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CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **99–166**

AN ORDER to create Phar 7.09, relating to the automated dispensing of prescription drugs.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

12–14–99 RECEIVED BY LEGISLATIVE COUNCIL.
01–13–00 REPORT SENT TO AGENCY.

RNS:DD:rv;jal

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☐ NO ☑

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

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CLEARINGHOUSE RULE 99–166

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated September 1998.]

2. Form, Style and Placement in Administrative Code

a. The department's analysis of the rule describes the need for and objective of the rule but does not adequately summarize the content of the rule. [See s. 1.02 (2) (b), Manual.]

b. In Phar 7.09 (1), the phrase "but is not limited to" should not be used with the word "means" in a definition. [See s. 1.01 (7) (c), Manual.] More importantly, it is not clear why "but is not limited to" is included in the definition; if other systems are contemplated as being included within the definition of "automated dispensing system," those should be specified in the definition, if possible.

c. In Phar 7.09 (2), "automated dispensing system" should be in the singular and reference should be to a "pharmacy" rather than "licensed pharmacies"; see the definition of "pharmacy" in Phar 1.02 (10).

d. The relationship of subs. (2) and (3) is unclear. Reference in sub. (2) to "where legally permissible" is vague. Does sub. (3) specify when an automated dispensing system is "legally permissible" in an inpatient health care facility? Better coordination of the subsections is in order.

e. In Phar 7.09 (3), ", where there is" should be replaced by "that have." Who determines whether an inpatient health care facility has an established program of pharmaceutical care that ensures medication orders are reviewed by a pharmacist in accordance

with established policies and procedures and good pharmacy practice? Reference to "inpatient health care facilities" in this subsection should be in the singular.

f. In s. Phar 7.09 (4) (intro.), "is" should replace "shall be" and "all of the following" should be inserted before the colon. The latter language also needs to be inserted elsewhere in the rule.

g. In s. Phar 7.09 (4) (c) (intro.), it appears that ", but is not limited to the" should be replaced by "all of the following:".

h. In subd. 1. of s. Phar 7.09 (4) (c), should "or the inpatient health care facility" be added?

i. It is suggested that Phar 7.09 (5) (intro.) be deleted and that all the paragraphs following that introductory clause be changed into separate subsections. This change will necessitate making specific reference, as appropriate, to an automated dispensing system in some of the new subsections. See current pars. (a) (intro.), (b) and (i).

j. It is suggested that Phar 7.09 (5) (a) (intro.) be revised to read: "A pharmacy shall maintain on-site the following documentation relating to an automated dispensing system:". Reference to serial numbers should then be added to the list of required information following the introductory clause. It is not clear why the original introductory clause states "may include, but is not limited to." Is the intent that the documentation may include additional information if desired or that the board may require additional information?

k. Section Phar 7.09 (5) (b) appears inconsistent with the requirement of sub. (5) (a) (intro.) that policies and procedures be maintained "on-site in the pharmacy."

l. It is suggested that s. Phar 7.09 (5) (c) not be subdivided; the paragraph can be stated in a single sentence.

m. It appears that s. Phar 7.09 (5) (e) unnecessarily repeats par. (c). Also, "must" should be replaced by "shall" if the provision is retained. The latter change should also be made in par. (f).

n. In s. Phar 7.09 (5) (i), "all" should be deleted.

o. In s. Phar 7.09 (j), "all" and "existing" should be deleted and "laws" should be singular.

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In s. Phar 7.09 (1) (a), "collects," "controls," and "maintains" should reflect the plural subject "systems."

b. In s. Phar 7.09 (1) (b), "sanitorium" should replace "sanitarium."

c. In s. Phar 7.09 (5) (d) 2. a., "the" should be inserted after "of."

d. The use of "managing pharmacist" in s. Phar 7.09 (4) (intro.) raises questions concerning who has the listed responsibilities for an automated dispensing system located in an inpatient health care facility. See the definition of "managing pharmacist" in s. Phar 1.02 (6). Section Phar 7.09 (5) (f) raises the question why an automated dispensing system that is not located in a pharmacy is subject to apparently less stringent supervision of its stocking than when located within a pharmacy. In general, it appears that the rule could be clearer regarding the treatment of an automated dispensing system that is located in an inpatient health care facility rather than a pharmacy.

State of Wisconsin \ DEPARTMENT OF REGULATION & LICENSING

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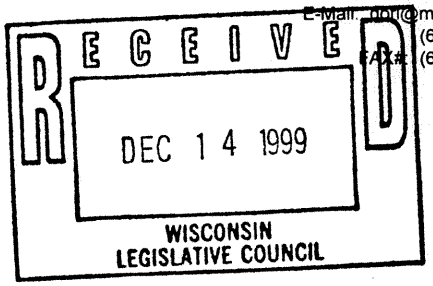

December 14, 1999

TO: Ron Sklansky, Director
Rules Clearinghouse
Wisconsin Legislative Council
1 East Main Street, Suite 401

FROM: Pamela A. Haack, Paralegal
Office of Administrative Rules
Department of Regulation and Licensing
Room 171, 1400 East Washington Avenue
(608) 266-0495

RE: Proposed Rule-Making Order of the Pharmacy Examining Board

Attached please find a proposed rule-making order of the Pharmacy Examining Board submitted under s. 227.15, Wis. Stats. The proposed order contains citations to the statutory authority under which the board intends to adopt the proposed rules and a description of the effect of the proposal.

Please stamp or sign a copy of this letter to acknowledge receipt. Please call me at 266-0495 if I can be of any assistance to the Clearinghouse in reviewing this rule.

Thank you.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED 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.

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.

Specific and good but not confined

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, but is not limited to, mechanical systems 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 sanitarium, but does not include community-based residential facilities.

(2) Automated dispensing systems may be utilized in licensed pharmacies and inpatient health care facilities where legally permissible.

(3) Automated dispensing systems may only be used in inpatient health care facilities, where there is an established program of pharmaceutical care that ensures medication orders are reviewed by a pharmacist in accordance with established policies and procedures and good pharmacy practice.

(4) The managing pharmacist shall be responsible for:

(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 while maintaining appropriate recordkeeping and security safeguards.

(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. Location of the automated equipment.

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) Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained on-site in the pharmacy. The documentation may include, but is not limited to, the following:

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

2. Manufacturer's name and model.

3. Description of how the device is used.

4. Quality assurance procedures to determine continued appropriate use of the automated device.

5. Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access and malfunction.

(b) All policies and procedures shall be maintained in the pharmacy responsible for the system and, if the system is not located within the facility where the pharmacy is located, at the location where the system is being used.

(c) An automated dispensing system shall have adequate security systems and procedures, evidenced by written policies and procedures to:

1. Prevent unauthorized access to comply with federal and state laws.

2. Maintain patient confidentiality.

(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. Identity of 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) Access to and limits on access to the automated dispensing system shall be defined by policy and procedures and ~~must~~ shall comply with state and federal laws.

(f) 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.

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

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

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

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

(k) The automated dispensing system shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal laws.

(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

FISCAL ESTIMATE

1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is: $0.00.

2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: $0.00.

3. The projected net annualized fiscal impact on state funds of the proposed rule is: $0.00.

INITIAL REGULATORY FLEXIBILITY ANALYSIS

These proposed rules will be reviewed by the department through its Small Business Review Advisory Committee to determine whether there will be an economic impact on a substantial number of small businesses, as defined in s. 227.114 (1) (a), Stats.

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12/13/99

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

TO: Senator Judy Robson, Senate Co-Chairperson
Joint Committee for the Review of Administrative Rules
Room 15 South, State Capitol
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the PHARMACY EXAMINING BOARD is submitting in final draft form rules relating to the automated dispensing of prescription drugs.

Please stamp or sign a copy of this letter to acknowledge receipt. If you have any questions concerning the final draft form or desire additional information, please contact Pamela Haack at 266-0495.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	**:**	**REPORT TO THE LEGISLATURE**
PROCEEDINGS BEFORE THE	**:**	**ON CLEARINGHOUSE 99-166**
PHARMACY EXAMINING BOARD	**:**	**(s. 227.19 (3), Stats.)**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS:

No new or revised forms are required by these rules.

III. FISCAL ESTIMATES:

These rules will have no significant impact upon state or local units of government.

IV. STATEMENT EXPLAINING NEED:

The objective of these rules is to establish minimum requirements for pharmacies and inpatient health care facilities that use automated dispensing 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.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on January 12, 2000. Steve Rough, M.S., R.Ph., Director, Pharmacy Service Organizations, UW Hospital and Clinics, Clinical Instructor, UW School of Pharmacy, Madison, Wisconsin, appeared in support of the rules.

Written comments were also received from Steve Rough, together with Tom Thielke, M.S., R.Ph., Director of Pharmacy, UW Hospital and Clinics, Clinical Professor, UW School of Pharmacy, and Dave Musa, M.B.A., R.Ph., Assistant Director of Pharmacy, UW Hospital and Clinics, Clinical Instructor, UW School of Pharmacy, Madison, Wisconsin.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 2.h. In subd. 1. of s. Phar 7.09 (4) (c) (intro.), should "or the inpatient health care facility" be added: Response: This change was not accepted because the managing pharmacist at the inpatient health care facility, still has the enumerated duties. Therefore, the use of the term "pharmacy" in subd. 1. is correct. Subsection (4) (a) was revised to make clear that the managing pharmacist is responsible for assuring compliance with subsections (4) and (5). This is the case regardless of whether the system is in a retail pharmacy, or an institutional pharmacy serving in and inpatient health facility.

Comment 2.i. It is suggested that Phar 7.09 (5) (intro.) be deleted and that all the paragraphs following that introductory clause be changed into separate subsections. This change will necessitate making specific reference, as appropriate, to an automated dispensing system in some of the new subsections. Response: Section Phar 7.09 (5) (intro.) was kept separate with the noted revisions to the paragraphs that follow to clarify the paragraph.

Comment 2.k. Section Phar 7.09 (5) (b) appears inconsistent with the requirement of sub. (5) (a) (intro.) that policies and procedures be maintained "on-site in the pharmacy." Response: This section is appropriate as written, because it encompasses the scenario where a system in an inpatient health care facility is located at a site different from the pharmacy.

Comment 5.a. In s. Phar 7.09 (1) (a), "collects," "controls," and "maintains" should reflect the plural subject "systems." Response: This is correct as written, following the change of "systems" to singular.

Comment 5.d. The use of "managing pharmacist" in s. Phar 7.09 (4) (intro.) raises questions concerning who has the listed responsibilities for an automated dispensing system located in an inpatient health care facility. See the definition of "managing pharmacist" in s. Phar 1.02 (6). Section Phar 7.09 (5) (f) raises the question why an automated dispensing system that is not located in a pharmacy is subject to apparently less stringent supervision of its stocking than when located within a pharmacy. In general, it appears that the rule could be clearer regarding the treatment of an automated dispensing system that is located in an inpatient health care facility rather than a pharmacy. Response: The changes made to s. Phar 7.09 (4) and (5) address the concern pertaining to the duties of the managing pharmacist in the inpatient health care facility setting.

The remaining recommendations suggested in the Clearinghouse Report were accepted in whole.

VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

The rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1) (a), Stats.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED 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.

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.

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 sanitorium, 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.

(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

FISCAL ESTIMATE

1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is: $0.00.

2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: $0.00.

3. The projected net annualized fiscal impact on state funds of the proposed rule is: $0.00.

FINAL REGULATORY FLEXIBILITY ANALYSIS

These rules will have no significant economic impact on a substantial number of small businesses, as defined in s. 227.114 (1) (a), Stats.

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