TEXT OF PROPOSED RULE WITH MODIFICATIONS REQUESTED BY THE ASSEMBLY COMMITTEE ON HEALTH

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) The information created by the board to satisfy the requirements in s. Phar 18.12.

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

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

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

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

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

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

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

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

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

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

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

(3) Tramadol.

Phar 18.04 Dispensing data. (1) As used in this section:

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

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

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

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

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

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

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

(a) The dispenser's full name.

(b) The dispenser identifier.

(c) The date dispensed.

(d) The prescription number, if applicable.

(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 identifier.

(j) The date prescribed.

(k) The quantity prescribed.

(L) The patient's full name.

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

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

(o) The patient's gender.

(4) A dispenser who fails 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) If a veterinary dispenser does not dispense a monitored prescription drug for 90 days, the veterinary dispenser shall submit a zero report to the board.

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

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

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

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

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

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

(9) A veterinary dispenser who fails to submit dispensing data or a zero report as required by subs. (4) and (5), be granted an emergency waiver under sub. (6), or submits false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

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.

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 18.08 Exemptions from compiling and submitting dispensing data. (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew his or her license, or

until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

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

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

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

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

Phar 18.09 Direct access to PDMP information. (1) Dispensers, practitioners, dispenser delegates and practitioner delegates may access PDMP information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records.

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

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

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

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

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

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

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

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

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

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

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

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

(b) The denial of an emergency waiver requested pursuant to ss. Phar 18.06 (3) or (6).

(c) The denial, suspension, revocation or other restriction or limitation imposed on the dispenser's, dispenser delegate's, practitioner's or practitioner delegate's account pursuant to s. Phar 18.09 (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 18.11 Methods of obtaining PDMP information. (1) The board shall disclose PDMP information about a patient to the patient if he or she does all of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) Other legally authorized purposes.

Phar 18.13 Confidentiality of PDMP information. (1) The PDMP information maintained by the board, department or a vendor contracting with the department which is submitted to, maintained, or stored as a part of the program is not subject to inspection or copying under s. 19.35, Stats.

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

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

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

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

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

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

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

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

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

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

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