Clearinghouse Rule 12-009

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 -)

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 s. 227.135 (2), 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:

Chapters 961 and 450, 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., as amended by 2009 Act 362, the legislature directs the Pharmacy Examining Board (Board) to establish by rule a prescription drug monitoring program (PDMP). 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, 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 any 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;
- name and strength of the prescription drug;
- NDC number;
- 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 submit the data to the Board electronically, in the standard established by the American Society for Automation in Pharmacy's Implementation Guide for Prescription Monitoring Programs.

Under the proposed rule, the Board may grant waivers to dispensers who are not able to comply with the 7-day reporting or the electronic data submission requirements. Therefore, dispensers who are not able to comply with one or both of the reporting or submission requirements may submit to the Board an application for a 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 and dispensers will be able create accounts with the Board to access the database and view information that may be helpful in determining whether a patient is using any of the specific prescription drugs illicitly. 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.

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 seven 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 has also solicited feedback from approximately forty stakeholders that represent practitioners, pharmacists, pharmacies, public health agencies and law enforcement agencies. Stakeholders have been updated throughout the development of the draft rules and have provided comments on the proposed rule. The Board will consult with the stakeholders as implementation of the PDMP continues.

Further, there are currently 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 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 Grant that the Department received 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 has 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. During that period, the Department held an informal roundtable with stakeholders and members of the public who expressed interest on January 15, 2012 to solicit feedback.

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. The comments are attached to the Economic Impact Analysis. 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 Initial Regulatory Flexibility Analysis.

Anticipated costs incurred by the private sector:

As described in the Economic Impact Analysis and Initial 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:

Attached is the Fiscal Estimate and Economic Impact Analysis.

Effect on small business:

Attached is the Initial Regulatory Flexibility Analysis.

Copies of the Proposed Rule, Fiscal Estimate, Economic Impact Analysis or Initial 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), 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 ch. Phar 18:

(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) “Business day” means a business day, as defined in s. 421.301 (6), Stats., that is not a legal holiday under s. 995.20, Stats. or a federal legal holiday.

(6) “Controlled substance” means a drug, substance, analog or precursor that is included in:

(a) Schedule II, III, IV or V in the federal controlled substances act, 21 USC 812(b)(2), (b)(3), (b)(4), (b)(5) and (c)); or

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

(7) “DEA registration number” means the registration number issued to a pharmacy or practitioner by the department of justice, drug enforcement administration.

(8) “Department” means the department of safety and professional services.

(9) “Dispense” has the meaning given in s. 450.01 (7), Stats.

(10) “Dispenser” means a person licensed in this state to dispense drugs or licensed in another state and recognized by this state as a person authorized to dispense drugs.

(11) “Dispenser delegate” means an agent or employee of a dispenser to whom it has delegated the task of inputting or accessing PDMP information.

(12) “Dispensing data” means data compiled pursuant to s. Phar 18.03.

(13) “Drug” has the meaning given in s. 450.01 (10), Stats.

(14) “NDC number” means the universal product identifier used in the U.S. to identify a specific human drug product.

(15) “NPI number” means 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 data compiled and stored by the board from dispensing data submitted to it by dispensers and other information pertaining to the program.

(19) "Pharmacy" means any place of practice licensed by the board under s. 450.06, 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 it has delegated the task of accessing PDMP information.

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

(23) "Prescription drug" (a) means the following:

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

2. a controlled substance as defined in s. Phar 18.02 (6); and

3. a drug identified by the board as having a substantial potential for abuse, including Tramadol.

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

(24) "Prescription Order" has the meaning given in s. 450.01 (21), Stats.

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

(26) "Submit" means the electronic delivery of dispensing data compiled pursuant to s. Phar 18.03 to the board.

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

Phar 18.03 Dispensing data. (1) Subject to s. 18.06, a dispenser shall compile dispensing data that contains information about each time he or she dispenses a prescription drug to a patient.

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

(a) dispenser's full name;

(b) dispenser's NPI number or DEA registration number;

(c) date dispensed;

(d) prescription number;

(e) name and strength of the prescription drug;

(f) NDC number;

(g) quantity dispensed;

(h) estimated number of days of drug therapy;

(i) practitioner's full name;

(j) practitioner's NPI number or DEA registration number, if applicable;

(k) date prescribed;

(L) quantity prescribed;

(m) patient's full name;

(n) patient's address, including street address, city, state and ZIP code;

(o) patient's date of birth; and

(p) patient's gender.

(3) A dispenser who fails to compile dispensing data as required under this chapter is subject to disciplinary action by the appropriate licensing board.

Phar 18.04 Submission of dispensing data. (1) Subject to s. 18.06 and subs. (3) and (4), a dispenser shall submit dispensing data to the board electronically within 7 days of dispensing a prescription drug.

(2) Subject to s. 18.06 and sub. (5), a dispenser shall submit dispensing data to the board electronically in the format identified in the American society for automation in pharmacy (ASAP) implementation guide for prescription monitoring programs.

(3) The board may grant a waiver from the requirements of sub. (1) to a dispenser if the dispenser is not able to submit dispensing data within 7 days of dispensing a prescription drug if:

(a) the dispenser is unable to submit dispensing data as required by sub. (1) because of circumstances beyond its control; and

(b) the dispenser files with the board a written application for an extension on a form provided by the board prior to the required submission of dispensing data under sub. (1).

(4) The board may grant a waiver from the requirements of subs. (1) and (6) to a dispenser who solely dispenses a prescription drug to a patient that is an animal if the dispenser:

(a) agrees to submit dispensing data in accordance with the electronic reporting requirements of this section, unless waived by the board;

(b) agrees to submit dispensing data compiled under s. Phar 18.03 to the board every 90 days;

(c) agrees to submit a zero report to the board if he or she does not dispense a prescription drug for 90 days; and

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

(5) If a dispenser is not able to electronically submit dispensing data as required by sub. (2), the board may grant a waiver to a dispenser under the following conditions:

(a) The dispenser does not have an electronic recordkeeping system capable of compiling dispensing data as specified in s. Phar 18.03 and both of the following conditions are met:

1. The dispenser agrees in writing to immediately begin filing paper dispensing data on a form provided by the board for each prescription drug dispensed.

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

(b) The dispenser has an electronic recordkeeping system capable of compiling dispensing data as specified in s. Phar 18.03 and both of the following conditions are met:

1. A substantial hardship is created by circumstances beyond the dispenser's control.

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

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

(7) A dispenser who fails to submit dispensing data or submits false information to the board is subject to disciplinary action by the appropriate licensing board.

Phar 18.05 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 3 business days and submit written documentation that identifies the erroneous information and includes the correct information.

Phar 18.06 Exemptions from compiling and submitting dispensing data. (1) A dispenser is not required to compile or submit dispensing data when the prescription drug is administered directly to a patient.

(2) 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 prescription drug, if the dispenser:

(a) provides evidence sufficient to the board that he or she does not dispense a prescription drug; and

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

Phar 18.07 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, vendors and other agents of the board shall only have access to the minimum amount of PDMP information necessary for the following purposes:

(a) the design, implementation, operation, and maintenance of the PDMP database, including the electronic reporting system, 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; and

(c) other legally authorized purposes.

Phar 18.08 Access to and disclosure of PDMP information. (1) The board shall provide access to and disclose PDMP information in accordance with ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of health care information.

(2) The board shall not grant access to or disclose PDMP information to a person unless the person provides evidence satisfactory to the board that the person requesting PDMP information is entitled to the information.

(3) The board shall grant access to PDMP information to a dispenser or dispenser delegate and a practitioner or practitioner delegate. To obtain access to PDMP information, a dispenser or dispenser delegate or practitioner or practitioner delegate shall file with the board a written application for an account on a form provided by the board.

(4) Subject to pars. (a) to (i), upon receiving evidence satisfactory to the board that the person requesting PDMP information is entitled to the information, the board shall disclose PDMP information to the following persons:

(a) *Patient*. To obtain PDMP information, a patient shall:

1. file with the board a notarized request for PDMP information on a form provided by the board; or

2. appear in person at the department with two forms of valid government-issued proof of identity, one of which is photographic, and a request for PDMP information on a form provided by the board.

(b) *Person authorized by the patient*. To obtain PDMP information, a person authorized by a patient shall file with the board a notarized request for PDMP information on a form provided by the board and in accordance with s. 146.82, Stats.

(c) *Health care facility staff committee, or accreditation or health care services review organization.* To obtain PDMP information, a health care facility staff committee, or accreditation or health care services review organization shall file with the board a written request for PDMP information on a form provided by the board and in accordance with s. 146.82, Stats.

(d) *Public health official and other public and private entity*. To obtain PDMP information, a public health official or other public or private entity shall file with the board a written request for PDMP information on a form provided by the board and in accordance with s. 146.82, Stats.

(e) *Federal and state governmental agency*. To obtain PDMP information, a federal or state governmental agency shall file with the board a written request for PDMP information on a form provided by the board and in accordance with s. 146.82, Stats.

(f) *Law enforcement authority*. To obtain PDMP information, a federal, state or local law enforcement authority shall file with the board:

1. a written request for PDMP information on a form provided by the board; and

2. a lawful order of a court of record or evidence otherwise required by s. 146.82, Stats.

(g) *Coroner, deputy coroner, medical examiner or medical examiner's assistant*. To obtain PDMP information following the death of a patient, a coroner, deputy coroner, medical examiner or medical examiner's assistant shall file with the board a written request for PDMP information on a form provided by the board and in accordance with s. 146.82, Stats.

(h) *Department staff*. To obtain PDMP information, department staff or staff of another licensing board who have been delegated the authority to investigate a dispenser or practitioner shall file with the board a written application for an account on a form provided by the board and in accordance with s. 146.82, Stats.

(i) *Relevant agency in another state*. To obtain PDMP information, staff of a relevant agency in another state with which the program is not currently exchanging PDMP information under s. 18.12 shall file with the board:

1. a written application for an account on a form provided by the board; and

2. a written request for PDMP information that specifically indicates the legally authorized purpose for the information.

(5) A person in possession of PDMP information shall only use PDMP information for purposes authorized under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of health care information.

Phar 18.09 Limiting access to PDMP information. The board may suspend, revoke or otherwise restrict or limit a dispenser's, dispenser delegate's, practitioner's or practitioner delegate's account to access PDMP information for any of the following reasons:

(1) the dispenser, dispenser delegate, practitioner or practitioner delegate is no longer licensed in this state to prescribe or dispense prescription drugs;

(2) the dispenser, dispenser delegate, practitioner or practitioner delegate is no longer licensed in another state and recognized by this state as a person authorized to prescribe or dispense prescription drugs;

(3) the board disciplines the dispenser, dispenser delegate, practitioner or practitioner delegate;

(4) another licensing board disciplines the dispenser, dispenser delegate, practitioner or practitioner delegate;

(5) a licensing board or equivalent agency in another jurisdiction disciplines the dispenser, dispenser delegate, practitioner or practitioner delegate;

(6) 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 health care information; or

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

Phar 18.10 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 health care information, shall be subject to disciplinary action by the appropriate licensing board and all appropriate civil penalties.

Phar 18.11 Exchange of PDMP information. (1) The board may exchange PDMP information with a relevant agency in another U.S. state subject to the following:

(a) The relevant agency's prescription drug monitoring program is compatible with the program.

(b) The relevant agency in the other jurisdiction agrees to exchange similar information with the program.

(2) In determining the compatibility of the relevant agency's prescription drug monitoring program, the board may consider the following:

(a) the safeguards for privacy of patient records and the agency's success in protecting patient privacy;

(b) the persons authorized by the agency to access the information stored by its prescription drug monitoring program;

(c) the schedules of controlled substances monitored by the agency;

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

(e) the costs and benefits to the board of mutually sharing information with the agency.

(3) The board may assess the agency's 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