

Clearinghouse Rule 13-075

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE)

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PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal 7.08 (1) (note); and amend 8.05 (4), 8.07 (2), 8.09(1),(2),(3), and (4) relating to electronic prescriptions.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

Statutes interpreted: §§ 450.11 (2) and 961.38, Stats.

Statutory authority: §§ 15.08 (5)(b), 450.02(3)(a), 961.31, Stats

Explanation of agency authority:

15.08 (5) (b), Stats., allows each examining board to “promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession.”

450.02 (3) (a), Stats., authorizes the Board to promulgate rules “[r]elating to the...distribution and dispensing of prescription drugs.”

961.31, Stats., authorizes the Board to promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within the state.

Related statute or rule: § 961.38, Stats.

Plain language analysis:

2011 Wisconsin Act 159 amended § 961.38, Stats. to allow electronic prescriptions for schedule II controlled substances. This rule updates the Pharmacy Examining Board rules accordingly.

Section 1 repeals the note following Phar 7.08(1) which stated that prescription orders for schedule II controlled substances may not be transmitted electronically except in emergency.

Section 2 amends Phar 8.05(4) to indicate that a prescription containing a controlled substance can only be dispensed pursuant to a written hard copy or electronic order signed by the prescribing practitioner.

Section 3 amends Phar 8.07(2) to indicate the notation of the partial quantity provided is written on the hard copy of the prescription or the electronic order. The word “emergency” is moved to solely modify oral prescription.

Sections 4, 5 and 7 amends Phar 8.09(1),(2) and (4) to remove electronic from the emergency prescriptions and to reflect the provisions relate solely to oral authorizations in an emergency situation.

Section 6 amends Phar 8.09(3) to remove the reference to electronic in this emergency prescription provision. It also removes the reference to the “practitioner’s phone number as listed in the telephone directory” to reflect current technologies may be used rather than the outdated method of looking phone numbers up in a telephone directory.

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

21 CFR §1311 allows electronic prescriptions for controlled substances.

Comparison with rules in adjacent states:

Illinois: Per Ill. Admin. Code Title 68, § 1330.760, electronically transmitted prescriptions for controlled substances may be dispensed only as provided by federal law.

Iowa: Per Iowa Admin. Code 657 - 8.19, electronic prescriptions may be accepted for controlled substances.

Michigan: Per Mich. Admin. Code § 333.7333, electronic prescriptions of controlled substances are allowed, if not prohibited by federal law.

Minnesota: Per Minnesota Rules 6800.3000 Subp. 3, electronic prescriptions are allowed if they conform to the rules of the federal Drug Enforcement Administration.

Summary of factual data and analytical methodologies:

The methodology used was to update the rule to reflect the changes to the statutes as a result of 2011 Wisconsin Act 159.

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

This rule was posted for economic comments for 14 days and none were received. This rule updates the code to reflect the statutory change to allow for electronic prescriptions and will not have an economic impact.

Fiscal Estimate and Economic Impact Analysis:

The fiscal estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8935, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, 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 Sharon.Henes@wisconsin.gov. Comments must be received on or before October 30, 2013 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.08 (1) (note) is repealed.

SECTION 2. Phar 8.05 (4) is amended to read:

Phar 8.05 (4) A prescription containing a controlled substance listed in schedule II may be dispensed only pursuant to a written hard copy or electronic order signed by the prescribing individual practitioner, except in emergency situations. A prescription for a controlled substance listed in schedule II may not be dispensed more than 60 days after the date of issue on the prescription order.

SECTION 3. Phar 8.07 (2) is amended to read:

Phar 8.07 (2) The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency electronic or oral prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written hard copy prescription order or written record of the ~~emergency~~ electronic or emergency oral prescription order. The remaining portion of the prescription may be dispensed within 72 hours of the first partial dispensing. If the remaining portion is not dispensed within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.

SECTION 4. Phar 8.09 (1) is amended to read:

Phar 8.09 (1) For the purpose of authorizing an ~~electronic or~~ oral prescription order for a schedule II controlled substance, the term “emergency” means those situations in which the prescribing practitioner determines that:

SECTION 5. Phar 8.09 (2) is amended to read:

Phar 8.09 (2) In an emergency a pharmacist may dispense a controlled substance listed in schedule II upon receiving ~~electronic or~~ oral authorization of a practitioner if:

SECTION 6. Phar 8.09 (3) is amended to read:

Phar 8.09 (3) If the practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the ~~electronic or~~ oral authorization came from an authorized practitioner, which may include a call back to the prescribing practitioner using ~~the practitioner’s phone number as listed in the telephone directory and other~~ good faith efforts to insure the practitioner’s identity.

SECTION 7. Phar 8.09 (4) is amended to read:

Phar 8.09 (4) Within 7 days after authorizing an emergency ~~electronic or~~ oral prescription order, the practitioner shall cause a written order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of s. Phar 8.05, the order shall contain on its face “authorization for emergency dispensing” and the date of the ~~electronic or~~ oral order. The written order may be delivered to the pharmacist in person or by mail, but if delivered by mail it shall be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription order to the ~~electronic or~~ oral emergency order reduced to writing under sub. (2) (b). The pharmacist shall notify the board or department of safety and professional services if the practitioner fails to deliver the written order. Failure of the pharmacist to provide notification shall void the authority conferred by this section to dispense without a written order of a practitioner.

SECTION 8. EFFECTIVE DATE. The rule 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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Dated _____ Agency _____
Member of the Pharmacy Examining Board