STATE OF WISCONSIN PHARMACY EXAMINING BOARD _____

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD

: PHARMACY EXAMINING BOARD : **ADOPTING RULES** : CLEARINGHOUSE RULE 13-018

PROPOSED ORDER

An order of the Pharmacy Examining Board to amend s. Phar 7.01 (1) (e) relating to delivery of prescription drugs.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: Sections 450.01 (7) and 450.11, Stats.

Statutory authority: Sections 15.08 (5) (b) and 450.02 (3) (a), Stats.

Explanation of agency authority:

Section 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."

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

Related statute or rule: Chapter Phar 7.

Plain language analysis:

The proposed amendment to Phar 7.01(1) (e) allows the delivery of the prescription medication(s) to be delivered to a location of the patient's choice. The consultation requirement is met by the pharmacist providing a notice that consultation is available relative to the prescription(s) being delivered. In these cases directions and a means of contacting the pharmacist must accompany the delivery.

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

None.

Comparison with rules in adjacent states:

Illinois: Under Illinois law, dispensing does not mean the physical delivery to a patient or a patient's representative in a home or institution by a designee of a pharmacist by a common carrier [Pharmacy Practice Act, 225 ILCS 85/sec. 3(m)].

Under III. Admin. Code title 68, s. 1330.70: "If, in the pharmacist's professional judgment, oral counseling is not practicable for the patient or patient's agent, the pharmacist shall use alternative forms of patient information. When used in place of oral counseling, alternative forms of patient information shall advise the patient or agent that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free or collect telephone service."

Iowa: Under Iowa law, there is a requirement that pharmacists be responsible for delivery of prescription drugs to the patient or patient's agent; no specific location of such delivery is mentioned. If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may use alternative forms of patient information. "Not practicable" refers to patient variables including, but not limited to, the absence of the patient or patient's caregiver. When used in place of oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone or collect telephone call. [Iowa Admin. Code 657-6.2(7); 657-6.14(4)]

Michigan: Under Michigan administrative rules, a prescription is dispensed to the patient or the patient's caregiver. A caregiver is defined as the parent, guardian or other individual who has assumed responsibility for providing a patient's care. A pharmacist shall communicate to the patient or the patient's caregiver, necessary and appropriate information regarding safe and effective medication use at the time a prescription is dispensed. The information shall be communicated orally and in person, except when the patient or patient's caregiver is not at the pharmacy or when a specific communication barrier prohibits oral communication. In either situation, providing printed material designed to help the patient use the medication safely and effectively satisfies the requirements. A consultation is not required if a patient or a patient's caregiver refuses a consultation. [Mich. Admin. Code r 338.490]

Minnesota: Under Minnesota administrative rules, when a new filled prescription or a refilled prescription for which counseling is required is being mailed or delivered to the patient by common carrier or delivery services, the consultation must still be provided but may be accomplished by providing written information to the patient regarding the medication being dispensed and the availability of the pharmacist to answer questions and through a toll-free phone number for long distance calls.. There is nothing in the administrative code which indicates a specific location for a delivery. [Minn. R. 6800.0910]

Summary of factual data and analytical methodologies:

Pharmacy Examining Board receives and grants many requests for variances to Phar 7.01 (1) (e). The Pharmacy Examining Board determined that permitting the delivery to a location of a patient's choice would be beneficial to patients and to pharmacies without negatively impacting public safety.

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

This rule was posted for public comment on the economic impact of the proposed rule, including how this proposed rule may affect businesses, local government units and individuals, for a period of 14 days. No comments were received relating to the economic impact of the rule.

Fiscal Estimate and Economic Impact Analysis:

Fiscal Estimate and EIA is attached.

Effect on small business:

Delivery of prescriptions is already allowed by rule. The location of the delivery will not have an impact on small business. This rule change will not have an effect on small business.

Agency contact person:

Sharon Henes, Paralegal, 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, Paralegal, 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 at or before the public hearing to be held on April 15, 2013 to be included in the record of rule-making proceedings.

TEXT OF RULE

Section 1. Phar 7.01 (1) (e) is amended to read:

Phar 7.01 (1) (e) Give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a location of the patient's residence choice if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a location of the patient's residence choice, is not satisfied by only offering to provide consultation.

Section 2. EFFECTIVE DATE. This rule shall take effect on the first day of the month following publication in the Wisconsin Administrative Register as provided in s. 227.22 (2) (intro.), Stats.

_____ (END OF TEXT OF RULE) _____

This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Dated _____ Agency _____

Chair Pharmacy Examining Board