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 (CLEARINGHOUSE RULE 15-064)

ORDER

An order of the Pharmacy Examining Board to amend Phar 1.02 (10) and 8.07 (2) relating to definitions and controlled substances.

Analysis prepared by the Department of Safety and Professional Services.

<u>ANALYSIS</u>

Statutes interpreted: ss. 450.06, 450.065, 961.38, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (2), and 961.31 Stats.

Explanation of agency authority:

The Pharmacy Examining Board shall promulgate rules for its own guidance and for the guidance of the profession and define and enforce professional conduct and unethical practices not inconsistent with the law relating to pharmacy.

The Pharmacy Examining Board shall adopt rules defining the active practice of pharmacy.

The Pharmacy Examining Board may promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state.

Related statute or rule: N/A

Plain language analysis:

Section 1 clarifies that the definition pharmacy includes out-of-state pharmacies licensed by the board.

Section 2 moves the word "emergency" to only modify an oral prescription order. Electronic prescriptions are allowed for controlled substances regardless of whether it is an emergency. Oral prescriptions are allowed for controlled substances only in an emergency. Later in this sentence, the word "emergency" correctly only modifies oral prescription. This rule creates consistency in the treatment of electronic orders within the subsection.

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: Illinois does not have a definition for the word "pharmacy". Their definitions define specific types of pharmacies. Electronically transmitted prescriptions for controlled substances may be dispensed only as provided by federal law.

Iowa: Iowa does not have a definition for the word "pharmacy". Electronic prescriptions may be accepted for controlled substances.

Michigan: Michigan does not have a definition for the word "pharmacy". Electronic prescriptions of controlled substances are allowed, if not prohibited by federal law.

Minnesota: Minnesota does not have a definition for the word "pharmacy". Electronic prescriptions are allowed if they conform to the rules of the federal Drug Enforcement Administration.

Summary of factual data and analytical methodologies:

The Board reviewed the rule and clarified provisions for consistency purposes.

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

This rule was posted for 14 days for economic impact comments and none were received.

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 Jeff.Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

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TEXT OF RULE

SECTION 1. Phar 1.02 (10) is amended to read:

Phar 1.02 (10) "Pharmacy" means any place of practice licensed by the board under s. ss. 450.06 or 450.065, Stats. unless otherwise provided for in s. 450.065.

SECTION 2. 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 emergency 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 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 3. 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)