

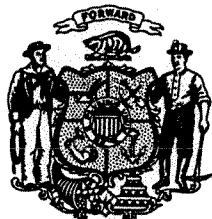
WISCONSIN LEGISLATIVE COUNCIL STAFF



RULES CLEARINGHOUSE

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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 00-048

AN ORDER to create Phar 7.015, relating to delegation of duties by a pharmacist.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

03-06-00 RECEIVED BY LEGISLATIVE COUNCIL.

03-30-00 REPORT SENT TO AGENCY.

RNS:DLS: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)]

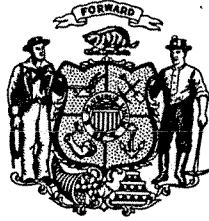
Comment Attached YES NO

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CLEARINGHOUSE RULE 00-048

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. In s. Phar 7.015 (1), second sentence, ", but are not limited to," should be deleted. The term "include" is sufficient.

b. In s. Phar 7.015 (2) (m), it appears that ", receiving and checking orders" should be "or receiving and checking drug orders." In par. (p), "approved" by whom? Can this be specified?

c. In s. Phar 7.015 (3) (intro.), "may not" should replace "shall not."

d. In s. Phar 7.015 (3) (a), a comma should be inserted after "specific judgment."

JAN 26 2001

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 00-048)

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 delegation of duties by a pharmacist.

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 00-048
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:

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

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

The projected net annualized fiscal impact on state funds of the proposed rule is: These rules would increase agency costs due to printing and postage costs for mailings for approximately 6,000 pharmacists. A copy of the rules and a cover letter would need to be mailed and associated with this mailing would be approximately \$15,000. This cost to print and mail each rule is estimated at \$2.50 multiplied by 6,000. This is a one-time cost.

IV. STATEMENT EXPLAINING NEED:

Rules of the Pharmacy Examining Board identify in s. Phar 7.01 that non-pharmacist employees may be assigned duties by a pharmacist relating to receiving prescriptions, preparing and dispensing drugs. The rules proposed will more specifically define the responsibilities of a pharmacist who delegates duties and describe the types of duties related to compounding and delivering drugs that may be delegated.

Section Phar 7.015 is created to define a pharmacy technician as a non-pharmacist or non-pharmacist intern, who is under the immediate and direct supervision of the pharmacist. The functions of the pharmacy technician are technical and nonjudgmental. The technical dispensing functions which may be delegated to a pharmacy technician are listed, as well as those dispensing functions which may not be delegated to a pharmacy technician. The delegation of approved dispensing functions to a pharmacy technician by

the pharmacist does not relieve the pharmacist of responsibility for the proper filling of the prescription order.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on June 14, 2000. The following individuals appeared at the hearing:

Joe Wiedenholz, University of Wisconsin School of Pharmacy, Madison, WI

Betty Cherning, Madison, WI

David Kreling, Oregon, WI

Tom McGregor, Waukesha, WI

Lisa Reese, Pharmacy Society of Wisconsin Technician Section, Madison, WI

Scott Whitmore, Pharmacy Society of Wisconsin, Madison, WI

Diane Darvey, NACDS, Alexandria, VA

Written comments were submitted by:

Douglas Johnson, Sr. Vice President/General Counsel, Wisconsin Merchants Federation, Madison, WI

Christopher J. Decker, Executive Vice President, Pharmacy Society of Wisconsin, Madison, WI

Diane Darvey, Director, State Pharmacy Affairs, NACDS, Alexandria, VA

Tom McGregor, Waukesha Professional Pharmacies, Waukesha, WI

David H. Kreling, Ph.D., R.Ph., Associate Professor of Pharmacy Administration, UW School of Pharmacy, Madison, WI

Richard G. Nerbun, R.Ph., Director of Pharmacy, Cumberland Memorial Hospital, Cumberland, WI

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

All of the 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

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 00-048)

PROPOSED ORDER

An order of the Pharmacy Examining Board to create Phar 7.015, relating to delegation of duties by a pharmacist.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 15.08 (5) (b), 227.11 (2), 450.02 (2), (3) (a) and (d) and 450.11 (3), Stats.

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

Rules of the Pharmacy Examining Board identify in s. Phar 7.01 that non-pharmacist employees may be assigned duties by a pharmacist relating to receiving prescriptions, preparing and dispensing drugs. The rules proposed will more specifically define the responsibilities of a pharmacist who delegates duties and describe the types of duties related to compounding and delivering drugs that may be delegated.

Section Phar 7.015 is created to define a pharmacy technician as a non-pharmacist or non-pharmacist intern, who is under the immediate and direct supervision of the pharmacist. The functions of the pharmacy technician are technical and nonjudgmental. The technical dispensing functions which may be delegated to a pharmacy technician are listed, as well as those dispensing functions which may not be delegated to a pharmacy technician. The delegation of approved dispensing functions to a pharmacy technician by the pharmacist does not relieve the pharmacist of responsibility for the proper filling of the prescription order.

TEXT OF RULE

SECTION 1. Phar 7.015 is created to read:

Phar 7.015 Pharmacy technicians. (1) As used in this section, "pharmacy technician" means a non-pharmacist or non-pharmacist intern who, under the general supervision of a pharmacist who regularly coordinates, directs and inspects the activities of the pharmacy technician, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescription orders and inventory management.

“Pharmacy technician” does not include ancillary persons which include, clerks, secretaries, cashiers or delivery persons, who may be present in the pharmacy.

(2) A pharmacist may delegate technical dispensing functions to a pharmacy technician, but only under the general supervision of the pharmacist where the delegated functions are performed. Technical dispensing functions include:

(a) Accepting written or electronic prescription orders of the prescribing practitioner or from the prescribing practitioner’s agent.

(b) Accepting original oral prescription orders from the prescribing practitioner or prescribing practitioner’s agent, if the conversation is recorded and listened to and verified by the pharmacist prior to dispensing.

(c) Requesting authorization for a refill from the prescribing practitioner.

(d) Accepting oral authorization for a refill from the prescribing practitioner or prescribing practitioner’s agent, provided there are no changes to the original prescription order.

(e) Accepting a request from a patient to refill a prescription.

(f) Obtaining and entering patient or prescription data into the patient information system.

(g) Preparing a prescription label.

(h) Retrieving medication from stock, counting or measuring medication, and placing the medication in its final container.

(i) Reconstituting prefabricated dosage forms.

(j) Compounding pharmaceuticals pursuant to written policies and procedures.

(k) Affixing a prescription label to its final container.

(l) Placing ancillary information on the prescription label.

(m) Prepackaging and labeling drugs for dispensing by a pharmacist.

(n) Preparing unit dose carts for final review by a pharmacist.

(o) Retrieving and transporting stock medication to and from pharmacist approved areas.

(p) Other technical functions that do not require the professional judgment of a pharmacist.

(3) A pharmacy technician may not do any of the following:

(a) Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

(b) Perform any of the following tasks:

1. Participate in final drug utilization reviews.
2. Make independent therapeutic alternate drug selections.
3. Participate in final drug regimen screening, including screening for therapeutic duplication, drug-to-drug interactions, incorrect dosage, incorrect duration of treatment, drug allergy reactions and clinical abuse or misuse.
4. Perform any act necessary to be a managing pharmacist.
5. Administer any prescribed drug products, devices or vaccines.

(c) Provide patient counseling, consultation, or patient specific judgment, such as interpreting or applying information, including advice relating to therapeutic values, potential hazards and uses.

(d) Transfer the prescription to the patient or agent of the patient.

(4) The pharmacist shall provide the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative.

(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: These rules would increase agency costs due to printing and postage costs for mailings for approximately 6,000 pharmacists. A copy of the rules and a cover letter would need to be mailed and associated with this mailing would be approximately \$15,000. This cost to print and mail each rule is estimated at \$2.50 multiplied by 6,000. This is a one-time cost.

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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1/26/01