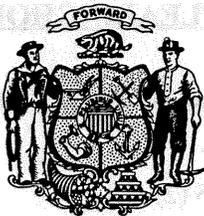


WISCONSIN LEGISLATIVE COUNCIL STAFF

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 00-157

AN ORDER to repeal Phar 2.06 (1) (title), (2) and (3) and 4.02 (3) and (4); and to amend Phar 2.03 (1), 2.06 (1), 12.03 (2) (d) and (e), 13.05 (2) and 16.02 (1), relating to consultation programs and licensure requirements.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

11-06-00 RECEIVED BY LEGISLATIVE COUNCIL.

11-30-00 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)]

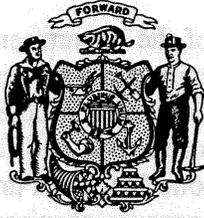
Comment Attached YES NO

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CLEARINGHOUSE RULE 00-157

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.]

1. Statutory Authority

Will the requirement referred to in the new language of s. Phar 16.02 (1) be of general applicability or be applied on an individual basis? If the former, the specific requirements should be promulgated as a rule. See the definition of the term "rule" in s. 227.01 (13), Stats.

2. Form, Style and Placement in Administrative Code

- a. The department's analysis is deficient in several respects:
 - (1) The first narrative paragraph of the analysis cites ss. Phar 2.06 (4) and 4.02 (5) and (6). These sections are not treated in the rule.
 - (2) The first paragraph is also misleading. The rule does more than remove the consultation requirement from the licensure examination; it removes the entire laboratory practical examination, not merely the part that relates to consultation of patients. Further, the analysis indicates that the rule requires consultation programs as a part of continuing education. The rule does not expressly require this; s. RL 16.02 merely provides that the board may require that not more than 15 continuing education hours in each two-year period be acquired within specified topic areas. Finally, the last sentence of the first paragraph is also misleading. The current exam is the laboratory

practical examination which determines an applicant's competence in compounding and dispensing medication, including consultation of patients.

- (3) The second paragraph of the department's analysis fails to specify what the current examination requirements are for original licensure and for licensure of applicants already licensed in another state; fails to specify what the rule does to the current requirements; and fails to specify what the requirements will be if the rule is promulgated. Further, it does not appear that the rule achieves "consistent" licensure requirements as stated in the analysis; they may be more consistent than current requirements but there still is some variation. Furthermore, there are other ways to achieve consistency than by repealing current examination requirements. There is no indication why this method was utilized.
- (4) The last paragraph of the analysis should be part of the second paragraph; the amendment to s. Phar 2.03 (1) reflects a repeal cited in the second paragraph.
 - b. The underscored citation in s. Phar 2.03 (1) to s. Phar 4.02 (2) appears to assume the renumbering of s. Phar 4.02 (5), which the rule does not accomplish.
 - c. The statutes cited in the department's analysis under statutes authorizing promulgation and statutes interpreted do not include ss. 450.05 and 450.085, Stats. The department should review those sections to determine if they should be listed as well.

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-)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 2.06 (1) (title), (2) and (3) and 4.02 (3) and (4); and to amend Phar 2.03 (1), 2.06 (1), 12.03 (2) (d) and (e), 13.05 (2) and 16.02 (1), relating to consultation programs and licensure requirements.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 15.08 (5) (b), 227.11 (2), 450.02 (2g) (a) and (3) (e), 450.03 (2) and 450.04 (1), Stats.

Statutes interpreted: ss. 450.02 (3) (e), 450.03 (2), 450.04 (1) and 450.02 (2g) (a), Stats.

The objective of the proposed amendment of ss. Phar 2.03 (1), 2.06 (1) and (4), 4.02 (5) and (6) and 16.02 is to remove the consultation requirement from the examination for licensure for all applicants and to instead require consultation programs as a part of continuing education. Currently, an applicant for original licensure in this state and pharmacists licensed in another state seeking licensure in this state must successfully pass an examination pertaining to the consultation of patients.

The object of the proposed repeal of ss. Phar 2.06 (2) and (3) and 4.02 (3) and (4), relating to the active practice of pharmacy, equivalency examinations, practice of pharmacy examination, and laboratory practical examination is to provide consistent licensure requirements between applicants licensed in another state and residents of this state seeking original licensure.

The object of amending ss. Phar 12.03 (2) (d) and (e) and 13.05 (2) is to remove a federal citation date which no longer applies.

Section Phar 2.03 (1) is amended to remove a reference to an examination that is no longer required.

See 4th committee

not treated

not treated

Doesn't say what is added what's a change...

includes in 2nd

SEC. 1

5-5-5 6-7

27
Phar 2.06 (2) not

TEXT OF RULE

SECTION 1. Phar 2.03 (1) is amended to read:

Phar 2.03 (1) An applicant for original licensure as a pharmacist is required to pass the examinations identified in s. Phar 4.02 (1), ~~(4)~~ and ~~(5)~~ (2).

SECTION 2. Phar 2.06 (1) (title) is repealed.

SECTION 3. Phar 2.06 (1) is amended to read:

Phar 2.06 Examinations for persons licensed in another state. (1) An applicant licensed as a pharmacist in another state ~~who is engaged in the active practice of pharmacy,~~ shall take the multi-state pharmacy jurisprudence examination described in s. Phar 4.02 (1), ~~and the patient consultation portion of the laboratory practical examination described in s. Phar 4.02 (4).~~ The applicant shall submit, on forms furnished by the board, information describing his or her ~~practice experience preceding the filing of the application.~~ The board shall ~~shall~~ may review requests for reciprocity.

SECTION 4. Phar 2.06 (2) and (3) are repealed.

SECTION 5. Phar 4.02 (3) and (4) are repealed.

SECTION 6. Phar 12.03 (2) (d) and (e) are amended to read:

Phar 12.03 (2) (d) Register with the food and drug administration and comply with all applicable requirements of 21 CFR 200, 201, 202, 207, 210 and 211 (1985).

(e) If applicable, register with the drug enforcement administration and comply with all appropriate requirements of 21 CFR 1301, 1302, 1303, 1304, 1305, 1307, 1311 and 1312 (1985).

SECTION 7. Phar 13.05 (2) is amended to read:

Phar 13.05 (2) Pass an inspection of the facility conducted by the board or its representative to determine if the location meets standards specified in Phar 13.08 to 13.11, 21 USC 351 and 352 (1990) and 21 CFR 211.142 (b) (1991).

SECTION 8. Phar 16.02 (1) is amended to read:

Phar 16.02 (1) Each pharmacist required to complete the continuing education requirement provided under s. 450.085, Stats., shall, at the time of making application for renewal of a license under s. 450.08 (2) (a), Stats., sign a statement on the application for renewal certifying that the pharmacist has completed at least 30 hours of acceptable continuing education programs within the 2-year period immediately preceding the date of his or her application for renewal. The board may require that not more than 15 continuing education

laboratory practical exam

why? see of sub (2) etc

equivalency exam

state practice of pharmacy exam

(5) or laboratory practical exam

includes but not limited to consultation

by rule or will this be on individual basis?

2000 Manual

hours in each 2-year period immediately preceding the date of the application for renewal be acquired within specified topic areas, such requirement to first apply to applications that are submitted to the department to renew a license to practice pharmacy that expires on June 1, 2004.
The 30 hours of continuing education for pharmacists first applies to applications that are submitted to the department to renew a license to practice pharmacy that expires on June 1, 2000. This subsection does not apply to an application for renewal of a license that expires on the first renewal date after the date on which the board initially granted the license.

(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
(See attached)

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.

g:\rules\phm18.doc
10/24/00

FISCAL ESTIMATE

ORIGINAL

UPDATE

CORRECTED

Rule No. PHAR 2.03 (1), 2.06(1), 2.06(2), 4.02(3), 12.03(2), 13.05(2), 16.02(1)

Subject: Examination for licensure for all pharmacy applicants.

Fiscal Effect

State: No State Fiscal Effect

Check columns below only if bill makes a direct appropriation or affects a sum sufficient appropriation.

Increase Existing Appropriation

Increase Existing Revenues

Increase Costs - May be possible to absorb within agency's budget Yes No

Decrease Existing Appropriation

Decrease Existing Revenues

Create New Appropriation

Decrease Costs

Local: No local government costs

1. Increase Costs
 Permissive Mandatory

3. Increase Revenue
 Permissive Mandatory

5. Types of local government units affected:

Towns Villages Cities

2. Decrease Costs
 Permissive Mandatory

3. Decrease Revenue
 Permissive Mandatory

Counties Others _____

School Districts WTCS Districts

Fund Sources Affected

GPR FED PRO PRS
 SEG-S

Affected Ch. 20 Appropriations
20.165 (1) (i)

Assumptions Used in Arriving at Fiscal Estimate

This rule would have revenue and expense impact if passed. There would be revenue decreased by \$72,352, which is based on 272 candidates at \$266 per patient consultant examination. The annual budgeted expenses for the pharmacy practical is \$5870.

These lost revenues would be recovered by increasing the written test fees for the pharmacy examination.

There is no local fiscal impact.

Long-Range Fiscal Implications

The fiscal estimate shall include the major assumptions used in its preparation and a reliable estimate of the fiscal impact of the proposed rule, including:

1. The anticipated effect on county, city, village, town, school district, technical college district and sewerage district fiscal liabilities and revenues.
2. A projection of the anticipated state fiscal effect during the current biennium and a projection of the net annualized fiscal impact on state funds.

If a proposed rule interpreting or implementing a statute has no independent fiscal effect, the fiscal estimate prepared under this subsection shall be based on the fiscal effect of the statute.

Agency/Prepared by:
Department of Regulation and Licensing
Gail M. Riedasch
(608) 266-0746

Authorized Signature
William J. Conway, Deputy Secretary
267-2435

Date
11/2/2000