CR 13-065

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CR 13-065)

ORDER

An order of the Pharmacy Examining Board to repeal Phar 18.02 (22), 18.06 (4) to (6) and (9), 18.06 (4) to (6) and (9); renumber Phar 18.06 (7) and (8) to 18.06 (4) and (5); 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), 18.05 (2), 18.06 (1) to (3) (intro.), 18.06 (4); create Phar 18.02 (3m) and (13e), relating to the prescription drug monitoring program (PDMP) and the exclusion of veterinarians from reporting.

Analysis prepared by the Department of Safety and Professional Services.

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 was published in the Wisconsin Administrative Register December 2012 and became

effective January 1, 2013 in response to s. 961.31, Stats., providing the board authority to promulgate the PDMP 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 enacted only two months later. It should be noted that both pharmacists and veterinarians dispense prescriptions for animals; only the requirements for veterinarians to submit to the PDMP registry, which provides the basis for this proposed rule revision, which was excluded in Act 3.

SECTIONS 1. to 3. These sections relate to definitions; two new definitions are created—ASAP, the acronym for the American Society for Automation in Pharmacy, and PDMP. The definition for pharmacy now includes those who solely dispense for animal patients. The statutory reference for practitioner was change in 2013 Act 3 and is reflected here.

SECTION 4. The definition for veterinary dispenser is no longer applicable, consistent with 2013 Act 3.

SECTIONS 5 and 10. This section is amended to reflect statutory change in 2013 Act 3.

SECTION 6. This section encompasses the identification numbers accepted in the PDMP and recognizes the availability of such identifiers.

SECTION 7. The removal of veterinary dispenser is the subject of this amendment, consistent with 2013 Act 3.

SECTIONS 8. and 9. These section delete various references specific to veterinary dispensers and renumber the listing sequentially.

SECTION 11. The effective date is referenced.

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:
None required.

Agency contact person:

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TEXT OF RULE

SECTION 1. Phar 18.02 (3m) is created to read:

Phar 18.02 (3m) "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), (3) (b), (d), (i) and (k), and 18.05 (2) are amended to read:

Phar 18.04 (1) (b) "Dispenser identifier" means the DEA registration number~~,~~ or when the DEA registration number is not available, the NPI number ~~or unique state-issued credential, permit or license number issued to a dispenser~~.

(e) "Practitioner identifier" means the DEA registration number~~,~~ or when the DEA registration number is not available, the NPI number ~~or unique state-issued credential, permit or license number issued to a practitioner~~.

(3) (b) The dispenser identifier, if available.

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

(i) The practitioner identifier~~.~~, if available.

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

Phar 18.04 (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)~~ ASAP implementation guide for prescription monitoring programs identified by the board or other electronic format identified by the board.

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).

SECTION 10. Phar 18.06 (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 11. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____ Agency _____

Board Chairperson
Pharmacy Examining Board