

Clearinghouse Rule 06-052

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 06-)

PROPOSED ORDER

An order of the Pharmacy Examining Board to amend Phar 8.02 (3) (f), relating to controlled substances theft and loss reporting requirements.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes interpreted:

Sections 450.02 (3) (d) and (e), and 450.11 (8) (a), Stats.

Statutory authority:

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

Explanation of agency authority:

The board is authorized by statute to promulgate rules necessary for the administration and enforcement of chapters 450 and 961, Stats., and establishing minimum standards for the practice of pharmacy.

Related statute or rule:

There are no related statutes or rules other than those listed above.

Plain language analysis:

Wisconsin Administrative Code s. Phar 8.02 (3) (f) currently requires pharmacies, practitioners and other federal drug enforcement administration (DEA) registrants authorized to possess controlled substances to notify the regional office of the DEA, the local police, and the Pharmacy Examining Board of any theft or any loss upon discovery. The DEA requires any theft to be reported but not any loss. Only significant losses must be reported to the DEA. The intent of this proposed rule change is to conform the state controlled substances theft and loss reporting requirement for pharmacies, practitioners or

other DEA registrants to federal law. The proposed rule change will eliminate the reporting of drug losses, not based on theft, by pharmacies, practitioners or other DEA registrants if the losses are not considered significant under federal law.

SECTION 1 creates the requirement for the reporting of a loss or theft of a controlled substance to the board if a pharmacy, practitioner or other DEA registrant is required to file with the DEA a report of theft or loss of controlled substances.

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

Chapter 21 CFR 13.01.74 (c) and 1301.76 (b). Federal law currently requires a DEA registrant to file a report with the DEA of any theft or significant loss of a controlled substance.

Comparison with rules in adjacent states:

Iowa

657—10.16(124) Report of theft or loss.

A registrant shall report in writing, on forms provided by the board, any theft or significant loss of any controlled substance upon discovery of the theft or loss. The report shall be submitted to the board office within two weeks of the discovery of the theft or loss. Thefts shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action is taken against them. A copy of the report shall be maintained in the files of the registrant.

Illinois

In every instance that a pharmacist-in-charge is required by federal law (21 CFR 1301.76) to file with the U.S. Drug Enforcement Agency a Report of Theft or Loss of Controlled Substances, Form 106, a copy shall be sent to the Division. Failure to do so may result in discipline of the pharmacist.

Michigan

R 338.3141 Thefts and diversions.

Rule 41. (1) An applicant or licensee shall provide effective controls against theft and diversion of controlled substances.

(2) A licensee shall determine that a person is licensed to possess a controlled substance before distributing the substance to the person.

(3) Within 10 days following discovery of a theft or loss of any controlled substance, a licensee shall notify the administrator of the theft or loss by submitting a United States drug enforcement administration theft and loss report form 106, a copy thereof, or equivalent document, whether or not the controlled substance is subsequently recovered

or the responsible party is identified and action is taken against the party, and whether or not it is also reported to the DEA.

Minnesota

6800.4800 REPORTING CONTROLLED SUBSTANCE LOSSES.

Any pharmacy, drug wholesaler, drug manufacturer, or controlled substance researcher detecting the theft or significant loss of any controlled substance drug, where the loss is attributable to other than inadvertent error, must report the loss, in writing, to the board and to the Drug Enforcement Administration immediately. The report must include a description of how the loss occurred, if known, the date the loss occurred, if known, the steps being taken to prevent future losses, and an inventory of the missing drugs.

Summary of factual data and analytical methodologies:

Asserting there is no uniform, objective standard to determine whether a loss is significant, and therefore subject to reporting, the United States Drug Enforcement Administration (DEA) initiated rule-making to further define what constitutes a significant loss of controlled substances. A final rule became effective on September 12, 2005. In view of the federal amendment, the Pharmacy Examining Board reviewed the Wisconsin rule, which requires notification of the DEA, the local police, and the Wisconsin Pharmacy Examining Board of any theft or loss. After considering the usefulness of loss reports, ranging from small losses to carelessness or inadvertent error to larger losses incurred for a variety of reasons, an assessment of the statutes and rules of Wisconsin's neighbors, a comparison of the relative value of maintaining a state requirement that is more comprehensive than the federal protections, and the simplicity merits of a uniform reporting requirement, the board decided to follow the federal rule.

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

The rule change will result in less reporting for small business pharmacies, which currently must report any theft or loss to the local police, in addition to the United States Drug Enforcement Administration and the Wisconsin Pharmacy Examining Board. The board's revision adopts the federal criteria for significant loss, places local police reporting within the pharmacist's discretion, and allows two weeks from the date of filing with the United States Drug Enforcement Administration for filing with the Wisconsin Pharmacy Examining Board.

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 of Regulation and Licensing estimates that this rule will require staff time in the Division of Management Services. The total staff salary and fringe is estimated at \$872.

Effect on small business:

These proposed rules will have no significant 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 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, 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 July 3, 2006 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 8.02 (3) (f) is amended to read:

Phar 8.02 (3) (f) ~~Any~~ In any instance that a pharmacy, practitioner or other drug enforcement administration DEA registrant authorized to possess controlled substances shall notify the regional office of the drug enforcement administration, the local police, and the pharmacy examining board of the theft or loss of any controlled substances upon discovery of such theft or loss is required to file with the DEA a report of theft or loss of controlled substances, a copy shall be sent to the board within 2 weeks of filing with the DEA.

(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 8.02 CR06- (Theft and loss reporting requirements) Draft to CH 5-12-06