CR 14-003

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	CLEARINGHOUSE RULE 14-003

ORDER

An order of the Pharmacy Examining Board to repeal Phar 18.04(3)(intro), 18.04(3)(k), 18.11(3), 18.11(4), 18.11(9)(a), 18.11(9)(b), and 18.11(9)(c); to renumber Phar 18.04(3)(a), 18.04(3)(b), 18.04(3)(c), 18.04(3)(d), 18.04(3)(e), 18.04(3)(f), 18.04(3)(g), 18.04(3)(h), 18.04(3)(i), 18.04(3)(j), 18.04(3)(o); to renumber and amend Phar 18.04(2), 18.04(3)(L), 18.04(3)(m), 18.04(3)(n); to amend Phar 18.02(8)(a), 18.02(9), 18.02(15)(intro), 18.02(17), 18.04(title), 18.04(4), 18.05(1), 18.05(1)(note), 18.05(2)(note), 18.05(3)(b)(note), 18.05(4), 18.06(2), 18.06(3)(b)(note), 18.06(6)(b)(note), 18.06(8), 18.07, 18.08(1)(a), 18.08(1)(b)(note), 18.09, 18.10(1)(intro), 18.10(2)(intro), 18.10(2)(b), 18.10(3), 18.10(6), 18.10(7), 18.11(6)(intro), 18.11(9)(intro), 18.11(10)(c)(note), 18.12(4), and 18.14(1)(intro); and to create Phar 18.02(11g), 18.02(11r), 18.02(15g), 18.02(15r), 18.04(2)(ge), 18.04(2)(gm), 18.04(2)(gs) and 18.08(3) relating to the prescription drug monitoring program.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: § 450.19, Wis. Stats.

Statutory authority: §§ 15.08 (5)(b), 450.19(2) and 961.31, Wis. Stats.

Explanation of agency authority:

The board has authority to promulgate rules for the guidance of the profession and to interpret the provisions of the statutes it enforces. The board also has authority to promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within Wisconsin.

Specifically, the legislature directs the board to establish rules to govern the prescription drug monitoring program.

Related statute or rule: § 450.19, Wis. Stats. and ch. Phar 18, Wis. Admin. Code

Plain language analysis:

This proposed rule modifies the ch. Phar 18 to improve the efficiency of the Prescription Drug Monitoring Program (PDMP) by ensuring consistency between the language of the rule and how PDMP functions.

Sections 1, 2, 3, 4, 5, 6 clarify and simplify definitions. A dispenser is a pharmacy. Dispenser delegate is a managing pharmacist or an agent or employee of a practitioner who has the delegated responsibility for data compilation and submission to PDMP. Managing pharmacist, pharmacist and practitioner definitions are identical to definitions in the statutes. Pharmacist delegate is an agent of a pharmacist who has been delegated access to PDMP information.

Section 7 clarifies the title of s. Phar 18.04 to "compilation of dispensing data".

Section 8 changes the "he or she" to dispenser. It also becomes an introduction paragraph to the items currently listed under s. Phar 18.04(3)(intro).

Section 9 repeals the introduction section.

Sections 10, 12, 14, 15 renumbers the dispensing data so that it is under the new introductory statement created in Section 8.

Sections 11, 13, 14 amend the dispensing data. The classification codes for payment type and refill information are added. The quantity prescribed is no longer required data. There is clarification of how to record an animal patient's name, address and birthdate.

Sections 16, 20 and 24 add dispenser delegate as subject to discipline for failing to compile required dispensing data.

Section 17 clarifies the rule that unless exempt, a dispenser shall electronically submit data.

Sections 18, 19, 22, 23, 27 and 39 update the P.O. Box number for the Department in all the notes in ch. Phar 18 which reference the Department's address.

Section 21 clarifies that the dispenser shall submit a zero report for each 7 day period during which the dispenser did not dispense a monitored prescription drug.

Section 25 clarifies if incorrect dispensing data had been submitted, the dispenser shall submit the correct information within 7 days.

Section 26 removes the "he or she" reference and inserts "dispenser".

Section 28 clarifies a dispenser is not required to compile or submit information on non-narcotics identified in schedule V of the Wisconsin Controlled Substances Act that are dispensed in an amount intended to last 7 days or less.

Sections 29, 30, 31, 33 and 34 remove "dispenser" and "dispenser delegate" throughout ss. Phar 18.09, 18.10(1)(intro), 18.10(b), 18.10(3), 18.10(6) and (7) and replaces with the terms "pharmacist" and "pharmacist delegate".

Section 32 requires a specific statute or rule to be given when requesting a review.

Section 35 repeals the requirement for the board to disclose PDMP information to staff of a relevant agency in another state who are authorized to access confidential patient health care records under ss. 146.82 and 450.19, Stats. It also repeals the requirement to disclose the minimum amount of PDMP information necessary to health care facility staff committees or accreditation or health care services review organizations.

Section 36 adds that the board will disclose the minimum amount of PDMP information necessary to staff who are investigating pharmacists and pharmacist delegates.

Section 37 clarifies that the board may disclose de-identified PDMP information which does not identify any patient upon request.

Section 38 repeals the requirements for a researcher to obtain PDMP information.

Section 40 adds pharmacist and pharmacist delegate to the list of people which the board maintains a log regarding their access to PDMP information.

Section 41 clarifies relevant agencies in other jurisdictions with prescription drug monitoring programs by adding the word "state."

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

None. Prescription drug monitoring programs are operated by the state jurisdictions.

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. Dispensers are required to submit the method of payment the patient used for a prescription. *See* 720 Illinois Compiled Statutes 570/316-21 and Illinois Administrative Code Title 77, Chapter X, Subchapter e, Part 2080. Dispensers are not required to submit refill information.

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. Dispensers are required to submit refill information and the method of payment the patient used for a prescription. *See* Iowa Code § 124.551-58 and Iowa Administrative Code Title 657, Chapter 37.

Michigan: The statutes, administrative rules, and requirements for the Michigan Automated Prescription System require dispensers to submit to a database similar information regarding the prescribing and dispensing of controlled substances. Dispensers are required to submit refill information and the method of payment the patient used for a prescription. *See* Michigan Public Health Code § 333.7333and Michigan Administrative Code R. 338.471, and "List of Required Fields," Michigan Automated Prescription System (MAPS). *See also* http://www.michigan.gov/documents/lara/lara_MAPS_ASAP2009_ListofRequiredFields_365562_7.pdf, accessed on Dec. 17, 2013.

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 on a daily basis. Dispensers are not required to submit refill information or the method of payment the patient used for a prescription. *See* Minnesota Statute 152.126.

Summary of factual data and analytical methodologies:

The Board received feedback while developing and deploying the prescription drug monitoring program and gained considerable expertise in ways to improve it once it became fully operational.

The Board is aware that currently there are some provisions which create inefficiencies and ambiguities that the PDMP has to overcome to be as effective of a tool to combat prescription drug misuse and abuse as it can be. This proposed rule corrects and updates those provisions.

All the modifications are based on feedback from stakeholders and the prescription drug monitoring program users as well as other information obtained while developing and deploying the prescription drug monitoring program.

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

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Tom.Engels@wisconsin.gov, or by calling (608) 266-8608.

Agency contact person:

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

TEXT OF RULE

SECTION 1. Phar 18.02(8)(a) is amended to read:

Phar 18.02(8)(a) A pharmacy ~~from where a pharmacist dispenses a monitored prescription drug~~.

SECTION 2. Phar 18.02(9) is amended to read:

Phar 18.02 (9) "Dispenser delegate" means ~~an agent or employee of a dispenser to whom the task of inputting or accessing PDMP information has been delegated~~ any of the following:

(a) A managing pharmacist of a pharmacy.

(b) An agent or employee of a practitioner who has been delegated the task of satisfying the data compilation and submission requirements of ss. Phar 18.04 and Phar 18.05.

SECTION 3. Phar 18.02(11g) and (11r) are created to read:

Phar 18.02 (11g) "Hospital" has the meaning given in s. 50.33(2), Stats.
Phar 18.02 (11r) "Managing pharmacist" has the meaning given in s. Phar 1.02(6).

SECTION 4. Phar 18.02(15)(intro) is amended to read:

Phar 18.02(15) "PDMP information" means ~~all~~ any of the following:

SECTION 5. Phar 18.02(15g) and (15r) is created to read:

Phar 18.02 (15g) "Pharmacist" has the meaning given in s. 450.01(15), Stats.

Phar 18.02 (15r) "Pharmacist delegate" means an agent of a pharmacist to whom the pharmacist has delegated the task of accessing PDMP information.

SECTION 6. Phar 18.02(17) is amended to read:

Phar 18.02(17) "Practitioner" has the meaning given in s. ~~450.01(17)~~ 450.19(1)(ar), Stats.

SECTION 7. Phar 18.04 (title) is amended to read:

Phar 18.04 ~~Dispensing~~ Compilation of dispensing data.

SECTION 8. Phar 18.04(2) renumbered to 18.04(2)(intro) and is amended to read:

Phar 18.04 (2)(intro) Subject to s. Phar 18.08, a dispenser shall compile dispensing data that contains the following information ~~about~~ each time ~~he or she~~ the dispenser dispenses a monitored prescription drug: ~~to a patient.~~

SECTION 9. Phar 18.04(3)(intro) is repealed.

SECTION 10. Phar 18.04(3)(a) to (g) is renumbered to Phar 18.04(2)(a) to (g)

SECTION 11. Phar 18.04(2)(ge), (gm) and (gs) are created to read:

Phar 18.04(2) (ge) The classification code for payment type.
Phar 18.04(2)(gm) The number of refills authorized by the prescriber.
Phar 18.04(2) (gs) The refill number of the prescription.

SECTION 12. Phar 18.04(3)(h) to (j) is renumbered to Phar 18.04(2)(h) to (j)

SECTION 13. Phar 18.04(3)(k) is repealed.

SECTION 14. Phar 18.04(3)(L) to (n) are renumbered to Phar 18.04(2)(L) to (n) and amended to read:

Phar 18.04(2)(L) The patient's full name or if the patient is an animal, the animal's name and the owner's last name.

Phar 18.04(2)(m) The patient's address, or if the patient is an animal, ~~the owner of the~~ patient's owner's address, including street address, city, state and ZIP code.

Phar 18.04(2)(n) The patient's date of birth, or if the patient is an animal, ~~the owner of the~~ patient's owner's date of birth.

SECTION 15. Phar 18.04(3)(o) is renumbered to Phar 18.04(2)(o).

SECTION 16. Phar 18.04(4) is amended to read:

Phar 18.04(4) A dispenser and dispenser delegate, if applicable, who ~~fails~~ fail to compile dispensing data as required by subs. (2) and (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.

SECTION 17. Phar 18.05(1) and (note) is amended to read:

Phar 18.05(1) ~~A~~ Unless exempt under s. Phar 18.08, a dispenser shall ~~create an account with the board through which the dispenser shall submit dispensing data to the board~~ electronically submit dispensing data through an account with 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~~ 8366, Madison, WI 53708.

SECTION 18. Phar 18.05(2)(note) is amended to read:

Phar 18.05(2) 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 obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box ~~8935~~ 8366, Madison, WI 53708.

SECTION 19. Phar 18.05(3)(b)(note) is amended to read:

Phar 18.05(3)(b) Note: The application for a waiver may be obtained 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~~ 8366, Madison, WI 53708.

SECTION 20. Phar 18.05(4) is amended to read:

Phar 18.05(4) A dispenser and dispenser delegate, if applicable, who ~~fails~~ fail to create an account with the board and submit dispensing data as required by subs. (1) and (2) or be granted a waiver sunder 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.

SECTION 21. Phar 18.06(2) as amended by Clearinghouse Rule 13-065 is further amended to read:

Phar 18.06 (2) If a dispenser does not dispense a monitored prescription drug for 7 days, the dispenser shall submit a zero report to the board for each 7-day period during which the dispenser did not dispense a monitored prescription drug.

SECTION 22. Phar 18.06(3)(b)(note) is amended to read:

Phar 18.06(3)(b)Note: The application for an emergency waiver may be obtained 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~~ 8366, Madison, WI 53708.

SECTION 23. Phar 18.06(6)(b)(note) is amended to read:

Phar 18.06(6)(b)Note: The application for an emergency waiver may be obtained 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~~ 8366, Madison, WI 53708.

SECTION 24. Phar 18.06(8) is amended to read:

Phar 18.06 (8) A dispenser and dispenser delegate, if applicable, who ~~fails~~ fail to submit dispensing data or a zero report as required by subs. (1) and (2), or be granted an emergency waiver under sub. (3), or a dispenser and a dispenser delegate, if applicable, who ~~submits~~ submit 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.

SECTION 25. Phar 18.07 is amended to read:

Phar 18.07 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 within 7 days. 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~~ 8366, Madison, WI 53708.

SECTION 26. Phar 18.08(1)(a) is amended read:

Phar 18.08(1)(a) The dispenser provides evidence sufficient to the board that ~~he or she~~ the dispenser does not dispense monitored prescription drugs.

SECTION 27. Phar 18.08(1)(b)(note) is amended to read:

Phar 18.08(1)(b)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~~ 8366, Madison, WI 53708. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

SECTION 28. Phar 18.08(3) is created to read:

Phar 18.08(3) A dispenser is not required to complile or submit dispensing data when the monitored prescription drug is a substance listed in the schedule in s. 961.22, Stats. and is not a narcotic drug, as defined in s. 961.01(15), Stats., and is dispensed pursuant to a prescription order for a number of doses that is intended to last the patient 7 days or less.

SECTION 29. Phar 18.09 is amended to read:

Phar 18.09 (1) ~~Dispensers, dispenser delegates,~~ Pharmacists, pharmacist delegates, practitioners, 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, dispenser delegates,~~ pharmacists, pharmacist delegates, practitioners, and practitioner delegates shall ~~create an account with the board on a form provided by the board~~ do one of the following:

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

(b) Create an account with a prescription monitoring program operated by a relevant agency in another jurisdiction with whom the board exchanges PDMP information pursuant to s. Phar 18.14.

(c) Create an account with a pharmacy or other entity at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of PDMP information or that is connected to and lawfully obtains data from the state-designated entity under ch. 153, Stats.

(d) Create an account with a hospital or other entity at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of PDMP information or that is connected to and lawfully obtains data from the state-designated entity under ch. 153, Stats.

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~~ 8366, Madison, WI 53708.

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

(a) The ~~dispenser, dispenser delegate,~~ pharmacist, pharmacist delegate, practitioner, or practitioner delegate uses PDMP information in violation of s. 146.82 or 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,~~ pharmacist, pharmacist 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, or other licensing board, or regulatory agency takes adverse action against the ~~dispenser, dispenser delegate,~~ pharmacist, pharmacist delegate, practitioner, or practitioner delegate.

(d) A licensing board or equivalent regulatory agency in another jurisdiction takes adverse action against the ~~dispenser, dispenser delegate,~~ pharmacist, pharmacist delegate, practitioner, or practitioner delegate.
(e) The federal department of justice, drug enforcement administration takes adverse action against the ~~dispenser, dispenser delegate,~~ pharmacist, pharmacist delegate, practitioner, or practitioner delegate.
(f) The ~~dispenser, dispenser delegate,~~ pharmacist, pharmacist 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~~ pharmacist delegate or practitioner delegate is no longer delegated the task of ~~inputting or~~ accessing PDMP information.

SECTION 30. Phar 18.10(1)(intro) is amended to read:

Phar 18.10(1) A ~~dispenser, dispenser delegate,~~ pharmacist, pharmacist delegate, practitioner, or practitioner delegate may request that the board review any of the following:

SECTION 31. Phar 18.10(2)(intro) is amended to read:

Phar 18.10 (2) To request a review, the ~~dispenser, dispenser delegate,~~ pharmacist, pharmacist 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:

SECTION 32. Phar 18.10(2)(b) is amended to read:

Phar 18.10(2) (b) The ~~reason for requesting a review~~ citation to the specific statute or rule on which the request is based.

SECTION 33. Phar 18.10(3) is amended to read:

Phar 18.10 (3) The board shall conduct the review at its next regularly scheduled meeting and notify the ~~dispenser, dispenser delegate~~, pharmacist, pharmacist delegate, practitioner, or practitioner delegate of the time and place of the review.

SECTION 34. Phar 18.10(6) and (7) are amended to read:

Phar 18.10 (6) The board shall provide the ~~dispenser, dispenser delegate,~~ pharmacist, pharmacist 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,~~ pharmacist, pharmacist 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.

SECTION 35. Phar 18.11(3) and (4) are repealed.

SECTION 36. Phar 18.11(6)(intro) is amended to read:

Phar 18.11 (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, pharmacists, pharmacist 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:

SECTION 37. Phar 18.11(9)(intro) is amended to read:

Phar 18.11 (9) The board ~~shall~~ may disclose ~~the minimum amount of~~ de-identified 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:~~ which does not and cannot be reasonably used to identify any patient upon written request.

SECTION 38. Phar 18.11(9)(a), (b) and (c) are repealed.

SECTION 39. Phar 18.11(10)(c)(note) is amended to read:

Phar 18.11(10)(c)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~~ 8366, Madison, WI 53708.

SECTION 40. Phar 18.12(4) is amended to read:

Phar 18.12 (4) The board shall maintain a log of information submitted ~~and accessed~~ by each dispenser, ~~dispenser delegate~~, ~~practitioner, and practitioner delegate~~.
(4g) The board shall maintain a log of information accessed by each pharmacist, pharmacist delegate, practitioner, and practitioner delegate.
(4r) The board shall maintain a log of information disclosed, including the name of the person towhom the information was disclosed.

SECTION 41. Phar 18.14(1)(intro) is amended to read:

Phar 18.14 (1) The board may exchange PDMP information with a prescription monitoring program operated by a relevant agency in another state or jurisdiction if the prescription monitoring program satisfies all of the following conditions:

SECTION 42. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____ Agency _____

Member of the Board
Pharmacy Examining Board