

**CERTIFICATE**

**STATE OF WISCONSIN  
DEPARTMENT OF REGULATION AND LICENSING**

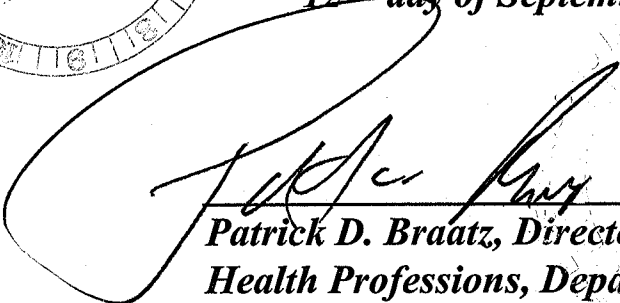
**TO ALL WHOM THESE PRESENTS SHALL COME, GREETINGS:**

*I, Patrick D. Braatz, Director, Bureau of Health Professions in the Wisconsin Department of Regulation and Licensing and custodian of the official records of the Pharmacy Examining Board, do hereby certify that the annexed rules were duly approved and adopted by the Pharmacy Examining Board on the 12<sup>th</sup> day of September, 2000.*

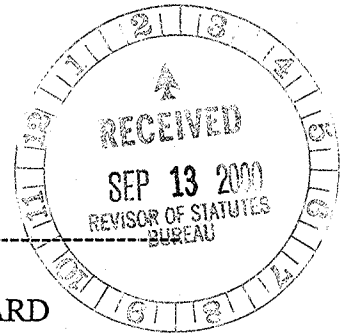
*I further certify that said copy has been compared by me with the original on file in this office and that the same is a true copy thereof, and of the whole of such original.*



**IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the board at 1400 East Washington Avenue, Madison, Wisconsin this 12<sup>th</sup> day of September, 2000.**

  
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**Patrick D. Braatz, Director, Bureau of Health Professions, Department of Regulation and Licensing**

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD



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IN THE MATTER OF RULE-MAKING : ORDER OF THE  
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD  
PHARMACY EXAMINING BOARD : ADOPTING RULES  
: (CLEARINGHOUSE RULE 99-166)  
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ORDER

An order of the Pharmacy Examining Board to create Phar 7.09, relating to the automated dispensing of prescription drugs.

Analysis prepared by the Department of Regulation and Licensing.

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ANALYSIS

Statutes authorizing promulgation: ss. 15.08 (5) (b), 227.11 (2) and 450.02 (3) (a), (b), (d) and (e), Stats.

Statutes interpreted: s. 450.02 (3) (a), (b), (d) and (e), Stats.

The objective of these rules is to establish minimum requirements for pharmacies and inpatient health care facilities that use automated systems, similar to vending machines, to store, package and dispense patient medications.

Technologies are available that mechanically dispense patient medications pursuant to prescription or medical orders. These systems also collect, control and maintain transactional information such as the identity of the individual accessing the system, the name, strength, dosage form and quantity of the drug accessed and the name of the patient for whom the drug is prescribed or ordered. This technology results in efficiencies over labor intensive pharmaceutical acts such as manually filling medication containers and labeling the containers. Such cost saving devices should be permitted in those settings in which there are adequate measures taken to assure the accuracy, accountability, security and patient confidentiality when the devices are utilized.

Accordingly, rules need to be developed defining minimum standards for assuring these systems are working properly by accurately dispensing patient medications; that only authorized and qualified personnel have access to them; that required records are maintained; and that procedures are in place to assure the security of the system and patient confidentiality.

SECTION 1. Defines an automated dispensing system and provides that such a system may be used in a pharmacy and inpatient health care facilities under the provisions of the section. To use an automated dispensing system in an inpatient health care facility the use must be pursuant to accepted inpatient institutional drug distribution systems of the type permissible under s. Phar 7.01 (2). For any automated dispensing system that is used the managing pharmacist is responsible to insure the functioning and accuracy of the system and must comply with the

requirements delineated to fulfill the recordkeeping, security safeguards, and notice requirements of the section.

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TEXT OF RULE

SECTION 1. Phar 7.09 is created to read:

**Phar 7.09 Automated dispensing systems.** (1) In this section:

(a) "Automated dispensing system" means a mechanical system that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

(b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, or tuberculosis sanatorium, but does not include community-based residential facilities.

(2) An automated dispensing system may be used in a community pharmacy, as provided in this section.

(3) An automated dispensing system may be used as provided in this section by an institutional pharmacy serving an inpatient health care facility, that has an established program of receiving prescription orders, and dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. An automated dispensing system used by an institutional pharmacy shall only be located in that institutional pharmacy or within the inpatient health care facility.

(4) The managing pharmacist of a community pharmacy or an institutional pharmacy is responsible for all of the following:

(a) Assuring that the automated dispensing system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed and complying with the recordkeeping and security safeguards pursuant to sub. (5).

(b) Implementing an ongoing quality assurance program that monitors performance of the automated dispensing system, which is evidenced by written policies and procedures.

(c) Providing the board with prior written notice of the installation or removal of an automated dispensing system. The notice provided shall include, but is not limited to the:

1. Name and address of the pharmacy.

2. Initial location of the automated dispensing system. The automated dispensing system may thereafter be relocated within the pharmacy or inpatient health care facility without providing subsequent notification to the board.

3. Identification of the managing pharmacist.

(d) Assigning, discontinuing or changing personnel access to the system.

(e) Assuring that access to the medications comply with state and federal laws.

(f) Assuring that the automated dispensing system is stocked accurately and in accordance with established written policies and procedures.

(5) An automated dispensing system shall comply with the following provisions:

(a) A pharmacy shall maintain on-site the following documentation relating to an automated dispensing system:

1. Name and address of the pharmacy or inpatient health care facility where the system is being used.

2. The system manufacturer's name, model and serial number.

3. Description of how the system is used.

4. Written quality assurance procedures to determine continued appropriate use of the system.

5. Except as required pursuant to par. (b), written policies and procedures for system operation, safety, security, accuracy, access and malfunction.

(b) All written policies and procedures shall be maintained in the pharmacy responsible for the automated dispensing system.

(c) An automated dispensing system shall have adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

(d) Records and data kept by the automated dispensing system shall meet the following requirements:

1. All events involving the contents of the automated dispensing systems must be recorded electronically.

2. Records shall be maintained by the pharmacy and be available to the board. Records shall include:

- a. The time and location of the system accessed.
- b. Identification of the individual accessing the system.
- c. Type of transaction.
- d. Name, strength, dosage form and quantity of the drug accessed.
- e. Name of the patient for whom the drug was ordered.
- f. Such additional information as the managing pharmacist may deem necessary.

(e) The stocking of all medications in the automated dispensing system shall be accomplished by qualified personnel under no less than the general supervision of a licensed pharmacist; except that when an automated dispensing system is located within a pharmacy the supervision must be direct.

(f) A record of medications stocked into an automated dispensing system shall be maintained for 5 years and shall include identification of the person stocking and pharmacist checking for accuracy.

(g) All containers of medications stored in the automated dispensing system shall be packaged and labeled in accordance with state and federal law.

(h) All aspects of handling controlled substances shall meet the requirements of all state and federal law.

(i) The automated dispensing system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated dispensing system, in accordance with state and federal law.

(j) The automated dispensing system shall provide a mechanism for securing and accounting for medication returned to the system and accounting for wasted medications in accordance with state and federal law.

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(END OF TEXT OF RULE)

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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 9/12/00

Agency John F. Sakhan, Rph  
Chairperson  
Pharmacy Examining Board

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8/28/00



State of Wisconsin

DEPARTMENT OF REGULATION AND LICENSING

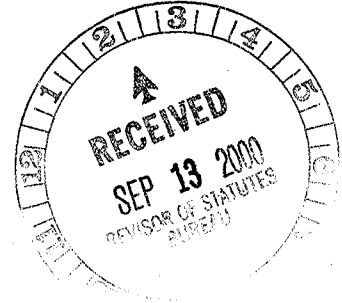
CORRESPONDENCE/MEMORANDUM

**DATE:** September 13, 2000

**TO:** Gary Poulson  
Assistant Revisor of Statutes

**FROM:** Pamela A. Haack, Paralegal  
Department of Regulation and Licensing  
Office of Administrative Rules

**SUBJECT:** Final Order Adopting Rules



**Agency: Pharmacy Examining Board**

**Clearinghouse Rule 99-166**

Attached is a copy and a certified copy of a final order adopting rules relating to the automated dispensing of prescription drugs.

Please stamp or sign a copy of this letter to acknowledge receipt.

Thank you.