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(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS

2011-12
(session year)

Assembly
(Assembly, Senate or Joint)

Committee on Health...

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
  (**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
  (**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

* Contents organized for archiving by: Stefanie Rose (LRB) (October 2013)

STATE OF WISCONSIN
Department of Safety and Professional Services
1400 E Washington Ave.
Madison WI 53703

Governor Scott Walker **Secretary Dave Ross**

Mail to:
PO Box 8935
Madison WI 53708-8935

Email: dsps@wisconsin.gov
Web: http://dsps.wi.gov

Voice: 608-266-2112 • FAX: 608-267-0644 • TTY: 608-267-2416

May 29, 2012

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

RE: Committee on Health's Requested Modifications to CR 12-009

Dear Representative Stone:

The Pharmacy Examining Board has received notification of the Assembly Committee on Health's proposed modifications to Clearinghouse Rule 12-009, relating to the prescription drug monitoring program and affecting small business. The Pharmacy Examining Board agrees to consider the proposed modifications during its meeting on May 30, 2012. Therefore, you should expect to receive a response from the Board by noon on May 31, 2012 as requested.

Please contact the PDMP Project Manager, Chad Zadrazil, at 608-266-0011 or chad.zadrazil@wisconsin.gov if you have any questions or concerns.

Sincerely,

Gregory C. Weber, M.S., R.Ph.
Chairperson
Pharmacy Examining Board

STATE OF WISCONSIN
Department of Safety and Professional Services
1400 E Washington Ave.
Madison WI 53703

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May 30, 2012

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

RE: Acceptance of the Committee on Health's Requested Modifications to CR 12-009

Dear Representative Stone:

The Pharmacy Examining Board had a meeting today at which it considered the modifications to the proposed Prescription Drug Monitoring Program rules, CR 12-009, that were requested by the Assembly Committee on Health on May 23, 2012. Through motion, the Board accepted the requested modifications in their entirety. The text of the proposed rule, including the changes from the Board's germane modification submitted on April 4, 2012 and the modifications requested by the Assembly Committee on Health, is attached.

Please contact the PDMP Project Manager, Chad Zadrazil, at 608-266-0011 or chad.zadrazil@wisconsin.gov if you have any questions or concerns.

Sincerely,

Gregory C. Weber, M.S., R.Ph.
Chairperson
Pharmacy Examining Board

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.

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

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.

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

(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.

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

(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.

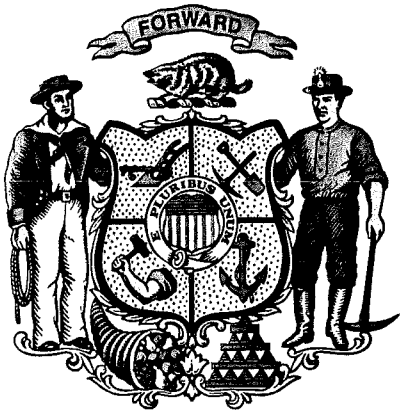
(b) The persons authorized to access the information stored by the prescription monitoring program.

(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.


FORWARD

SBRRB
SMALL BUSINESS REGULATORY REVIEW BOARD

October 18, 2012

Assembly Speaker Jeff Fitzgerald
Rep.fitzgerald@legis.wisconsin.gov

Senate Majority Leader Mark Miller
Sen.miller@legis.wisconsin.gov

Representative Peter Barca
Rep.barca@legis.wisconsin.gov

Senate Minority Leader Scott Fitzgerald
Sen.fitgerald@legis.wisconsin.gov

Co-chairs Joint Committee for the Review of Administrative Rules
Senator Chris Larson
Sen.larson@legis.wisonsin.gov

Representative Jim Ott
Rep.ottj@legis.wisconsin.gov

Dear colleagues,

Recently, Wisconsin's Small Business Regulatory Review Board reviewed Wis. Admin. Code Ch. Phar. 18, the prescription drug monitoring program, to the Small Business Regulatory Review Board.

The Board reviews Wisconsin's administrative rules to determine whether rules have a significant impact on a substantial number of small businesses (2011 Wisconsin Act 46). Agencies have been directed to refer to the Board rules that may have an impact on small businesses (2011 Executive Order 61).

According to the Department of Administration, the proposed rule implements the legislative mandate in 2009 Wisconsin Act 362, which directs the Pharmacy Examining Board to establish through rule a prescription drug monitoring program (PDMP). The primary purpose of the PDMP is to decrease the illicit use of prescription drugs and the resulting health care, social and law enforcement costs.

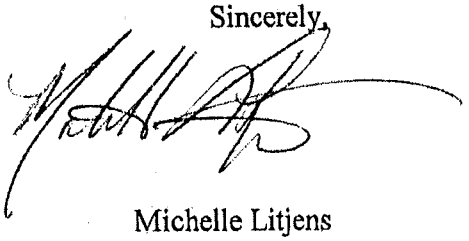
Upon review of the rule, as well as testimony from the Department of Safety and Professional Services agency staff and representatives of Wisconsin Veterinary Medical Association, the Board determined the rule has a significant economic impact on a substantial number of small

businesses. The Board recommended an automatic extension for the reporting requirement for veterinarians, changing the time from seven to 90 days.

Further, the Board recommends that the statute be amended to exclude veterinarians from the reporting requirements, as including veterinarians does not create a benefit to Wisconsin that outweighs compliance costs.

Thank you for your time and consideration. Please contact me with any questions.

Sincerely,



Michelle Litjens
Chair, Small Business Regulatory Review Board
Representative, Wisconsin's 56th Assembly District
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CC: State Representative and Senate emails

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	FINAL REGULATORY FLEXIBILITY ANALYSIS (CLEARINGHOUSE RULE 12-009)

PROPOSED RULE

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

BACKGROUND

Under 2009 Wis. Act 362, the legislature directed the Wisconsin Pharmacy Examining Board (Board) to create a prescription drug monitoring program (PDMP) by rule. The proposed rule fulfills the legislative directive by establishing a PDMP to collect and maintain information 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 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 information about each time they dispense a monitored prescription drug. The information must be submitted to the Board within 7 days of the dispensing of the monitored prescription drug. The proposed rule also requires dispensers to submit a zero report to the Board for each 7-day period during which he or she does not dispense a monitored prescription drug.

Under the proposed rule, the Board may grant a waiver of the 7-day reporting requirements to a dispenser who only dispenses monitored prescription drugs to non-human animal patients. Instead, these dispensers would be required to submit the required information or zero report indicating that they have not dispensed a monitored prescription drug every 90 days.

The proposed rule requires a dispenser to electronically submit the information to the Board using the data standards established by the American Society for Automation in Pharmacy's Implementation Guide for Prescription Monitoring Programs or other electronic format identified by the Board.

Under the proposed rule, the Board may grant a waiver to a dispenser who is unable to comply with the electronic data submission requirement described above. Further, the Board may grant an emergency waiver to a dispenser who is unable to submit information within 7 days of dispensing a monitored prescription drug.

The proposed rule also requires the Board to develop and maintain a database to store the information submitted to the Board as part of the PDMP. Practitioners and dispensers will be able create accounts with the Board to access the database and view information that will be helpful in determining whether a patient is using monitored 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 create accounts to request information from the Board in accordance with s. 146.82, Stats.

METHODS TO REDUCE THE IMPACT ON SMALL BUSINESSES

In accordance with s. 227.114 (2), Stats., the Board considered the methods to reduce the impact on small businesses identified in the statute and incorporated three of them into the proposed rule. Specifically, the Board incorporated the methods indentified in ss. 227.114 (2) (a) to (c), Stats., into the proposed rule because they are feasible and consistent with the statutory objective of s. 450.19, Stats. The Board did not incorporate the method identified in s. 227.114 (2) (d), Stats., because it is inapplicable to the proposed rule. The Board did not incorporate the method identified in s. 227.114 (2) (e), Stats., because the Board lacks statutory authority to do so.

In accordance with s. 227.114 (2) (a), Stats., the Board incorporated "less stringent compliance or reporting requirements for small businesses" into the proposed rule to reduce the impact on small businesses. In general, the proposed rule requires dispensers to electronically submit information about monitored prescription drugs dispensed in a specified format to the Board every 7 days. The Board incorporated a waiver of the electronic reporting requirements to reduce the impact of the proposed rule on small businesses.

The waiver of the electronic reporting requirements reduces the proposed rule's impact on small businesses by giving dispensers options to submit information to the Board. Importantly, health care practitioners and pharmacists without the means to electronically submit information to the Board would not have to invest in hardware and software improvements to comply with the proposed rule. Instead, these dispensers may submit information to the Board on paper. The waiver is available to all dispensers and is especially beneficial to those who practice in small business settings.

The Board incorporated the waiver for less stringent compliance and reporting requirements, to give dispensers options to comply with the proposed rule. Because "dispensers" under the proposed rule consist of many types of health care practitioners and pharmacies whose practices vary significantly, the most practical way for a dispenser to comply with the proposed rule will also vary significantly. For example, a dispenser in a small business setting may not have suitable computer access or choose not to electronically submit information to the Board and want a waiver of the electronic reporting requirement. Conversely, another dispenser in a similar situation may choose to improve his or her electronic health records system (EHR) and to comply with the electronic reporting requirements of the proposed rule and submit information electronically.

Further, the Board incorporated less stringent reporting requirements to reduce the impact on small businesses by including the phrase "or other electronic method identified by the board" in

its description of the electronic reporting requirements. In the original text of the proposed rule submitted to the Legislative Clearinghouse, all dispensers would have been required to electronically submit information in the format identified in the American Society for Automation in Pharmacy (ASAP) Implementation Guide for Prescription Monitoring Programs. The Board received several comments stating that requiring all dispensers to comply with the ASAP format would significantly increase the compliance costs incurred by small businesses and non-pharmacy dispensers. The addition of "or other electronic method identified by the board" enables the Board to work with all dispensers to identify appropriate and cost-effective electronic methods through which dispensers unable to comply with the ASAP format can electronically submit information as required by the proposed rule.

Next, the Board incorporated less stringent compliance requirements by allowing health care practitioners and pharmacies who do not dispense monitored prescription drugs to apply for a complete exemption from the reporting requirements of the proposed rule. The Board correlated the application and expiration of the exemption to the licensure renewal process by making the exemption effective until licensure renewal or until the dispenser dispenses a monitored prescription drug. Therefore, the Board minimized the administrative burden that applying for and renewing an exemption may have created. Besides renewing the exemption, an exempt practitioner or dispenser would not be subject to any ongoing compliance or reporting requirements under the proposed rule.

In accordance with s. 227.114 (2) (b), Stats., the Board incorporated "less stringent schedules or deadlines for compliance or reporting requirements for small businesses." By default, the proposed rule requires dispensers to submit information about monitored prescription drugs dispensed to the Board every 7 days. The Board reduced the impact of the proposed rule on small businesses by enabling a dispenser who solely dispenses monitored prescription drugs to animal patients to apply for a waiver from the 7-day reporting requirement and to report information to the Board every 90 days. The waiver is limited to veterinarian dispensers for several reasons. First, a large majority of veterinarians practice in a small business setting and dispense from their clinics. Second, the use of EHR is less prevalent among veterinarians than it is among other health care practitioners. Third, the prolonged reporting period lessens the usefulness of the information stored by the PDMP database.

Similar to the waiver of the electronic reporting requirements, each veterinary dispenser has a choice in determining the most practical way for him or her to comply with the proposed rule. An individual dispenser is able to determine what reporting timeline is most practical based on his or her business processes and circumstances. For example, a veterinary dispenser in a small business setting may already rely on suitable electronic health records and choose to electronically submit information to the Board every 7 days. Similarly, a veterinary dispenser who dispenses higher volumes of monitored prescription drug may choose to report every 7 days. Conversely, a veterinary dispenser who dispenses monitored prescription drugs infrequently may decide that he or she will apply for the waiver to report information every 90 days.

In accordance with s. 227.114 (2) (c), Stats., the Board consolidated and simplified the compliance or reporting requirements for small businesses. Based on public comments, many of

which were from or on behalf of small businesses, the Board consolidated two of the originally separate data fields required to be submitted to the Board. Specifically, the proposed rule requires dispensers to submit either the National Drug Code (NDC) number or the name and strength of the monitored prescription drug. This consolidation gives dispensers more choice in how they report information to the Board. Pharmacies and other large volume dispensers with suitable EHR systems are able to submit the NDC number without having to manually enter the name and strength of the monitored prescription drug. Small volume dispensers who manually submit information to the Board may submit information to the Board without searching for the NDC number of every monitored prescription drug dispensed during a reporting period.

While the consolidation of reporting requirements benefits dispensers who practice in small businesses, the change is not limited to those dispensers. Any significant modifications to the required data fields must affect all dispensers. Otherwise, the varied data fields would reduce the potential benefits of the PDMP. The primary purpose of the PDMP is to correlate information in the database to identify patients exhibiting activities of prescription drug abuse. Therefore, the data must be cleansed and standardized among all dispensers. If the data fields and information are not standardized across all dispensers, queries for information would not return all relevant information and hinder the ability of the PDMP to effectively serve its purpose.

ISSUES RAISED BY SMALL BUSINESSES AND RESULTING CHANGES

The Board solicited feedback from businesses, associations representing businesses and interested members of the public throughout the development of the proposed rule. Several of the comments submitted to the Board were from small businesses, as defined in s. 227.114 (1), Stats., or from associations representing small businesses in Wisconsin.

The issues raised by or on behalf of small businesses primarily comprise three categories. The first category regards the requirement to report small dose and post-procedure dispensing of monitored prescription drugs. The second category regards the requirement of a dispenser to submit "zero reports" to the Board. Finally, the third category regards the effect of the proposed rule on veterinarians. The Board considered all issues raised in the comments and made substantive modifications to the proposed rule, where possible, in an effort to minimize the burden on small businesses.

Small Dose and Post-Operative Dispensing

Under the proposed rule, dispensers are required to submit information to the Board about each dispensing of a monitored prescription drug. There is no differentiation between dosage forms or amounts or reasons for the dispensing. The Board received several comments regarding health care practitioners who dispense small doses of a monitored prescription drug to a patient following surgery or other procedure. The comments suggest exempting the dispensing of small doses from the reporting requirements of the proposed rule. In general, the amount of drugs dispensed post-procedure is generally very small, 1-10 doses on average. Further, the comments state that because the dispensing is directly related to a medical procedure, it is unlikely that the patient underwent the procedure for the monitored prescription drugs or intends to use them illicitly.

Due to a lack of statutory authority, the Board made no changes to the proposed rule in response to the comments. Under s. 450.19 (2) (a), Stats., the Board shall create a PDMP that requires dispensers to "generate a record documenting each dispensing of a prescription drug and to deliver the record to the board, except that the program may not require the generation of a record when a drug is administered directly to a patient." The statute does not authorize the Board to create more exceptions to the requirement to report dispensing information to the Board.

Zero Reports

Under the proposed rule, dispensers are required to submit a "zero report" to the Board during a reporting period in which the dispenser did not dispense a monitored prescription drug. A reporting period is 7 days unless the dispenser is a veterinarian dispenser who has been granted a waiver of the 7-day reporting period and has a 90-day reporting period. The Board received several comments suggesting that the Board eliminate the zero report requirements.

The Board rejects the comments asking the Board to eliminate the zero report requirements to ensure the usefulness of the PDMP. The sole purpose of the zero report is to ensure that the Board has information from all dispensers at all times. Without complete information, the information stored as part of the PDMP is of limited value because the Board would have no way to determine whether a dispenser who failed to submit information during a reporting period simply forgot or did not dispense a monitored prescription drug during that time.

Further, the zero report is designed not to be a burden to a dispenser. In fact, a dispenser should be able to complete a zero report in seconds. As described by other state prescription monitoring programs, a dispenser can submit a zero report by entering the dates of the report and confirming that he or she did not dispense a monitored prescription drug during that time. Therefore, zero reports contain significantly less information than the reports with dispensing information and require no data compilation.

Veterinary Dispensers

Under the proposed rule, veterinary dispensers are required to report information to the Board just as all other dispensers. The Board received several comments suggesting that the Board exempt veterinary dispensers from the requirements of the proposed rule. However, the Board lacks statutory authority to exempt veterinary dispensers. Under s. 450.19 (2) (a), Stats., the Board is directed create a PDMP that shall require practitioners and dispensers to "generate a record documenting each dispensing of a prescription drug and to deliver the record to the board, except that the program may not require the generation of a record when a drug is administered directly to a patient." The statute does not authorize the Board to create any exemptions or more exceptions to the requirement to report dispensing information to the Board.

In response to comments submitted by veterinary dispensers, the Board modified the language describing the electronic submission requirements to clarify that the phrase "electronically submit" is not intended to define a software or hardware platform through which a dispenser

must submit information to the Board. The Board changed the language "the format identified in the American society for automation in pharmacy (ASAP) implementation guide for prescription monitoring programs" to "the data standards in the version and release of the American society for automation in pharmacy (ASAP) implementation guide for prescription monitoring programs identified by the board or other electronic format identified by the board." The modification is intended to clarify that the Board does not limit electronic submission to a virtual interface between a dispenser and the Board through which databases can send and receive information. Based on the practices of operational prescription monitoring programs in other states, the Board would accept information entered through a secure website, sent in a secure e-mail, included on mailed CD-ROMs and included on mailed diskettes as "electronically submitted" information under the proposed rule. The Board also added the phrase "or other electronic format identified by the board" in response to comments suggesting that the Board adopt an electronic format suitable to the practice of veterinary medicine.

Further, the Board consolidated data fields to reduce the burden on veterinary dispensers, among the reasons already discussed. Specifically, the proposed rule requires a dispenser to submit either the National Drug Code (NDC) number or the name and strength of the monitored prescription drug. The consolidation gives veterinary dispensers more choice in how they choose to report information. The data field is also now relevant for veterinary drugs that may not have an NDC number.

Finally, under the proposed rule, disciplinary authority over each of the licensed health care practitioners, pharmacies and pharmacists affected by the rule is with the board that issued him, her or it the license authorizing the dispensing or prescribing of monitored prescription drugs. The Board received comments suggesting that the Board specifically give the disciplinary authority of veterinarians affected by the rule to the Veterinary Examining Board. In response to the public comments and the Clearinghouse Report, the Board modified the language describing the disciplinary authority of other licensing boards for violations of the proposed rule.

NATURE OF REPORTS REQUIRED AND THEIR ESTIMATED COSTS

In general, the proposed rule requires dispensers to submit two types of reports to the Board: reports containing dispensing information and zero reports. Dispensers must submit the reports containing dispensing information within 7 days, or 90 days for veterinary dispensers granted a waiver, of dispensing a monitored prescription drug to a patient. The reports contain specific information about the prescriber, dispenser, patient and monitored prescription drug.

The estimated cost of an individual report with dispensing information would range from *de minimis* to less than one hundred dollars. The range would not likely be static for dispensers and would depend on several variables. While there is no exhaustive list of variables, several variables have the most significant affect on the estimated cost of a report with dispensing information.

A significant variable that affects the cost of a report with dispensing information is whether the dispenser currently utilizes compatible EHR that can compile and submit information to the Board. For example, the cost of an individual report to a dispenser who already utilizes

compatible EHR software and reports similar information to another state's prescription monitoring program would be less than a dispenser who decides to invest in retrofitting his or her EHR software to be compatible with the PDMP. Either way, the costs of an individual report will decrease over time for dispensers utilizing EHR.

The potential up-front costs of utilizing EHR to compile and submit information to the Board is not required. In fact, a dispenser may not use EHR at all and submit information to the Board through other electronic methods or by submitting the information on paper. In that case, a significant variable is whether the dispenser is required to report every 7 days or every 90 days. A dispenser submitting a report with dispensing information to the Board every 90 days would incur less frequent personnel costs to compile the reports to the Board than a dispenser who submits information to the Board every 7 days.

A related variable is the frequency a dispenser dispenses monitored prescription drugs. A dispenser who dispenses monitored prescription drugs numerous times per day would have more information to compile and submit that a dispenser who dispenses monitored prescription drugs infrequently. An individual report that contains information regarding numerous dispensing events that is compiled and submitted manually, either electronically or on paper, would likely cost more to compile and submit than a report that contains less information.

The estimated cost to complete a zero report is *de minimis*. The zero report contains very little information, much less information than the reports with dispensing information. In fact, a dispenser can complete a zero report in seconds by simply logging into their account and completing a brief form online. The zero reports require no data compilation and are only intended to ensure that the PDMP has complete information from all non-exempt dispensers at all times.

Finally, under the proposed rule, a dispenser that does not dispense monitored prescription drugs may apply for a complete exemption from the reporting requirements. The proposed rule associates the expiration of the exemption to licensure renewal to eliminate the administrative burden that applying for an exemption may have created. Under the proposed rule, the exemption would last until licensure renewal or until the dispenser dispenses a monitored prescription drug. Therefore, a pharmacy, pharmacist or health care practitioner applying for the exemption can indicate so as part of the licensure renewal process. There would be no further reporting requirements or associated costs incurred by dispensers.

NATURE OF OTHER MEASURES OR INVESTMENTS REQUIRED

Besides the costs associated with the required compiling and submitting of information relating to the dispensing of monitored prescription drugs, there are no other investments required by the proposed rule. Large-volume dispensers, such as pharmacies and physicians in large practices, may invest in modifying their current EHR software to automatically compile the required information. However, the investment is not required by the proposed rule, because the proposed rule is flexible in the methods through which dispensers can submit information to the Board.

COSTS TO THE AGENCY OF ADMINISTERING THE PROPOSED RULE

Based on the operating costs incurred by similar prescription monitoring programs, the Department estimates that it will cost approximately $210,000 annually to operate the PDMP created by the proposed rule. The annual costs are primarily comprised of a full-time program and planning analyst to monitor the program and work with the vendor and others to manage the PDMP and the contractual costs for a vendor to host and maintain the PDMP database, website and other related IT components of the PDMP.

IMPACT ON HEALTH, WELFARE AND SAFETY

The PDMP created by the proposed rule will have a significant impact on the health, welfare and safety of the people of Wisconsin. It creates an effective tool that will enable the approximately 50,000 pharmacies; pharmacists; health care practitioners, including physicians, dentists and veterinarians; law enforcement agencies and public health officials to obtain invaluable information to assist in the effort to curb prescription drug abuse in Wisconsin.

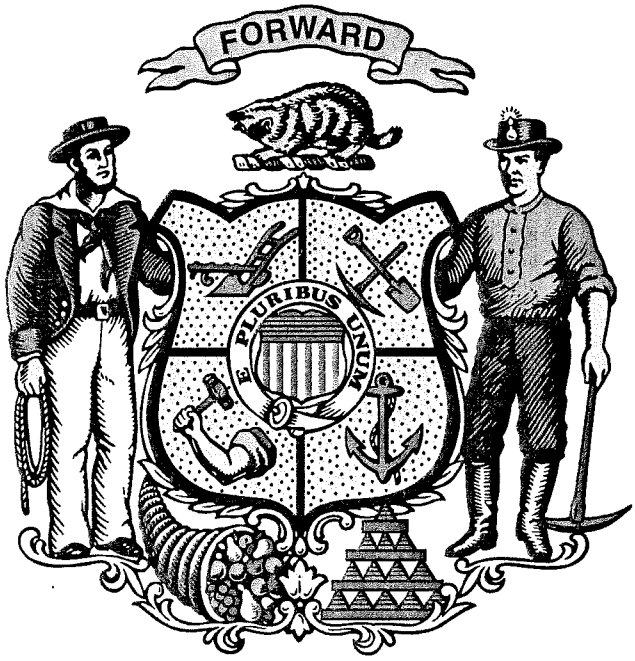
Currently, "prescription drug abuse is America's fastest growing drug problem" (Controlled Substances Workgroup of the Wisconsin State Council on Alcohol and Other Drug Abuse (SCAODA), "Reducing Wisconsin's Prescription Drug Abuse: A Call to Action," 8, Jan. 2012, citing CDC, "Public Health Grand Round Presentation," 10, Feb. 2011). In fact, one person died every 19 minutes in the United States in 2007 because of an "unintentional drug overdose" (CDC, "Grand Rounds: Prescription Drug Overdoses — a U.S. Epidemic," Jan. 13, 2012). Unintentional drug overdoses have become the second leading cause of accidental death in the United States (Susan Okie, A "Flood of Opioids, a Rising Tide of Deaths," New England Journal of Medicine, Nov. 18, 2010).

The prescription drug problem in Wisconsin is similar to the national problem (see SCAODA, 5-9). Wisconsin's prescription drug abuse rate is slightly higher than the national average of approximately 5%, with 5.83% of Wisconsin residents age 12 and older reporting using pain relievers for non-medical purposes in 2005-06 (Wisconsin Department of Health Services (DHS), "Wisconsin Epidemiological Profile on Alcohol and Other Drug Use," 2008; SCAODA, 6). According to the Controlled Substances Workgroup of the Wisconsin State Council on Alcohol and Other Drug Abuse, the prescription drug abuse problem is exacerbated in Wisconsin because the State does not have a PDMP (SCAODA, 8). In its January 2012 report "Reducing Wisconsin's Prescription Drug Abuse: A Call to Action," SCAODA states that:

> [a] well designed PDMP will provide an early warning system for emerging drug abuse trends, assist in enhancing patient care, and serve as a vehicle for communication with other states subsequently reducing doctor shopping across state lines. In addition, with appropriate confidentiality protections built into the Wisconsin PDMP for patient-identifiable health information, a PDMP will enhance the ability of law enforcement to conduct investigations of the illegal diversion of prescription medications. (*id.*)

Further, a Cost-Benefit Analysis conducted by the LaFollette School of Public Affairs states that "[p]rescription drug abuse has a significant impact on society. Drug abuse causes decreased productivity and absences from work, increased health care costs, and increased law enforcement costs" and that "[s]tates with PDMPs realize health care benefits through the reduction in excess hospital admissions including both in- and out-patient, reduction in addiction treatment, and reduction of prescription drug costs associated with prescription drug abuse" (Christine Durkin, et al., "Cost-Benefit Analysis of a Prescription Drug Monitoring Program in Wisconsin," LaFollette School of Public Affairs (LaFollette), 6, Dec. 20, 2010).

Finally, while the PDMP created by the proposed rule will improve the health, welfare and safety of Wisconsin citizens, the effectiveness of the PDMP is lessened by the modifications made to allow veterinarian dispensers to submit information every 90-days as opposed to every 7-days. The usefulness of the PDMP to identify cases of "doctor shopping," forged prescriptions and other activities at the time of providing a patient services is decreased because of the 90-day lapse in some of the information in the PMDP. In fact, the Board received comments suggesting the 7-day reporting requirement is too long and should be decreased as much as possible to increase the usefulness of the PDMP.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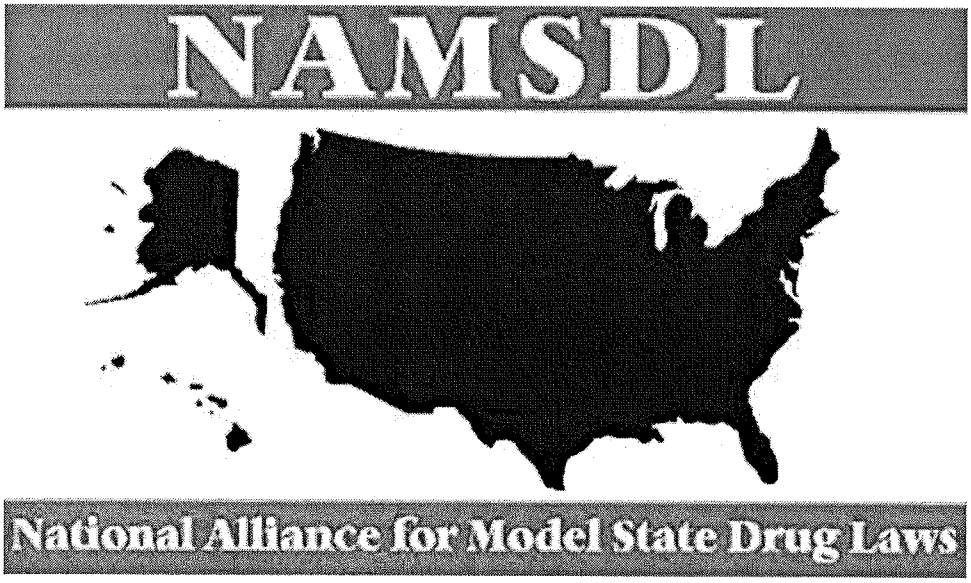
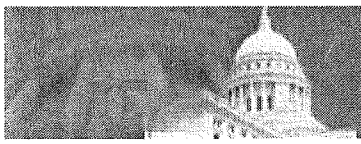


STATES WITH STATUTORY AUTHORITY TO REQUIRE VETERINARIANS TO REPORT TO PRESCRIPTION MONITORING PROGRAM[1]

[1] This chart represents those states with statutory authority to require veterinarians to report to the state Prescription Monitoring Program and does not reflect those states with such authority that are not actively collecting data from veterinarians.

States with PMP Programs	What the State Law or Regulation Says	Practical Application in States That Require all Practitioners and/or Dispensers to Report Prescription Data
Alabama	Specifically requires veterinarians to report	Veterinarians required to report
Alaska	Requires all pharmacists, pharmacists-in-charge, and practitioners who directly dispense to report	Veterinarians required to report
Arizona	Requires all medical practitioners that dispense to report	Veterinarians required to report
Arkansas	Requires all dispensers to report	Veterinarians required to report
California	Requires all dispensers to report	Veterinarians required to report
Colorado	Requires only pharmacies to report	Not applicable – only pharmacies required to report
Connecticut	Requires only pharmacies and outpatient pharmacies to report	Not applicable – only pharmacies required to report
Delaware	Requires all dispensers to report	Veterinarians not required to report
Florida	Requires all dispensing practitioners to report	Veterinarians not required to report
Georgia	Specifically exempts veterinarians from reporting	Veterinarians not required to report
Hawaii	Only requires pharmacies to report	Not applicable – only pharmacies required to report
Idaho	Only requires pharmacies to report	Not applicable – only pharmacies required to report
Illinois	Requires all dispensers to report	Veterinarians required to report
Indiana	Requires all dispensers to report	Veterinarians required to report
Iowa	Requires only pharmacies to report	Not applicable – only pharmacies required to report
Kansas	Requires all dispensers to report	Veterinarians not required to report at this time; task force to study veterinarian reporting created by statute
Kentucky	Requires all dispensers to report	Veterinarians required to report
Louisiana	Requires all dispensers to report	Veterinarians not required to report
Maine		
Maryland	Requires all dispensers to report	Veterinarians not required to report
Massachusetts	Only requires pharmacies to report	Not applicable – only pharmacies required to report
Michigan	Specifically requires veterinarians to report	Veterinarians required to report
Minnesota	Requires all dispensers to report	Veterinarians not required to report

Mississippi	All pharmacies and practitioners required to report	Veterinarians required to report
Montana	Requires only pharmacies and out of state pharmacies to report	Not applicable – only pharmacies required to report
Nebraska	Unknown	Unknown
Nevada	Requires all pharmacies and registered practitioners to report	Veterinarians not required to report
New Jersey	Only requires pharmacies to report	Not applicable – only pharmacies required to report
New Mexico	Requires all dispensers to report	Veterinarians not required to report
New York	Requires all pharmacies and dispensing practitioners to report	Veterinarians required to report
North Carolina	Requires all dispensers to report	Veterinarians not required to report
North Dakota	Requires all dispensers to report	Veterinarians required to report
Ohio	Only pharmacies required to report	Not applicable – only pharmacies required to report
Oklahoma	Requires all pharmacies and dispensing practitioners to report	Veterinarians required to report
Oregon	Only pharmacies required to report	Not applicable – only pharmacies required to report
Pennsylvania	Only pharmacies required to report	Not applicable – only pharmacies required to report
Rhode Island	Only pharmacies required to report	Not applicable – only pharmacies required to report
South Carolina	Requires all dispensers to report	Veterinarians required to report
South Dakota	Requires all dispensers to report	Veterinarians not required to report
Tennessee	Requires all dispensers to report	Veterinarians required to report
Texas	Only pharmacies required to report	Not applicable – only pharmacies required to report
Utah	Only pharmacies required to report	Not applicable – only pharmacies required to report
Vermont	Requires all dispensers to report	Veterinarians not required to report
Virginia	Specifically exempts veterinarians from reporting	Veterinarians not required to report
Washington	Requires all dispensers to report	Veterinarians required to report
West Virginia	Requires all medical service providers, pharmacies, and health care facilities to report	Veterinarians required to report
Wisconsin	Will require pharmacists or practitioners to report	Unknown at this time
Wyoming	Only pharmacies required to report	Not applicable – only pharmacies required to report



WISCONSIN STATE LEGISLATURE

WISCONSIN HOSPITAL ASSOCIATION, INC.

Guest Column: A Place We are Not Coming Back From

With or without PPACA, Wisconsin health systems moving forward with value driven "reform"

By Eric Borgerding, WHA Executive Vice President

Nearly five years ago, WHA sponsored a full-page ad in major Wisconsin dailies congratulating our members for helping Wisconsin achieve the top spot in the AHRQ quality rankings. Our message then was:

"Congratulations to the leaders and caregivers at Wisconsin's hospitals for your tireless pursuit of excellence in patient care. Improving health care quality and value ***is*** *health care reform."*

Fast forward to March 25, 2011, and this statement by then WHA Board Chair Nick Turkal in an interview with the Milwaukee Business Journal:

"All the dialogue and all the debate has pushed the (health care) industry in a way that it is not going to come back from...changes around value-based reimbursement are coming, regardless of what happens in D.C., and I think for businesses and consumers that's a good thing."

One year later, WHA sent a letter to several leading Wisconsin business organizations to engage them in the health care quality discussion:

"Improving quality and achieving better outcomes not only benefits our patients, but also helps create a more attractive Wisconsin business climate. High quality health care can make Wisconsin a more competitive place for employers to locate or expand."

In many parts of the country, talk by the health care community of quality, accountability, measuring performance, shifting from generating volume to focusing on outcomes, or the notion of VALUE-based payment would be considered foolhardy, risky or worse. *But not in Wisconsin.*

Jump ahead to March 27, 2012, the day ordinary people tuned-in to the U.S. Supreme Court to hear oral arguments that sent shockwaves through the political and health care worlds and made even the staunchest supporters of PPACA pessimistically speculate on prospects for real health care reform. *But not in Wisconsin.*

While the multi-level ramifications of the Court's coming decisions on PPACA will be massive, Wisconsin is indeed already heading to a place "it is not going to come back from." With or without PPACA, Wisconsin providers, and many payers, are moving down the road to value-driven health care reform...***and we need to keep our foot on the gas pedal.***

The focus on quality and value is being hastened, if not dictated, by the combined forces of federal deficit reduction and the need for health care cost containment in the context of employer labor costs in the globally competitive environment. Increasingly engaged payers, coupled with integrated systems of providers aligned toward a common goal—producing higher quality, better outcomes and greater value for employer and employee health care dollars—will continue pushing Wisconsin forward and set us apart from many other parts of the country...*with or without PPACA.* Here's why:

- **Wisconsin is the home of national leaders and pioneering organizations in the quality and value movement.** Dr. John Toussaint, founder of the ThedaCare Center for Healthcare Value, John Torinus, former CEO of Serigraph, Inc., the Wisconsin Health Information Organization

(WHIO) and a host of other Wisconsin business and health care leaders and organizations have been catalysts, and continue to push both providers and payers to seek superior quality and value and accelerate the pace of change.

- **Wisconsin has a strong presence of vertically integrated hospital and health systems, with employed physicians aligning towards a common goal—better outcomes.** According to the MGMA, in 2002 about 20 percent of U.S. physician practices were hospital-owned; in 2008 that figure was over 50 percent. At least two-thirds of Wisconsin's practicing physicians are employees of hospitals or growing integrated delivery systems. That means more and more care is happening "under one roof" and a shared philosophy—facilitating coordination of and honing focus on patients and delivering better quality, better outcomes and, ultimately, better value for Wisconsin's health care dollars.

- **Wisconsin's balanced and fair tort system attracts high quality physicians and staff:** Wisconsin already struggles attracting and retaining the physicians and other high-level providers we need to meet demand for care. Our balanced medical malpractice system is an attribute that serves to attract good practitioners to our state.

- **Wisconsin hospital and health systems have a long history of commitment to improving care:** Wisconsin is a national leader in ongoing, measurable quality improvement. One recent example is WHA's Partners for Patients, which aims to improve Wisconsin hospitals' already below-average readmission rates by another 20 percent. Hitting that target could save Wisconsin a quarter billion in health care costs annually

- **Commitment to transparent reporting of results:** Since 2005, WHA's CheckPoint program, the first of its kind in the nation, has been publicly reporting hospital quality indicators and is continuously updating its measures. In February, CheckPoint began reporting Wisconsin hospital infection rates. The Wisconsin Collaborative for Health Care Quality is also a pioneer in public reporting, bringing providers and payers together to develop and publicly report health care performance measures.

- **Wisconsin is a leader in adopting electronic health records:** In 2012, Wisconsin hospitals rank second in the nation in adoption of certified electronic health records (EHR) technology. Further, Wisconsin is ahead of nearly all of its Midwest neighbors in the adoption of more advanced EHRs.

- **Wisconsin providers are developing accountable systems of care that improve quality, reduce costs and work at managing the populations in their service areas:** Commercial reimbursement is changing: With or without Medicare-driven ACOs, the payment model in health care is moving away from unit pricing/fee-for-service and towards outcomes/total cost of care. There are several examples across the state of "accountable care" models in the private sector commercial market, outside of PPACA's Medicare-driven ACOs—Aurora, Bellin/ThedaCare, Dean, Gundersen Lutheran, and Quality Health Solutions are a few examples.

- **Wisconsin hospitals are reducing operating expenses through adoption of LEAN, Six Sigma and other efficiency initiatives.**

    - A 2011 study by Milliman and Mercer showed that from 2003-10 hospital operating expenses in SE Wisconsin increased by 17 percent compared to a 28 percent increase in the Hospital PPI and 37 percent increase in the CMS Hospital Market basket for the same period.

- Wisconsin hospital supply costs per discharge are now nearly 19 percent lower than the national median.

- **Hospital commercial payments and prices are reflecting improvements in efficiency and quality.**

  - From 2003-10, hospital commercial payments in SE Wisconsin increased 40 percent less than the Hospital CPI over the same period. Health care costs are a component of labor costs, and with over one-third of all Wisconsin jobs located in the seven county SE Wisconsin region, the impact on health care costs is significant.

  - Annualized hospital rate increases are trending downward, declining from 7.4 percent in 2002 to 4.8 percent in 2012

What we said five years ago is even truer today—improving health care quality and value ***is*** health care reform. Some in the health care and business community have been critical of the pace of change and refocus on quality and efficiency in health care. They are not wrong.

With or without PPACA, Wisconsin must, and will, continue down the "reform" path. Few other states are as well positioned to succeed, if not thrive, in the emerging value dynamic—A Wisconsin strength WHA believes can transform into competitive advantage. Stay tuned.