**Clearinghouse Rule 13-065**

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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| IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD | : | NOTICE OF PUBLIC HEARING |

NOTICE IS HEREBY GIVEN that pursuant to authority vested in the Pharmacy Examining Board in ss. 450.19 (2) and 961.31, Wis. Stats., and interpreting ss. 15.08 (5) (b) and 227.11 (2) (a) Wis. Stats., the Pharmacy Examining Board will hold a public hearing at the time and place indicated below to consider an order to repeal Phar 18.02 (22), 18.06 (4) to (6) and (9), 18.06 (4) to (6) and (9); renumber Phar 18.06 (8) to (5); renumber and amend Phar 18.06 (7) to (4); amend Phar 18.02 (7), Phar 18.02 (16) and (17), 18.03 (intro.), 18.04 (1) (b) and (e), and (3) (b), (d), (i) and (k), 18.06 (1) to (3) (intro.); create Phar 18.02 (13e); repeal and recreate Phar 18.02 (3), relating to the prescription drug monitoring program (PDMP) and the exclusion of veterinarians from reporting.

**Hearing Date, Time and Location**

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| **Date:** | **September 11, 2013** |
| **Time:** | **9:00 a.m.** |
| **Location:** | **1400 East Washington Avenue*<br>Room 121<br>Madison, Wisconsin** |

***Enter at 55 No. Dickenson Street**

**APPEARANCES AT THE HEARING:**

Interested persons are invited to present information at the hearing. Persons appearing may make an oral presentation but are urged to submit facts, opinions and argument in writing as well. Facts, opinions and argument may also be submitted in writing without a personal appearance by mail addressed to the Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8935, Madison, Wisconsin 53708-8935. Written comments must be received at or before the public hearing to be included in the record of rule-making proceedings.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** Section 450.19 (2), Stats.

**Statutory authority:** Sections ss. 15.08 (5) (b), and 227.11 (2) (a), and 961.31, Stats.

**Explanation of agency authority:**

Section 450.19 (2), Stats., directs the Board to establish rules to govern the PDMP. Section 961.31, Stats., authorizes the Board to promulgate rules relating to the dispensing of controlled substances. Finally, ss. 15.08 (5) (b), and 227.11 (2) (a), Stats., confers to the Board the powers to promulgate rules for the guidance of the profession and to interpret the provisions of statutes it enforces.

**Related statute or rule:** Chapter 450, Stats., and chs. Phar 1 to 17, Wis. Admin. Code

**Plain language analysis:**

Chapter Phar 18, Prescription Drug Monitoring Program (PDMP), created a prescription drug monitoring program to collect and maintain information relating to the prescribing and dispensing of prescription drugs, particularly controlled substances. Chapter Phar 18 became effective January 1, 2013 in response to s. 961.31, Stats., which provided the board authority to promulgate rules. As promulgated ch. Phar 18 contradicts the statutory directive to create the PDMP in s. 450.19, Stats., as modified by 2013 Act 3.

Sections 1 to 4 either create, amend or repeal definitions relating to changes consistent with 2013 Act 3 and the PDMP. Section 5 corrects statutory citations changed from the enactment of 2013 Act 3. Section 6 updates data requirements now that veterinarians are no longer required to report to the PDMP. Section 7 and 8 remove code text specific to veterinarian dispensers. Section 9 renumbers subsections after deleting text in Sections 7 and 8.

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

There is no existing or proposed federal regulation.

**Comparison with rules in adjacent states:**

An Internet-based search for similar prescription drug monitoring programs revealed that the states of Illinois, Michigan, and Minnesota allow veterinarians to access their on-line reporting website or specifically require veterinarians to report dispensing through their statues or codes. The search did not reveal that Iowa codes or statutes require or exempt veterinarians from their prescription drug monitoring program.

No factual data or analytical methodologies were used to draft the rules; the main purpose of the rule revisions is to conform to the Statutes after the enactment of 2013 Act 3.

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

None undertaken to draft the rules; the main purpose of the rule revisions is to conform to the Statutes after the enactment of 2013 Act 3.

**Fiscal Estimate and Economic Impact Analysis:**

The Fiscal Estimate and Economic Impact Analysis is attached.

**Initial Regulatory Flexibility Analysis or Summary:**

This rule change will not have an effect on small business.

**Environmental Assessment/Statement:**
N/A

**Agency contact person**:

Jean MacCubbin, Program Manager, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8935, Madison, Wisconsin 53708-8935; telephone 608-266-0955; email at Jean.MacCubbin@wisconsin.gov.

**Place where comments are to be submitted and deadline for submission**:

Comments may be submitted to Jean MacCubbin, Program Manager, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8935, Madison, WI 53708-8935, or by email to Jean.MacCubbin@wisconsin.gov; or via telecommunications relay services at 711. Comments must be received at or before the public hearing to be held on September 11, 2013 to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. Phar 18.02 (3) is repealed and recreated to read:

**Phar 18.02 (3)** "ASAP" means the American Society for Automation in Pharmacy.

**Note:** Contact: American Society for Automation in Pharmacy, 492 Norristown Road, Suite 160; Blue Bell, PA 19422; phone: (610) 825-7783; Fax: (610) 825-7641; webpage: http://asapnet.org/index.html.

SECTION 2. Phar 18.02 (13e) is created to read:

**Phar 18.02 (13e)** "PDMP" means the Wisconsin prescription drug monitoring program.

SECTION 3. Phar 18.02 (16) and (17) are amended to read:

**Phar 18.02** (16) "Pharmacy" means any place of practice licensed by the board under ss. 450.06 or 450.065, Stats., including a pharmacy that chooses to solely dispense to animal patients.

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

SECTION 4. Phar 18.02 (22) is repealed.

SECTION 5. Phar 18.03 (intro.) is amended to read:

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

SECTION 6. Phar 18.04 (1) (b) and (e), and (3) (b), (d), (i) and (k) are amended to read:

**Phar 18.04 (1)** (b) "Dispenser identifier" means the DEA registration number~~,~~. When the DEA registration number is not available, the NPI number or ~~unique state-issued credential, permit or license number issued to a dispenser~~ another identifier approved by the board shall be an acceptable alternative identifier.

(e) "Practitioner identifier" means the DEA registration number~~,~~. When the DEA registration number is not available, the NPI number or ~~unique state-issued credential, permit or license number issued to a practitioner~~ another identifier approved by the board shall be an acceptable alternate identifier.

**(3)** (b) The dispenser identifier, if available, or an acceptable alternate identifier.

(d) The prescription number~~, if applicable~~.

**(i)** The practitioner identifier~~.~~, if available, or an acceptable alternate identifier.

(k) The ~~quantity prescribed~~ partial fill indicator.

SECTION 7. Phar 18.06 (1) to (3) (intro.) are amended to read:

**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:

SECTION 8. Phar 18.06 (4) to (6) and (9) are repealed.

SECTION 9. Phar 18.06 (7) and (8) are renumbered 18.06 (4) and (5) and as renumbered (4) is amended to read:

**Phar 18.06 (4)** Unless otherwise specified by the board, an emergency waiver granted under ~~subs.~~ sub. (3) ~~or (6)~~ shall only be effective for 7 days.

SECTION 10. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

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(END OF TEXT OF RULE)

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COPIES OF RULE

Copies of this proposed rule are available upon request to Jean MacCubbin, Program Manager, Department of Safety and Professional Services, Division of Policy

Development, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708-8935, by email at Jean.MacCubbin@wisconsin.gov or on our website at http://dsps.wi.gov/Default.aspx?Page=44e541e8-abdd-49da-8fde-046713617e9e.

*File: 165-Phar 18 notice of Public hearing FINAl*