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 05-001)

ORDER

An order of the Pharmacy Examining Board to amend Phar 6.08, relating to variance alternatives of alarm systems.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes interpreted:

Section 450.02 (3) (b), Stats.

Statutory authority:

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

Explanation of agency authority:

Currently, s. Phar 6.08 requires a pharmacy to have a centrally monitored alarm system in the pharmacy or the immediate physical structure within which the pharmacy is located. Depending upon the physical structure or location of the pharmacy, other means may be available to provide for security of the pharmacy consistent with the public health, safety and welfare. Providing pharmacies a means to seek a variance from the requirements of s. Phar 6.08 will allow legitimate alternative methods of achieving security to be scrutinized and approved by the board.

Related statute or rule:

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

Plain language analysis:

The objective of this rule-making order is to improve security in pharmacies that are located within another structure. Currently such pharmacies may be licensed without requesting a variance from the board if the alarm system is monitored in the pharmacy proper or in the physical structure within which the pharmacy is located. The rule change would require pharmacies without a centrally monitored alarm system in the pharmacy or the immediate

physical structure within which the pharmacy is located to seek a variance, and the board would grant the variance request only after the board has reviewed and approved a specific plan.

SECTION 1. Provides greater flexibility to pharmacies in meeting the security requirements of s. Phar 6.08 consistent with the public health, safety and welfare.

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

Applicable Federal Law: Alarm systems are not required specifically, but may be considered a factor in obtaining substantial compliance with security regulations generally.

21 CFR Section 1301:71:

Section 1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in Secs. 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in Secs. 1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
(3) The quantity of controlled substances handled;
(4) The location of the premises and the relationship such location bears on security needs;
(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;
(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
(7) The type of closures on vaults, safes, and secure enclosures;
(8) The adequacy of key control systems and/or combination lock control systems;
(9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;
(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
(13) The availability of local police protection or of the registrant's or applicant's security personnel, and;
(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in Secs. 1301.72-1301.76 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or as a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in Secs. 1301.72-1301.76 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Special Agent in Charge in the region in which the system will be used, or to the Division Operations Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(e) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in Secs. 1301.72, 1301.73 and 1301.75. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Administration, shall not necessarily be deemed to comply substantially with the standards set forth in Secs. 1301.72, 1301.73 and 1301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Administration.

[36 FR 18729, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 47 FR 41735, Sept. 22, 1982; 51 FR 5319, Feb. 13, 1986]

21 CFR Section 1301.75:

Section 1301.75 Physical security controls for practitioners.

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

(d) Carfentanil etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

[39 FR 3674, Jan. 29, 1974, as amended at 39 FR 17838, May 21, 1974; 54 FR 33674, Aug. 16, 1989; 62 FR 13957, Mar. 24, 1997]

Comparison with rules in adjacent states:

Minnesota – none.
Michigan – none.

Illinois

TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF PROFESSIONAL REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS

PART 1330
PHARMACY PRACTICE ACT OF 1987

Section 1330.75 Security Requirements

a) Whenever the pharmacy (prescription area) is not occupied by a registrant, the pharmacy (prescription area) must be secured and inaccessible to non-licensed persons (employees and public). This may be accomplished by measures such as walling off, locking doors, electronic security equipment, as approved by the Department.

Iowa

657 IAC Chapter 6 GENERAL PHARMACY PRACTICE 657—6.7(124,155A) Security.

While on duty, each pharmacist shall be responsible for the security of the prescription department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records as provided in 657—Chapter 21.

6.7(1) Department locked. The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on site except as provided in subrule 6.7(2).

6.7(2) Temporary absence of pharmacist. In the temporary absence of the pharmacist, only the pharmacist in charge may designate persons who may be present in the prescription department to perform technical and nontechnical functions designated by the pharmacist in charge. Activities identified in subrule 6.7(3) may not be performed during such temporary absence of the pharmacist. A temporary absence is an absence of short duration not to exceed two hours. In the absence of the pharmacist, the pharmacy shall notify the public that the pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns.

Indiana

856 IAC 1-13-3 "Prescription department closed" closing hours; electronic monitoring; applicability

Authority: IC 25-26-13-4
Affected: IC 25-26-13-10; IC 25-26-13-19

Sec. 3. (a) This section and section 4 of this rule implement IC 25-26-13-19 concerning board approval for Type I and Type VI pharmacies to be opened to the general public without a pharmacist on duty. This section and section 4 of this rule apply only in situations where the entire area of the business is licensed as a pharmacy. This section, section 4 of this rule, and IC 25-26-13-19 do not apply where the only area of a business licensed as a pharmacy is the prescription department.

(b) The following definitions apply throughout this section:

(1) "Absence of pharmacist" means those periods when the prescription department is closed and secured and the pharmacist is not present in the pharmacy.

(2) "Electronic monitoring system" means a system having the ability by light beam, heat, motion, or other electronically activated method to detect the presence of unauthorized persons or instrumentalities in a given area, and relay or report that detection as described in this section.

(3) "Prescription department" means that area of the pharmacy where the legend drugs, devices, and other merchandise or items which can only be dispensed or delivered by a pharmacist are located and which must be secured in the absence of the pharmacist.

(4) "Reasonable barrier" means an obstruction or barricade that blocks or impedes the entry into the area by an ordinary person, and includes, but is not limited to, a latched or locked gate of sufficient height and construction that an ordinary person cannot breach the barrier and/or violate the space the space being monitored without detection.

(5) "Secured" means either of the following:

(A) An area is completely enclosed as to its perimeter, from floor to ceiling, and locked.

(B) Through installation of reasonable barriers, an area not readily accessible which is monitored by a board approved electronic monitoring system covering all portions of the secured areas.

(c) Before a pharmacy may be open to the general public without a pharmacist on duty, the pharmacy must file an application with the board and have it approved by the board under IC 25-26-13-19. The pharmacy must abide by the closing hours designated in the application. Any change from the hours as stated in the application must be submitted in writing to the board.

(d) Under IC 25-26-13-19, a prescription department may be locked or secured while the remainder of the pharmacy remains open to the public if the following criteria are met:

(1) The prescription department is constructed in such a manner or located in such an area that reasonable barriers are in place which prevent the easy and/or quick access to legend drugs and other articles which are in the prescription department. These barriers may be doors or other obstacles as the occasion requires.

(2) The prescription department, if not secured and locked as described in subsection (b)(5)(A), must be secured and monitored by a board approved electronic monitoring device that provides the following:

(A) On-site audible alarm that is clearly and continuously audible at all points within the pharmacy.

(B) Off-site audible or visual alarm that is continuously monitored at all times that the pharmacy remains open while the prescription department is closed and secured.

(3) Any violation or breach of the secured area shall be duly recorded by the qualifying pharmacist of the pharmacy and by the off-site security monitoring agency and reported to the board within seventy-two (72) hours of the violation or breach. This report shall include the nature of the violation or breach.

(4) Facilities monitored electronically must provide for backup power for the eventuality that there is an electronic power failure for any reason. Such backup power shall be capable of continuing the monitoring for a period of no less than thirty-six (36) hours.

(5) The electronic monitoring system shall be activated and inactivated only by key or combination. Alarms which have been triggered shall only be reset and/or reactivated by a pharmacist. The key or combination shall only be in the possession or knowledge of a pharmacist. Reasonable exceptions shall be made to this for security system operators. However, in no case shall a security system operator have access to the secured area without the presence of a pharmacist. Such exceptions shall be listed in the application under this section and shall be subject to approval by the board.

(e) Under IC 25-26-13-10(b), the board may revoke or limit the privilege to be open to the general public without a pharmacist on duty if the pharmacy violates this section or section 4 of this rule. *(Indiana Board of Pharmacy; Reg 13, Sec 3; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 124; filed May 15, 1992, 5:00 p.m.: 15 IR 2246; readopted filed Nov 13, 2001, 3:55 p.m.: IR 1330)*

Summary of factual data and analytical methodologies:

The board reviewed the current alarm rule in view of the security needs of pharmacies that exist in other structures. The draft of the rule was prepared after extensive analysis by both professional and public members of the board, expert advice of pharmacists who operate pharmacies located within another structure, and representatives from the small business community.

Determination of significant fiscal effect on the private sector:

The Department of Regulation and Licensing has determined that there will be no anticipated costs that would be incurred by the private sector.

Fiscal estimate:

The proposed rule will have an impact of $120 annually on the department's funds. This represents the salary and fringe benefits for staff to prepare two plans for variance to present to the board per year. The board's legal counsel and bureau director and a professional credentialing supervisor will each need to spend one half hour per variance plan.

Effect on small business:

Pursuant to s. 227.114 (1) (a), Stats., these proposed rules will have no significant economic impact on a substantial number of small businesses. The Department's Small Business Regulatory Review Coordinator may be contacted by email at christopher.klein@drl.state.wi.us, or by calling (608) 266-8608.

Agency contact person:

The agency contact person is Pamela Haack, Paralegal, Department of Regulation and Licensing, Office of Legal Counsel, 1400 East Washington Avenue, Room 171, P.O. Box 8935, Madison, Wisconsin 53708. Telephone: (608) 266-0495. Email address: pamela.haack@drl.state.wi.us.

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

A public hearing on these rules will be held on February 9, 2005 at 9:30 a.m. in Room 180 at the Department. Comments may be submitted to Pamela Haack at the Department of Regulation and Licensing, Office of Legal Counsel, Room 171, 1400 East Washington Avenue, P. O. Box 8935, Madison, Wisconsin 53708, or by email at pamela.haack@drl.state.wi.us. Written comments must be received on or before February 21, 2005, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 6.08 is amended to read:

Phar 6.08 Security. ~~Effective January 1, 2000, a~~ A pharmacy shall have a centrally monitored alarm system in the pharmacy or the immediate physical structure within which the pharmacy is located. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the board.

(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 6.08 CR05-001 (Alarm system variance) Final Draft 5-5-05