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 07-097)

ORDER

An order of the Pharmacy Examining Board to amend Phar 7.02, relating to prescription labels.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes interpreted:

Sections 450.11 (1), (4) and (4g) (b) and 450.12, Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) and 450.02 (2), (3) (d) and (e), Stats.

Explanation of agency authority:

The Wisconsin Pharmacy Examining Board is granted the authority to protect the public health, safety and welfare by establishing minimum standards for the practice of pharmacy, which includes the practice activities for a pharmacist and for a pharmacy technician.

Related statutes or rule:

Section 450.11 (4g) (b), Stats., and s. Phar 7.02, Wis. Adm. Code.

Plain language analysis:

This proposed rule-making will conform a pharmacy practice rule to recent statutory changes brought about by 2005 Wisconsin Act 195. In instances when a drug product equivalent is dispensed, the Act permits inclusion on the label of both the generic name and the brand name of the drug product equivalent specified in the prescription order. The brand name must be omitted from the label if the prescribing practitioner requests that it be omitted. If a brand name drug product is dispensed, the label may contain both the brand name and the generic name of the drug product unless the prescribing practitioner requests that the generic name of the drug product equivalent be omitted from the label.

SECTION 1 amends s. Phar 7.02 to conform the rules to recent statutory changes brought about by 2005 Wisconsin Act 195.

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

There is no existing or proposed federal regulation for summary and comparison.

Comparison with rules in adjacent states:

Iowa:

Iowa Admin. Code r. 657-6.(10)(1), does not allow a container label to identify a name of a drug product other than that dispensed.

Illinois:

225 Ill. Comp. Stat. 85/25, does not allow a container label to identify a name of a drug product other than that dispensed. No administrative code provision exists.

Michigan:

Mich. Admin. Code r. 338.479 (3), allows that if a drug is dispensed that is not the brand prescribed, the purchaser shall be notified and the prescription label shall indicate both the name of the brand prescribed and the brand dispensed. If the dispensed drug does not have a brand name, the label shall indicate the name of the brand prescribed followed by the generic name of the drug dispensed or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products. This does not apply when the prescriber indicates, "do not label."

Minnesota:

Minn R. 6800.3400, the label must contain the generic or trade name of a drug and its strength, except when specified by the prescriber to the contrary.

Summary of factual data and analytical methodologies:

The proposed rule will conform a pharmacy practice rule to recent statutory changes brought about by 2005 Wisconsin Act 195, which created s. 450.11 (4g) (b), Stats. Section Phar 7.02, Wis. Adm. Code, is therefore being amended for conformity with statute.

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

The board did not consult supporting documents other than 2005 Wisconsin Act 195. It is merely updating its rules based on the legislative change.

Section 227.137, Stats., requires an "agency" to prepare an economic impact report before submitting the proposed rule-making order to the Wisconsin Legislative Council. The Department of Regulation and Licensing is not included as an "agency" in this section.

Anticipated costs incurred by private sector:

The department finds that this rule has no significant fiscal effect on the private sector.

Fiscal estimate:

The department estimates that the proposed rule will have no significant fiscal impact.

Effect on small business:

These proposed rules will have no significant economic impact on a substantial number of small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at larry.martin@drl.state.wi.us, or by calling (608) 266-8608.

Agency contact person:

Pamela Haack, Paralegal, Department of Regulation and Licensing, Office of Legal Counsel, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, Wisconsin 53708-8935; telephone 608-266-0495; email pamela.haack@drl.state.wi.us.

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

Comments may be submitted to Pamela Haack, Paralegal, Department of Regulation and Licensing, Office of Legal Counsel, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, Wisconsin 53708-8935, or by email at pamela.haack@drl.state.wi.us Comments must be received on or before December 7, 2007, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.02 is amended to read:

Phar 7.02 Prescription label; name of drug or drug product dispensed. No ~~prescription~~ drug product may be dispensed unless the prescription label discloses the brand name and strength, or the generic name, strength, and manufacturer or distributor of the ~~drug or~~ drug product dispensed unless the prescribing practitioner requests omission of the above information. ~~The prescription label shall not contain the brand or generic name of any drug or drug product other than that actually dispensed.~~ If a pharmacist, pursuant to a prescription order that specifies a drug product by its brand name, dispenses the drug product equivalent of the drug product specified in the prescription order, the prescription label may include both the generic name of the drug product equivalent and the brand name specified in the prescription order,

unless the prescribing practitioner requests that the brand name be omitted from the label. If a brand name drug product is dispensed, the prescription label may contain both the brand name and the generic name of the drug product equivalent dispensed unless the prescribing practitioner requests that the generic name of the drug product equivalent be omitted from the label.

(END OF TEXT OF RULE)

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.

Dated: _____ Agency _____

Chairperson
Pharmacy Examining Board

Phar 7.02 CR07-097 (Prescription labels) Final for Adoption 3-18-08