accordingly, we asked two representative clinics to collect this data proactively as their work week progressed. We learned that it takes about 4 minutes per appointment to go through the file *prospectively* and collect the required PDMP information. A veterinarian on average has 14 appointments a day. That time, however, *does not* include uploading the information into an electronic format, as we cannot yet anticipate what would comprise the electronic format. We continue to evaluate time and costs of this program on Wisconsin veterinarians and will be providing additional information on this issue at the Assembly Health Committee's public hearing on Phar 18 scheduled for May 23, 2012.

For additional information, please contact Jordan Lamb at (608) 252-9358 or jkl@dewittross.com.


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Marked with WVMA's request for amendments

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.

Veterinarians do not have NPI nos.

OK for controlled substances

(c) The date dispensed.

(d) The prescription number. — n/a for animal patients

(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. — n/a for animal patients

(h) The practitioner's full name.

See (b) above

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

(j) The date prescribed.

(k) The quantity prescribed.

n/a for animal patients

(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. → the licensing board that issued the license ... (Vet Bd for veterinarians)

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 waives 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:

→ make this automatic for veterinarians

(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

State of Wisconsin

2009 Assembly Bill 227

Date of enactment: **May 18, 2010**
Date of publication*: **June 1, 2010**

2009 WISCONSIN ACT 362

AN ACT *to amend* 146.82 (1); and *to create* 450.19 of the statutes; **relating to:** directing the Pharmacy Examining Board to create a program to monitor the dispensing of prescription drugs and requiring the exercise of rule−making authority.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 146.82 (1) of the statutes is amended to read:

146.82 **(1)** CONFIDENTIALITY. All patient health care records shall remain confidential. Patient health care records may be released only to the persons designated in this section or to other persons with the informed consent of the patient or of a person authorized by the patient. This subsection does not prohibit reports made in compliance with s. 253.12 (2), 255.40, or 979.01; records generated or disclosed pursuant to rules promulgated under s. 450.19; testimony authorized under s. 905.04 (4) (h); or releases made for purposes of health care operations, as defined in 45 CFR 164.501, and as authorized under 45 CFR 164, subpart E.

SECTION 2. 450.19 of the statutes is created to read:

450.19 Prescription drug monitoring program. (1) In this section, "prescription drug" means a substance identified in s. 961.16 or 961.18 or a drug identified by the board by rule as having a substantial potential for abuse.

(2) The board shall establish by rule a program for monitoring the dispensing of prescription drugs. The program shall do all of the following:

(a) 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 require the generation of a record when a drug is administered directly to a patient.

(b) Identify specific data elements to be contained in a record documenting the dispensing of a prescription drug. In identifying specific data elements, the board shall consider data elements identified by similar programs in other states and shall ensure, to the extent possible, that records generated by the program are easily shared with other states.

(c) Specify the persons to whom a record may be disclosed and the circumstances under which the disclosure may occur. The rule promulgated under this paragraph shall permit the board to share a record generated by the program with relevant agencies of other states.

(d) Specify a secure electronic format for delivery of a record generated under the program and authorize the board to grant a pharmacist or practioner a waiver of the specified format.

(e) Specify a deadline for the delivery of a record to the board.

(f) Specify a penalty for failure to comply with rules promulgated under this subsection.

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* Section 991.11, WISCONSIN STATUTES 2007−08 : Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication as designated" by the secretary of state [the date of publication may not be more than 10 working days after the date of enactment].

(g) Maximize the potential for funding the operation of the program with available federal funding sources.

(h) Ensure that the program complies with s. 146.82 and 45 CFR part 164, subpart E.

(3) (a) A pharmacist or practitioner is immune from civil or criminal liability or professional discipline arising from the pharmacist's or practitioner's compliance in good faith with this section or with rules promulgated under this section.

(b) Nothing in this section may be construed to require a pharmacist or practitioner to obtain, before prescribing or dispensing a prescription to a patient, information about the patient that has been collected pursuant to the program described under sub. (2).

(4) Records generated under the program under this section are not subject to inspection or copying under s. 19.35.

(5) The department shall submit a timely application for a federal grant under 42 USC 280g–3 and under the Harold Rogers Prescription Drug Monitoring Program to fund the establishment and operation of the program under this section. If the department fails to obtain federal funding before January 1, 2015, this section is void.

SECTION 3m. Effective dates. This act takes effect on the day after publication, except as follows:

(1) The treatment of section 450.19 (2) of the statutes takes effect on the first day after the department of regulation and licensing receives federal funding under section 450.19 (5) of the statutes, as created by this act.


FORWARD
E PLURIBUS UNUM

Dake, Marsha

From: Jordan K. Lamb [jkl@dewittross.com]
Sent: Tuesday, May 15, 2012 9:38 AM
To: Dake, Marsha
Cc: Ron Kuehn
Subject: Update - Phar 18
Follow Up Flag: Follow up
Flag Status: Red
Attachments: WVMA Memo to SBRRB RE PDMP - May 9, 2012 (00558946).PDF

Good morning, Marsha. I just wanted to give you a brief update on the hearing that the Small Business Regulatory Review Board (SBRRB) held last Wednesday on Phar 18, the prescription drug monitoring rule. As you know, the WVMA was invited to testify as a part of the SBRRB's consideration of this rule. They also heard testimony from the DSPS.

The SBRRB was re-created by Governor Walker in 2012 as a result of 2011 Wisconsin Act 46 and Executive Order 61. This Board is charged with evaluating both new and existing administrative rules to determine whether the rules will have a "significant economic impact" on Wisconsin small businesses.

Kim Pokorny, Executive Director of the WVMA, and I presented the WVMA's projected economic effects of Phar 18 (the PDMP) on Wisconsin veterinarians, which included our projection that compliance with the rule will cost our members (as a group) at least $6 million per year (*i.e.*, about $8400 / year for the average clinic). (See attached memo that we prepared for the SBRRB hearing.)

The Board was very interested in and responsive to our concerns. They unanimously found that the rule did have a "significant economic impact" on small business in Wisconsin – in particular, Wisconsin veterinary clinics. And, they adopted motions to: (1) direct the DSPS to grant veterinarians an across-the-board 90-day timeline to report the required PDMP data; and (2) to send a letter to the Legislature to ask that when they reconvene in January 2013, they change the statute to exempt veterinarians from the PDMP entirely.

I do not have a copy of the adopted motions or report from the Board yet, but it is my understanding that they are preparing one. Representative Litjens is the chair of the SBRRB, so as a member of Assembly Health as well, she may have this information for your May 23rd hearing.

If you have any questions, please let me know.

Kind regards,

Jordan

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contained herein (including any attachments), unless specifically stated otherwise, is not intended or written to be used, and cannot be used, for the purposes of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter herein.

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DeWitt
Ross & Stevens S.C. Law Firm

MEMORANDUM

TO: Members of the Small Business Regulatory Review Board (SBRRB)

FROM: Jordan Lamb, on behalf of the Wisconsin Veterinary Medical Association (WVMA)

DATE: May 9, 2012

RE: Economic Impact of Proposed Phar 18 on WVMA Members

Thank you for inviting us to testify before the SBRRB on the potential economic impacts to Wisconsin veterinarians of proposed Wis. Admin. Code § Phar 18, creation of a prescription drug monitoring program (PDMP). The following bullets summarize our economic concerns:

- **The vast majority of Wisconsin veterinarians do not have electronic patient records.** Therefore, to comply with this rule as it is proposed, they will retype the information requested for each monitored substance into a reportable form or electronic database to send it to the Department of Safety and Professional Services (DSPS).

- Based on the WVMA's records, there are **719 veterinary clinics** in Wisconsin. Based on DSPS's records, there are about **3,000 licensed veterinarians** in Wisconsin. Therefore, the average number of veterinarians per clinic is 4.17.

- The WVMA 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 *retroactively* pull out the information listed in the rule from their records. The average time per week spent to collect this information was 4.5 hours for a week's worth of records. 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. This estimate does not include the time or costs associated with securing the state vendor's platform software or any additional software/hardware purchase.

- In response to criticism from DSPS on pulling the information retroactively, we also asked a clinic using paper records to pull out the information *prospectively* throughout one week. It took about 4 minutes per appointment to go through the patient file and collect the required information. A veterinarian on average has 14

appointments per day. That equates to **about 56 minutes per day to extract the information prospectively.** However, the clinic would have to upload the information manually into the selected electronic software. It is unclear how long that would take, but additional time would be required.

- It costs about $24/hour to pay a staff member to collect and upload this information.

- If a clinic spends 1 hour per day, 5 days a week to pull out the information and then 2 additional hours uploading that information, and pays its staff person $24/hour, the clinic will spend $168/week or **$8,400 per year** (assuming 50 weeks) complying with the rule. (Note: This estimate is only wages paid and does not include an estimate for lost revenue.)

- **If each of our 719 veterinary clinics in Wisconsin spent an average of $8,400 per year complying with this rule, the total compliance cost for Wisconsin veterinarians is at least $6,039,600 per year. If you included an estimate for lost revenue, that number would rise.**

Dake, Marsha

From: Jordan K. Lamb [jkl@dewittross.com]
Sent: Tuesday, May 15, 2012 10:14 AM
To: Dake, Marsha
Subject: Veterinarians Testifying on the 23rd

Marsha, below are the veterinarians who are coming to the Assembly Health Committee next week:

Dr. K.C. Brooks, Lodi Veterinary Care. http://www.lodivet.com/ -- President-elect of the WVMA
Dr. Dan Oberschlake, Heritage Animal Hospital, Hortonville-- also owns a second clinic in the area and has a son in veterinary school at the UW
Dr. Bob Klostermann, retired from the Middleton Veterinary Hospital -- WVMA president and a consultant to veterinary suppliers. (Practiced his whole life.)

In addition, Kim Porkorny, executive director of the WVMA, and I will also go up together.

Thanks,
Jordan

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Dake, Marsha

From: Jordan K. Lamb [jkl@dewittross.com]
Sent: Tuesday, May 15, 2012 10:51 AM
To: Dake, Marsha
Subject: Question for Leg Council - Phar 18

Good morning, Marsha. Last week at the SBRRB hearing, Senator Moulton asked whether the agency can exempt veterinarians from the PDMP Rule (proposed Phar 18). I agree with the Department when they responded that the statute requires veterinarians to be included and that an exemption must be accomplished statutorily.

However, this dialogue got me thinking about whether the statute (Wis. Stat. s. 450.19 – 2009 Wis. Act 362) would allow the Department / Pharmacy Examining Board to bifurcate the rule into two parts: (a) a PDMP for human patients and (b) a PDMP for animal patients. Then, the question is whether the DSPS could impose a delayed effective date for the animal patient potion of the rule (*i.e.*, delay the effective date for the animal patient PDMP until Jan. 1, 2015). The rule is currently set to go into effect on Jan. 1, 2013 – precisely when the next session begins. If splitting the rule into two parts and delaying the animal patient portion could be accomplished under the statute, then the delay would give the Legislature time to reconsider the policy behind including veterinarians in the PDMP, but would still, I believe, be in compliance with the statutory directive to create the monitoring program.

Would Representative Stone consider asking Legislative Council to look into this question?

Many thanks,
Jordan

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Dake, Marsha

From: Jordan K. Lamb [jkl@dewittross.com]
Sent: Wednesday, May 16, 2012 12:52 PM
To: Dake, Marsha
Subject: Meeting Summary - Phar 18
Follow Up Flag: Follow up
Flag Status: Red

Hi Marsha. As we briefly discussed, Tom Engels and I met this morning to discuss the WVMA's concerns with Phar 18, the prescription drug monitoring rule. The following blue text is what we agreed to try to accomplish with regard to the WVMA's 3 amendment requests:

Amendment #1: Waive the requirement that data in fields § 18.04 (b), (d), (g), (i), (L), (m), (n), and (o) be collected for animal patients as this information is not applicable to the practice of veterinary medicine and/or adds no value to the information collected by the PDMP. *I will verbally amend my request at the hearing and suggest/ask the PEB to allow a blanket waiver request on behalf of a large group of veterinarians under the provisions of 18.05(3). A "blanket waiver" would be used to request relief from these specifically problematic data fields for veterinarians as well as to request permission for paper filing, for those who need that option. I am not sure whether a blanket request would require a rule change, but it seems like a good way to accomplish relief from those problematic fields in 18.04.*

Amendment #2: Grant the Veterinary Examining Board, not the PEB, the authority under § 18.05 to specify the alternative electronic format used by veterinarians to collect information on monitored drugs dispensed to animal patients. *I will state at the hearing that this request does not necessarily require a rule change, but that we respectfully request that the PEB consult with the VEB as the vendor selection process proceeds. Their input into this process would be greatly appreciated.*

Amendment #3: Automatically apply the 90-day reporting requirement under § 18.07 to veterinarians so that no written request for a waiver is required. *I maintain this request for an automatic 90-day reporting period for veterinarians.*

In addition, I will touch base with Greg Gasper and ask him about the VEB participation in the vendor-selection process and alert him to my blanket waiver request to solve the issues related to Amendment #1. It would be helpful to know whether and how the Health Committee could request modifications to this rule and what the options are for agency/PEB response. I will look into this as well.

Please let me know if you or Rep. Stone has any questions.

Kind regards,

Jordan

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USPS May 18, 2012

CR 12-009
List of Draft Modifications

1) **Add definition of "veterinary dispenser" to 18.02**
   - "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 18.04 (1) to be made up of definitions of terms that are only used in the data elements**
   - Move 18.02 (6), (14) and (15) to the new 18.04 (1)
   - Create definitions for "dispenser identifier" and "practitioner identifier"
     - "Dispenser identifier" means the DEA registration number, NPI number or unique state-issued credential, permit or license number issued to a dispenser.
     - "Practitioner identifier" means the DEA registration number, NPI number or unique state-issued credential, permit or license number issued to a practitioner.

3) **Modify 18.04 (2) (b), (d), (i), (m) and (n) to state:**
   - (b) The dispenser's identifier.
   - (d) The prescription number, if applicable.
   - (i) The practitioner's identifier.
   - (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.
   - (n) The patient's date of birth, or if the patient is an animal, the owner of the patient's date of birth.

4) **Modify 18.06 to address "dispensers" and "veterinary dispensers"**
   - (1) A dispenser, other than a veterinary dispenser, shall submit dispensing data to the board within 7 days of dispensing a monitored prescription drug.
   - (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.
   - (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: . . .
   - (4) A veterinary dispenser shall submit dispensing data to the board within 90 days of dispensing a monitored prescription drug.
   - (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.
   - (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.
- (7) Unless otherwise specified by the board, an emergency waiver granted under subs. (3) or (6) shall only be effective for 7 days.
- (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.
- (9) A veterinary dispenser who fails to submit dispensing data or a zero report as required by 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.

5) Delete 18.07

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

7) Renumber the sections and update the internal references

CHAPTER PHAR 18

PRESCRIPTION DRUG MONITORING PROGRAM

Comment [CZ1]: The renumbering of the sections, subsections and paragraphs and the updates to internal references are made in-line with the text of the rule.

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.~~

Comment [CZ2]: Proposed Change

~~(7~~ (6) "Department" means the department of safety and professional services.

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

(~~9~~8) "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~~9) "Dispenser delegate" means an agent or employee of a dispenser to whom the task of inputting or accessing PDMP information has been delegated.

(~~11~~10) "Dispensing data" means data compiled pursuant to s. Phar 18.04.

(~~12~~11) "Drug" has the meaning given in s. 450.01 (10), Stats.

(~~13~~12) "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.~~

Comment [CZ3]: Proposed Change.

(~~16~~13) "Patient" has the meaning given in s. 450.01 (14), Stats.

(~~17~~14) "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~~15) "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~~12.

(~~19~~16) "Pharmacy" means any place of practice licensed by the board under ss. 450.06 or 450.065, Stats.

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

(~~21~~18) "Practitioner delegate" means an agent or employee of a practitioner to whom the practitioner has delegated the task of accessing PDMP information.

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

(~~23~~20) "Prescription order" has the meaning given in s. 450.01 (21), Stats.

(~~24~~21) "Program" means the prescription drug monitoring program established under this chapter.

(~~25~~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. Comment [CZ4]: Proposed Change.

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

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) As used in this section:

(a) "DEA registration number" means the registration number issued to a dispenser or practitioner by the federal department of justice, drug enforcement administration. Comment [CZ5]: April 4 Germane Modification.

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

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

(d) "NPI number" means national provider identifier number, the registration number issued to a dispenser or practitioner by the national provider identifier registry. Comment [CZ6]: April 4 Germane Modification.

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

(2) Subject to s. Phar 18.~~09~~08, a dispenser shall compile dispensing data that contains information about each time he or she dispenses a monitored prescription drug to a patient. Comment [CZ7]: Proposed Change.

(~~2~~3) 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~~identifier. Comment [CZ8]: Proposed Change.

(c) The date dispensed.

(d) The prescription number if applicable

Comment [CZ9]: Proposed Change

(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~~ identifier

Comment [CZ10]: Proposed Change

(j) The date prescribed.

(k) The quantity prescribed.

(L) The patient's full name.

(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

Comment [CZ11]: Proposed Change

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

Comment [CZ12]: Proposed Change

(o) The patient's gender.

(~~34~~) A dispenser who fails to compile dispensing data as required by subs. (~~1~~2) and (~~2~~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 18.05 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, other than a veterinary dispenser, shall submit dispensing data to the board within 7 days of dispensing a monitored prescription drug.

(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.

(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:

(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) A veterinary dispenser shall submit dispensing data to the board within 90 days of dispensing a monitored prescription drug.

(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.

(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.

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.

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

(~~5~~8) A dispenser who fails to submit dispensing data or a zero report as required by subs. (1) and (2), be granted ~~a~~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.

~~**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.~~

~~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)~~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.

Comment [CZ13]: Proposed Change.

Phar 18.~~08~~07 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~~08 Exemptions from compiling and submitting dispensing data. (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew 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 [CZ14]: April 4 Germane Modification.

Phar 18.~~10~~09 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~~10 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~~ss. Phar 18.06 (3~~.~~) or (6).

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

Comment [CZ15]: Proposed Change

(c) 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~~09 (3).

Comment [CZ16]: April 4 Germane Modification

(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~~11 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. 146.82 (2) (a) 21., Stats.

Comment [CZ17]: April 4 Germane Modification.

(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 ss. 146.82 (2) (a) 6. or 20., Stats.

Comment [CZ18]: April 4 Germane Modification.

(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 [CZ19]: April 4 Germane Modification.

(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 [CZ20]: April 4 Germane Modification.

(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~~12 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 dispensing data as part of the assigned duties and responsibilities under s. 450.19, Stats., and this chapter.

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

(d) Other legally authorized purposes.

Phar 18.~~14~~13 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~~14 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 monitoring program to the program, the board may consider any of the following:

Comment [CZ22]: April 4 Germane Modification.

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

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

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

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

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

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

Comment [CZ24]: April 4 Germane Modification.