STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

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

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted:

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

Statutory authority:

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

Explanation of agency authority:

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

Related statute or rule:

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

Plain language analysis:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There is no existing or proposed federal regulation.

Comparison with rules in adjacent states:

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

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

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

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

Summary of factual data and analytical methodologies:

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

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

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

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

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

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

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

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

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

Anticipated costs incurred by the private sector:

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

Fiscal Estimate:

The Fiscal Estimate and Economic Impact Analysis are attached.

Effect on small business:

The Final Regulatory Flexibility Analysis is attached.

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

The statutes interpreted are more specific per the Clearinghouse Report.

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

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

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

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

Agency contact person:

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

TEXT OF RULE

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

CHAPTER PHAR 18

PRESCRIPTION DRUG MONITORING PROGRAM

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

Phar 18.02 Definitions. As used in this chapter:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) Tramadol.

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

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

(a) The dispenser's full name.

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

(c) The date dispensed.

(d) The prescription number.

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

(f) The quantity dispensed.

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

(h) The practitioner's full name.

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

(j) The date prescribed.

(k) The quantity prescribed.

(L) The patient's full name.

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

(n) The patient's date of birth.

(o) The patient's gender.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Note: The written notice to the board may be submitted through an account with the board, sent by electronic mail or sent by U.S. mail to the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

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

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

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

Note: The application for an exemption may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) The reason for requesting a review.

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

(4) No discovery is permitted.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(6) The board shall disclose the minimum amount of PDMP information necessary to designated staff of the department who is charged with investigating dispensers, dispenser delegates, practitioners and practitioner delegates in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) Other legally authorized purposes.

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

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

Phar 18.15 Exchange of PDMP information. (1) The board may exchange PDMP information with a prescription monitoring program operated by a relevant agency in another jurisdiction if the prescription monitoring program satisfies all of the following conditions:

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

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

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

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

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

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

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

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

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

(END OF TEXT OF RULE)

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

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board