

03-096  
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**Carol Roessler**  
STATE SENATOR

To: Members of the Senate Committee on Health, Children, Families, Aging and Long Term Care

From: Senator Carol Roessler, Chair

Date: January 20, 2004

Re: Clearinghouse Rule 03-096 relating to the professional service area requirements where the pharmacist is absent.

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CR 03-096 has been referred to the Senate Health, Children, Families, Aging and Long Term Care Committee. CR 03-096 will allow a pharmacy to remain open without placement of physical barriers during temporary periods of absence from a pharmacy by a pharmacist.

If you would like the committee to hold a hearing on CR 03-096, please contact Jennifer Halbur in my office by **January 30, 2004**.

**STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD**

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**IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE  
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD  
PHARMACY EXAMINING BOARD : ADOPTING RULES  
: (CLEARINGHOUSE RULE 03-096)**

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TO: Alan J. Lasee  
President of the Senate  
Room 219 South, State Capitol  
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the PHARMACY EXAMINING BOARD is submitting in final draft form rules relating to the professional service area requirements where the pharmacist is absent.

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**

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**IN THE MATTER OF RULE-MAKING : REPORT TO THE LEGISLATURE  
PROCEEDINGS BEFORE THE : ON CLEARINGHOUSE RULE 03-096  
PHARMACY EXAMINING BOARD : (s. 227.19 (3), Stats.)**

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**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:**

The Department of Regulation and Licensing will incur \$500 in costs to print and distribute the rule change.

**IV. STATEMENT EXPLAINING NEED:**

Modifications of s. Phar 6.04 will allow a pharmacy to remain open without placement of physical barriers during temporary periods of absence from a pharmacy by a pharmacist under certain conditions, and sets forth permissible technician activities under s. Phar 7.015 during the temporary absence of a pharmacist. Currently, s. Phar 6.04 (3) (a) 1. and 2. provide that in the absence of a pharmacist a pharmacy may convert to a non-prescription or sundry outlet if certain requirements are met, in part the placement of a physical barrier. Modifying the rule will allow certain limited interactions between pharmacy staff and patients, as well as the carrying on of certain allowable pharmacy staff functions in the absence of a pharmacist. Patients will benefit by increased availability of pharmacy services.

**V. NOTICE OF PUBLIC HEARING:**

A public hearing was held on November 11, 2003. There were no appearances at the public hearing nor were any written comments received.

**VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:**

Comment 1. This rule permits a pharmacy to remain open without converting to a non-prescription or sundry outlet and erecting barriers to the pharmacy area during the temporary absence of a pharmacist. The department cites s. 450.09, Stats., as the statute being interpreted in this rule. Section 450.09 (2), Stats., provides that no pharmaceutical service (an undefined term) may be provided to any person unless a pharmacist is present

in the pharmacy to provide or supervise the service. How does the proposed rule permitting the temporary absence of a pharmacist without converting to a non-prescription area comport with the statutory requirement that a pharmacist be present in order for pharmaceutical services to be performed?

Response: The board considers that the proposed rule comports with s. 450.09 (2), Stats. The board's view that the rule comports with s. 450.09 (2), Stats., is based upon the use of the word "to" in that section, instead of the word "for," combined with the fact that a pharmacist must review, check and verify any technician action performed in the dispensing process prior to transferring a prescription drug to a patient. The act of dispensing is actually a process, containing many steps. The pharmacist is responsible for insuring that each step is carried out properly.

The word "to" is a preposition. The meaning of "to" in the sense of s. 450.09 (2), Stats., is derived from the New World Dictionary (Second College Edition) as follows; "15. with (a specified person or thing) as the recipient, or indirect object, of the action... [..give the book *to* her]". A pharmaceutical service therefore is seen for purposes of s. 450.09 (2), Stats., similar to the dictionary definition, as flowing from the pharmacy staff to the patient. The preposition "to" in this instance links the action to the recipient. However, under both current Wis. Admin. Code § Phar 6.04 (3), and the proposed rule, "pharmaceutical services," actions, or transfer of prescription drugs are not allowed from pharmacy technicians "to" patients in the absence of the pharmacist. Rather, technicians perform their duties in the dispensing process "for" a pharmacist, who is required to check and verify that the duties are done correctly.

Comment 5.b. Section Phar 6.04 (3) (c) (intro.) and 4., read together, provide that pharmacy technicians may only perform duties allowed by s. Phar 7.015 (2) where no pharmacist is present in the professional area. That provision sets forth technical dispensing functions that a pharmacist may delegate to a pharmacy technician, "but only under the supervision of the pharmacist where the delegated functions are performed." Can a pharmacist provide the requisite supervision if he or she is absent from the pharmacy for a period of time?

Response: The requisite supervision during the pharmacist's short absence will be provided by the pharmacist being accessible for communication with the remaining pharmacy staff by phone, pager or other device.

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

## VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

These 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

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IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE  
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD  
PHARMACY EXAMINING BOARD : ADOPTING RULES  
: (CLEARINGHOUSE RULE 03-096)

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PROPOSED ORDER

An order of the Pharmacy Examining Board to amend Phar 6.04 (3) (a) (intro.); and to create Phar 6.04 (3) (c), relating to the professional service area requirements where the pharmacist is absent.

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), Stats.

Statutes interpreted: s. 450.09, Stats.

Modifications of s. Phar 6.04 will allow a pharmacy to remain open without placement of physical barriers during temporary periods of absence from a pharmacy by a pharmacist under certain conditions, and sets forth permissible technician activities under s. Phar 7.015 during the temporary absence of a pharmacist. Currently, s. Phar 6.04 (3) (a) 1. and 2. provide that in the absence of a pharmacist a pharmacy may convert to a non-prescription or sundry outlet if certain requirements are met, in part the placement of a physical barrier. Modifying the rule will allow certain limited interactions between pharmacy staff and patients, as well as the carrying on of certain allowable pharmacy staff functions in the absence of a pharmacist. Patients will benefit by increased availability of pharmacy services.

SECTION 1 amends s. Phar 6.04 (3) (a) (intro.) and adds a provision allowing a pharmacy in the absence of a pharmacist to continue to operate without converting to a sundry outlet if specific conditions are met.

SECTION 2 creates s. Phar 6.04 (3) (c) specifying the conditions under which a pharmacy may continue to operate in the absence of a pharmacist without converting to a sundry outlet.

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TEXT OF RULE

SECTION 1. Phar 6.04 (3) (a) (intro.) is amended to read:

Phar 6.04 (3) PROFESSIONAL SERVICE AREA, REQUIREMENTS WHERE PHARMACIST IS ABSENT. (a) (intro.) A Except as provided in par. (c), if no pharmacist is present in the professional service area, a pharmacy may convert to a non-prescription or sundry outlet without a pharmacist present if the following requirements of the professional service area are met:

SECTION 2. Phar 6.04 (3) (c) is created to read:

Phar 6.04 (3) (c) Where no pharmacist is present in the professional service area a pharmacy is not required to convert to a non-prescription or sundry outlet if the following requirements are met:

1. The pharmacist is absent for a time period of one half hour or less.
2. The pharmacist must be accessible for communication with the remaining pharmacy staff by phone, pager or other device.
3. The pharmacy must indicate that the pharmacist is not available in the professional service area and indicate the period of absence and the time of the pharmacist's return.
4. Pharmacy technicians may only perform duties allowed by s. Phar 7.015 (2).

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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 \_\_\_\_\_

Agency \_\_\_\_\_

Chairperson  
Pharmacy Examining Board

FISCAL ESTIMATE

The Department of Regulation and Licensing will incur \$500 in costs to print and distribute the rule change.

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.

Phar 6.04(3) CR03-096 (Pharmacist absence) Draft to Leg 01-15-04



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**WISCONSIN LEGISLATIVE COUNCIL  
RULES CLEARINGHOUSE**

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**Ronald Sidansky**  
*Clearinghouse Director*

**Terry C. Anderson**  
*Legislative Council Director*

**Richard Sweet**  
*Clearinghouse Assistant Director*

**Laura D. Rose**  
*Legislative Council Deputy Director*

**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 03-096**

AN ORDER to amend Phar 6.04 (3) (a) (intro.); and to create Phar 6.04 (3) (c), relating to the professional service area requirements where the pharmacist is absent.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

09-29-2003 RECEIVED BY LEGISLATIVE COUNCIL.

10-27-2003 REPORT SENT TO AGENCY.

RNS:PS

**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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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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Ronald Sklansky  
Clearinghouse Director

Terry C. Anderson  
Legislative Council Director

Richard Sweet  
Clearinghouse Assistant Director

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Legislative Council Deputy Director

### CLEARINGHOUSE RULE 03-096

#### 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 October 2002.]**

#### 1. Statutory Authority

This rule permits a pharmacy to remain open without converting to a non-prescription or sundry outlet and erecting barriers to the pharmacy area during the temporary absence of a pharmacist. The department cites s. 450.09, Stats., as the statute being interpreted in this rule. Section 450.09 (2), Stats., provides that no pharmaceutical service (an undefined term) may be provided to any person unless a pharmacist is present in the pharmacy to provide or supervise the service. How does the proposed rule permitting the temporary absence of a pharmacist without converting to a non-prescription area comport with the statutory requirement that a pharmacist be present in order for pharmaceutical services to be performed?

#### 2. Form, Style and Placement in Administrative Code

- a. In the description of SECTIONS 1 and 2 in the rule analysis, "par." should be replaced by "s." In the previous paragraph of the analysis, "s." should replace "subs."
- b. In SECTION 1, "par. c." should be replaced by "par. (c)".

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

- a. In s. Phar 6.04 (3) (c) (intro.), a comma should be inserted after the word "area."
- b. Section Phar 6.04 (3) (c) (intro.) and 4., read together, provide that pharmacy technicians may only perform duties allowed by s. Phar 7.015 (2) where no pharmacist is present in the professional service area. That provision sets forth technical dispensing functions that a

pharmacist may delegate to a pharmacy technician, "but only under the general supervision of the pharmacist where the delegated functions are performed." Can a pharmacist provide the requisite supervision if he or she is absent from the pharmacy for a period of time?

Also, in s. Phar 6.04 (3) (c) 5., the statement that pharmacy technicians may not perform "the *remaining* prohibited activities" listed in s. Phar 7.015 (3) or (4) gives the impression that the technician *may* perform certain prohibited activities listed in those subsections. This language should be reviewed and rewritten as necessary to state clearly which activities a pharmacy technician may and may not perform during the temporary absence of a pharmacist. Possibly, s. Phar 6.04 (3) (c) 5. can be deleted, since sub. (3) lists practices that a pharmacy technician may not do, regardless of whether a pharmacist is present, and sub. (4) is a duty for pharmacists, not pharmacy technicians.