

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 16-018)

ORDER

An order of the Pharmacy Examining Board to create Phar 8.02 (2m) and 8.13 relating to identification card required for certain controlled substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.11 (1b), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.11 (1b) (a) 1. and 450.11 (1b) (bm), 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. [s. 15.08 (5) (b)]

Health care facility means any other facility identified by the board by rule and the pharmacist shall maintain the record for a time established by the board by rule. [s. 450.11 (1b) (a) 1. and 450.11 (1b) (bm)].

Related statute or rule: Phar 7.05 (1m)

Plain language analysis:

The statutes requiring an identification card for certain controlled substances contains an exemption for drugs delivered to a health care facility and allows the board to identify other

facilities by rule to the definition of health care facility provided in the statute. This rule adds an inpatient hospice to the definition of health care facility.

The rule also requires the record of the name of the person the drug is dispensed or delivered to shall be maintained for 5 years or until the name is submitted to the prescription drug monitoring program, whichever is sooner.

Summary of, and comparison with, existing or proposed federal regulation: None

Comparison with rules in adjacent states:

Illinois: Illinois requires identification for a prescription to be dispensed. The name and address of the purchaser is recorded and maintained for not less than 2 years.

Iowa: Iowa does not require identification for a prescription to be dispensed.

Michigan: Michigan does not require identification for a prescription to be dispensed.

Minnesota: Minnesota requires identification for a controlled substance being dispensed if the purchase is not covered in whole or in part by a health plan company or other third party payor. Minnesota requires prescription records to be kept for a minimum of 2 years.

Summary of factual data and analytical methodologies:

The Board recognizes an inpatient hospice is similar in nature to the other health care facilities in the definition. The 5 year timeframe to maintain records is consistent with the length of time other pharmacy records are to be maintained.

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

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

Agency contact person:

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8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 8.02 (2m) is created to read:

Phar 8.02 (2m) Records required under s. 450.11 (1b) (bm) shall be maintained for at least 5 years from the date the drug was dispensed, or, for a record that is subject to s. 961.385, Stats., until the name of a person to whom a drug is dispensed is delivered to the controlled substances board under s. 961.385, whichever is sooner.

SECTION 2. Phar 8.13 is created to read:

Phar 8.13 Identification card exception for a health care facility. In s. 450.11 (1b) (e) 3., Stats, "Health care facility" means a facility, as defined in s. 647.01(4); any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under ss. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under ss. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.

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)