

MAR 27 2001

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FORM 2



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Ronald Sklansky
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Terry C. Anderson
Legislative Council Director

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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 01-023

AN ORDER to repeal Phar 6.06 (1) (c) Note; and to amend Phar 6.06 (1) (intro.) and (a), (b), (c), (j) (intro.) and (k), relating to minimum equipment.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

02-28-01 RECEIVED BY LEGISLATIVE COUNCIL.

03-26-01 REPORT SENT TO AGENCY.

RS:DD;jal;tlu

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 01-023

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 6.06 (1) (a), the underscored word "that" should be deleted. It duplicates the word that precedes the stricken material.

b. In s. Phar 6.06 (1) (k), "references" should be stricken and "References," underscored, should be inserted before "appropriate."

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

It is suggested that consideration be given to providing a note to s. Phar 6.06 (1) (j) to explain the rationale of the revision to the introductory clause made by the rule.

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 01-)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal the Note following s. Phar 6.06 (1) (c); and to amend Phar 6.06 (1) (intro.), (a), (b), (c), (j) (intro.) and (k), relating to minimum equipment.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 15.08 (5) (b), 227.11 (2), 450.02 (3) (e) and 450.09 (3), Stats.

Statutes interpreted: s. 450.09 (3), Stats.

Currently, s. Phar 6.06 references equipment and standards that are out-of-date with current pharmacy practice. A problem has arisen in providing pharmacists guidance on acceptable equipment which is currently available which meets the intent of the board as comporting with good pharmacy practice. Modifying s. Phar 6.06 clarifies the standards for minimum equipment to be contained in the service area of a pharmacy. The modification to s. Phar 6.06 (1) (a) recognizes that an electronic as well as a torsion prescription balance is permitted, and the corresponding sensitivity for each. Section Phar 6.06 (1) (b) requires that an appropriate set of accurate weights be maintained for any mechanical torsion prescription balance used, according to the purpose of compounding. This modification acknowledges the wide range of types of compounding undertaken by pharmacists and allows discretion and professional judgment in the selection of weights appropriate to use. Section Phar (1) (c) requires a range of single metric scale graduates capable of weighing 5 ml. to 100 ml. The reference to handbook 44 has been deleted as unnecessary. Section Phar (1) (j) recognizes that statutes and rules may be made available via electronic means and therefore now allows for immediate accessibility to those statutes and rules as satisfying that portion of the rule. (j) (k) ?

TEXT OF RULE

SECTION 1. Phar 6.06 (1) (intro.), (a), (b) and (c) are amended to read:

Phar 6.06 Minimum equipment. (1) (intro.) The professional service area of a pharmacy shall have equipment of appropriate design and size for the intended pharmacy practice consisting of at least the following equipment:

(a) ~~A~~ An electronic balance that has a sensitivity of 1 milligram, or a mechanical torsion prescription balance that conforms to the specifications of a class 3 balance and meets the requirements of the national bureau of standards handbook 44 ~~that has a sensitivity quotient of 6 milligrams.~~

(b) ~~One set of accurate metric weights capable of weighing substances of 50 mg. to 50 g. and which meets the requirements of the national bureau of standards handbook 44~~ appropriate for any mechanical torsion prescription balance being used for the purpose of compounding.

(c) ~~A supply of transparent glass graduates in single metric scale capable of measuring 5 ml. to 100 ml. and which meets the requirements of the national bureau of standards handbook 44.~~

SECTION 2. The Note following s. Phar 6.06 (1) (c) is repealed.

SECTION 3. Phar 6.06 (1) (j) (intro.) and (k) are amended to read:

Phar 6.06 (1) (j) (intro.) The latest available ~~revision~~ or immediately accessible version of federal and state pharmacy laws consisting of:

provide note of analysis

(k) ~~Copies of current references~~ ^{references} appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

Not mentioned in analysis

(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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2/28/01

MAY 22 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 01-023)**

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 minimum equipment.

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 01-023
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:

Currently, s. Phar 6.06 references equipment and standards that are out-of-date with current pharmacy practice. A problem has arisen in providing pharmacists guidance on acceptable equipment which is currently available which meets the intent of the board as comporting with good pharmacy practice. Modifying s. Phar 6.06 clarifies the standards for minimum equipment to be contained in the service area of a pharmacy. The modification to s. Phar 6.06 (1) (a) recognizes that an electronic as well as a torsion prescription balance is permitted, and the corresponding sensitivity for each. Section Phar 6.06 (1) (b) requires that an appropriate set of accurate weights be maintained for any mechanical torsion prescription balance used, according to the purpose of compounding. This modification acknowledges the wide range of types of compounding undertaken by pharmacists and allows discretion and professional judgment in the selection of weights appropriate to use. Section Phar (1) (c) requires a range of single metric scale graduates capable of weighing 5 ml. to 100 ml. The reference to handbook 44 has been deleted as unnecessary. Section Phar (1) (j) recognizes that statutes and rules may be made available via electronic means and therefore now allows for immediate accessibility to those statutes and rules as satisfying that portion of the rule.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on April 10, 2001. Paul Rosowski, Stoughton, WI, appeared in support of the proposed rules. There were no other appearances at the public hearing nor were any written comments received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

The board is not providing a note as suggested in Comment 5.

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.

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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
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PROPOSED ORDER

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(END OF TEXT OF RULE)

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Dated _____

Agency _____

Chairperson
Pharmacy Examining Board

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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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5/21/2001