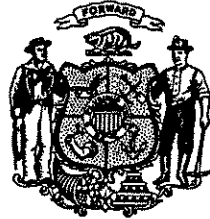


RULES CLEARINGHOUSE

Ronald Sklansky
Director
(608) 266-1946

Richard Sweet
Assistant Director
(608) 266-2982



Terry C. Anderson, Director
Legislative Council Staff
(608) 266-1304

One E. Main St., Ste. 401
P.O. Box 2536
Madison, WI 53701-2536
FAX: (608) 266-3830

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)]

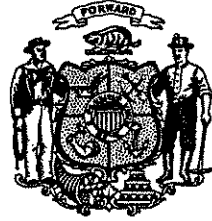
Comment Attached YES NO

WISCONSIN LEGISLATIVE COUNCIL STAFF

RULES CLEARINGHOUSE

Ronald Sklansky
Director
(608) 266-1946

Richard Sweet
Assistant Director
(608) 266-2982



Terry C. Anderson
Director
Legislative Council Staff
(608) 266-1304

One E. Main St., Ste. 401
P.O. Box 2536
Madison, WI 53701-2536
FAX: (608) 266-3830

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 00-157)**

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 consultation programs and licensure requirements.

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 00-157
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:

See attached.

IV. STATEMENT EXPLAINING NEED:

The objective of the proposed amendment of ss. Phar 2.03 (1) and 2.06 (1) is to require the patient consultation portion of the laboratory practical examination for all applicants for original licensure and as part of an equivalency examination for persons licensed in another state who have not been engaged in the active practice of pharmacy as defined in the rules. The objective of the proposed amendment of s. Phar 16.02 is to provide that the board may require that not more than 15 continuing education hours in each 2-year period be acquired within specified topic areas. Currently, the rules require that an applicant for original licensure in this state and pharmacists licensed in another state seeking licensure in this state who have not engaged in the active practice of pharmacy successfully pass the laboratory practical examination. The laboratory practical examination currently consists solely of an examination testing competence in the consultation of patients, and does not otherwise test compounding and dispensing competence. Currently, the rules do not allow the board to require any portion of continuing education to be acquired within specified topic areas.

The objective of the proposed repeal of ss. Phar 2.06 (3) (a) and 4.02 (3) and the relettering of s. Phar 2.06 (3) (b) and (c), and the renumbering and amending of s. Phar 4.02 (4) and the renumbering of s. Phar 4.02 (5) and (6) are to provide consistent examination references for applicants licensed in another state and residents of this state seeking original licensure. The objective of amending ss. Phar 2.06 (3) (b) and 4.02 (4) is to provide consistent nomenclature between those sections for the practical examination. The current examination requirements for original licensure are set forth in s. Phar 4.02 and include the multi-state pharmacy jurisprudence examination, the state practice of pharmacy examination, the laboratory practical examination, and the NAPLEX. The

current examination requirements set forth in s. Phar 2.06 (3) for an applicant licensed in another state who has not engaged in the active practice of pharmacy include the state practice of pharmacy examination, the laboratory practical examination, and the multi-state pharmacy jurisprudence examination. The use of the NAPLEX national examination is determined by the board to adequately safeguard the health, safety and welfare of the citizens of this state. Therefore, to provide clarity and consistency between chapters, the references to the state practice of pharmacy examination are being deleted from current ss. Phar 2.06 (3) (b) and 4.02 (4). The multi-state pharmacy jurisprudence examination will be retained as a requirement of all applicants. Section Phar 2.03 (1) is amended to provide consistency with the other amended rules.

Sections Phar 12.03 (2) (d) and (e), and 13.05 (2) are amended to remove dates which are no longer applicable.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on December 12, 2000. Written comments were received from:

Joseph B. Wiederholt, Ph.D., Professor of Pharmacy Administration, School of Pharmacy, University of Wisconsin-Madison, Madison, WI

Steve Rough, M.S., R.Ph., Director, Pharmacy Service Organization, University of Wisconsin Hospital and Clinics, Madison, WI

Tom Thielke, M.S., F.A.S.H.P., Director of Pharmacy, University of Wisconsin Hospital and Clinics, Clinical Professor, University of Wisconsin, School of Pharmacy, Madison, WI

Tom Engels, Director of Government Affairs, Pharmacy Society of Wisconsin, Madison, WI

Paul G. Rosowski, M.S., R.Ph., Director of Pharmacy Internship, University of Wisconsin-Madison, School of Pharmacy, Madison, WI; and Chair of the Exam Task Force

Kenneth R. Schaefer, R.Ph.

Tom Reilly, Director, Government Affairs, Aurora Health Care, Milwaukee, WI

Prati Agarwal, M.S., Manager, Aurora Health Care, Pharmaceutical Services, Milwaukee, WI

Chris Klink, R.Ph., Beloit Memorial Hospital, Beloit, WI

George F. Christiansen, R.Ph., Past Member and Chair of the Wisconsin Pharmacy Examining Board, West Salem, WI

Betty Chewing, Ph.D., Associate Professor, Director Sonderegger Research Center, School of Pharmacy, University of Wisconsin-Madison, Madison, WI

David H. Kreling, Ph.D., Associate Professor of Social & Administrative Pharmacy, University of Wisconsin-Madison, Madison, WI

Christopher T. Ehlenbach, Wauwatosa, WI

Doug and Kay Palmer

Kim T. Kass, R.Ph.

Thomas J. Lausten, Pharmacy Director, St. Francis Hospital

Roger A. Gottschalk, R.Ph.
Clyde Birringer, Pharm D, Meriter Hospital, Madison, WI
Mark Zwaska, R.Ph.
Teri Luebbering, R.Ph., CGP
Ronn Teri
Mike Moses, R.Ph., Director of Pharmacy & Inpatient Support, Waukesha Memorial
Hospital, Waukesha, WI
Beth A. Martin, R.Ph., Madison, WI

VI. EXPLANATORY SUMMARY:

As originally drafted, Sections 3, 4 and 5 of the proposed rule-making were intended to delete entirely the requirement for an applicant for licensure to take and pass the consultation portion of the laboratory practical examination contained in s. Phar 4.02 (4). Upon further review by the board following the public hearing for the proposed rule, it was decided that the consultation portion of the laboratory practical examination would be retained for all applicants for original licensure under s. Phar 2.03, and for persons licensed in another state who were not engaged in the active practice of pharmacy under s. Phar 2.06 (2). The proposed rule has been modified to reflect the board's decision to maintain the consultation examination under these circumstances. Accordingly, ss. Phar 2.06 and 4.02 have undergone revision to remove references to examinations no longer offered, and provide for consistent nomenclature for the state practical examination, which includes the consultation of patients.

VII. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 1. 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.

Response: The rule as proposed mirrors the wording of s. Psy 4.02 (1).

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

VIII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

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

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.

<input type="checkbox"/> Increase Existing Appropriation	<input type="checkbox"/> Increase Existing Revenues	<input type="checkbox"/> Increase Costs - May be possible to absorb within agency's budget <input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> Decrease Existing Appropriation	<input checked="" type="checkbox"/> Decrease Existing Revenues	
<input type="checkbox"/> Create New Appropriation	<input checked="" type="checkbox"/> Decrease Costs	

Local: No local government costs

1. <input type="checkbox"/> Increase Costs <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	3. <input type="checkbox"/> Increase Revenue <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	5. Types of local government units affected: <input type="checkbox"/> Towns <input type="checkbox"/> Villages <input type="checkbox"/> Cities <input type="checkbox"/> Counties <input type="checkbox"/> Others _____ <input type="checkbox"/> School Districts <input type="checkbox"/> WTCS Districts
2. <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	3. <input type="checkbox"/> Decrease Revenue <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	

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

FISCAL ESTIMATE WORKSHEET

Detailed Estimate of Annual Fiscal Effect

- ORIGINAL UPDATE
 CORRECTED SUPPLEMENTAL

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

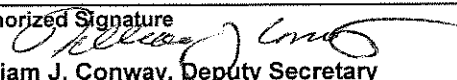
Subject
Examination for licensure for all pharmacy applicants.

I. One-time Costs or Revenue Impacts for State and/or Local Government (do not include in annualized fiscal effect):

II. Annualized Costs:	Annualized Fiscal impact on State funds from:	
A. State Costs by Category	Increased Costs	Decreased Costs
State Operations - Salaries and Fringes	\$	\$ -
(FTE Position Changes)	(FTE)	(- FTE)
State Operations - Other Costs		-5,870
Local Assistance		-
Aids to Individuals or Organizations		-
TOTAL State Costs by Category	\$	\$ -5,870
B. State Costs by Source of Funds	Increased Costs	Decreased Costs
GPR	\$	\$ -
FED		-
PRO/PRS		-5,870
SEG/SEG-S		-
III. State Revenues - Complete this only when proposal will increase or decrease state revenues (e.g., tax increase, decrease in license fee, etc.)	Increased Costs	Decreased Costs
GPR Taxes	\$	\$ -
GPR Earned		\$ 7,235
FED		-
PRO/PRS		\$72,352
SEG/SEG-S		-
TOTAL State Revenues	\$	\$ \$79,587

NET ANNUALIZED FISCAL IMPACT

	<u>STATE</u>	<u>LOCAL</u>
NET CHANGE IN COSTS	\$ (5,870) _____	_____
NET CHANGE IN REVENUES	\$ (\$79,587) _____	_____

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
---	---	-------------------

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 00-157)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 2.06 (1) (title), (3) (a) and 4.02 (3); to renumber Phar 2.06 (3) (c) and 4.02 (5) and (6); to renumber and amend Phar 2.06 (3) (b) and 4.02 (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), 450.04 (1), 450.05 and 450.085, 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) and 2.06 (1) is to require the patient consultation portion of the laboratory practical examination for all applicants for original licensure and as part of an equivalency examination for persons licensed in another state who have not been engaged in the active practice of pharmacy as defined in the rules. The objective of the proposed amendment of s. Phar 16.02 is to provide that the board may require that not more than 15 continuing education hours in each 2-year period be acquired within specified topic areas. Currently, the rules require that an applicant for original licensure in this state and pharmacists licensed in another state seeking licensure in this state who have not engaged in the active practice of pharmacy successfully pass the laboratory practical examination. The laboratory practical examination currently consists solely of an examination testing competence in the consultation of patients, and does not otherwise test compounding and dispensing competence. Currently, the rules do not allow the board to require any portion of continuing education to be acquired within specified topic areas.

The objective of the proposed repeal of ss. Phar 2.06 (3) (a) and 4.02 (3) and the relettering of s. Phar 2.06 (3) (b) and (c), and the renumbering and amending of s. Phar 4.02 (4) and the renumbering of s. Phar 4.02 (5) and (6) are to provide consistent examination references for applicants licensed in another state and residents of this state seeking original licensure. The objective of amending ss. Phar 2.06 (3) (b) and 4.02 (4) is to provide consistent nomenclature between those sections for the practical examination. The current examination requirements for original licensure are set forth in s. Phar 4.02 and include the multi-state pharmacy jurisprudence examination, the state practice of pharmacy examination, the laboratory practical examination,

and the NAPLEX. The current examination requirements set forth in s. Phar 2.06 (3) for an applicant licensed in another state who has not engaged in the active practice of pharmacy include the state practice of pharmacy examination, the laboratory practical examination, and the multi-state pharmacy jurisprudence examination. The use of the NAPLEX national examination is determined by the board to adequately safeguard the health, safety and welfare of the citizens of this state. Therefore, to provide clarity and consistency between chapters, the references to the state practice of pharmacy examination are being deleted from current ss. Phar 2.06 (3) (b) and 4.02 (4). The multi-state pharmacy jurisprudence examination will be retained as a requirement of all applicants. Section Phar 2.03 (1) is amended to provide consistency with the other amended rules.

Sections Phar 12.03 (2) (d) and (e), and 13.05 (2) are amended to remove dates which are no longer applicable.

As originally drafted, Sections 3, 4 and 5 of the proposed rule-making were intended to delete entirely the requirement for an applicant for licensure to take and pass the consultation portion of the laboratory practical examination contained in s. Phar 4.02 (4). Upon further review by the board following the public hearing for the proposed rule, it was decided that the consultation portion of the laboratory practical examination would be retained for all applicants for original licensure under s. Phar 2.03, and for persons licensed in another state who were not engaged in the active practice of pharmacy under s. Phar 2.06 (2). The proposed rule has been modified to reflect the board's decision to maintain the consultation examination under these circumstances. Accordingly, ss. Phar 2.06 and 4.02 have undergone revision to remove references to examinations no longer offered, and provide for consistent nomenclature for the state practical examination, which includes the consultation of patients.

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) and (3).

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~~ may review requests for reciprocity.

SECTION 4. Phar 2.06 (3) (a) is repealed.

SECTION 5. Phar 2.06 (3) (b) is renumbered Phar 2.06 (3) (a) and amended to read:

Phar 2.06 (3) (a) ~~Laboratory practice~~ Practical examination.

SECTION 6. Phar 2.06 (3) (c) is renumbered Phar 2.06 (3) (b).

SECTION 7. Phar 4.02 (3) is repealed.

SECTION 8. Phar 4.02 (4), (5) and (6) are renumbered Phar 4.02 (2), (3) and (4) and as renumbered Phar 4.02 (2) is amended to read:

Phar 4.02 (2) The ~~laboratory~~ practical examination shall determine an applicant's competence in compounding and dispensing medications, which includes consultation of patients.

SECTION 9. 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 10. 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 ss. Phar 13.08 to 13.11, 21 USC 351 and 352 ~~(1990)~~ and 21 CFR 211.142 (b) ~~(1991)~~.

SECTION 11. 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 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)

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.

g:\rules\phm18.doc
4/17/2001

**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 00-157)**

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 resubmitting in final draft form rules relating to consultation programs and licensure requirements.

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 00-157
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:

See attached.

IV. STATEMENT EXPLAINING NEED:

The objective of the proposed amendment of ss. Phar 2.03 (1) and 2.06 (1) is to require the patient consultation portion of the laboratory practical examination for all applicants for original licensure and as part of an equivalency examination for persons licensed in another state who have not been engaged in the active practice of pharmacy as defined in the rules. The objective of the proposed amendment of s. Phar 16.02 is to provide that the board may require that not more than 6 continuing education hours in each 2-year period be acquired within specified topic areas. Currently, the rules require that an applicant for original licensure in this state and pharmacists licensed in another state seeking licensure in this state who have not engaged in the active practice of pharmacy successfully pass the laboratory practical examination. The laboratory practical examination currently consists solely of an examination testing competence in the consultation of patients, and does not otherwise test compounding and dispensing competence. Currently, the rules do not allow the board to require any portion of continuing education to be acquired within specified topic areas.

The objective of the proposed repeal of ss. Phar 2.06 (3) (a) and 4.02 (3) and the relettering of s. Phar 2.06 (3) (b) and (c), and the renumbering and amending of s. Phar 4.02 (4) and the renumbering of s. Phar 4.02 (5) and (6) are to provide consistent examination references for applicants licensed in another state and residents of this state seeking original licensure. The objective of amending ss. Phar 2.06 (3) (b) and 4.02 (4) is to provide consistent nomenclature between those sections for the practical examination. The current examination requirements for original licensure are set forth in s. Phar 4.02 and include the multi-state pharmacy jurisprudence examination, the state practice of pharmacy examination, the laboratory practical examination, and the NAPLEX. The

current examination requirements set forth in s. Phar 2.06 (3) for an applicant licensed in another state who has not engaged in the active practice of pharmacy include the state practice of pharmacy examination, the laboratory practical examination, and the multi-state pharmacy jurisprudence examination. The use of the NAPLEX national examination is determined by the board to adequately safeguard the health, safety and welfare of the citizens of this state. Therefore, to provide clarity and consistency between chapters, the references to the state practice of pharmacy examination are being deleted from current ss. Phar 2.06 (3) (b) and 4.02 (4). The multi-state pharmacy jurisprudence examination will be retained as a requirement of all applicants. Section Phar 2.03 (1) is amended to provide consistency with the other amended rules.

Sections Phar 12.03 (2) (d) and (e), and 13.05 (2) are amended to remove dates which are no longer applicable.

At a duly noticed meeting of the board on December 11, 2001, the Pharmacy Examining Board considered and approved a modification to this rule. Based upon public comment offered at the public hearing on this rule before the Senate Committee on Health, Utilities, Veterans and Military Affairs on May 23, 2001, the board became aware of concerns of the Pharmacy Society of Wisconsin relating to the proposed continuing education requirements contained in the rule. Clearinghouse Rule 00-157, as modified, is resubmitted for legislative committee review.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on December 12, 2000. Written comments were received from:

Joseph B. Wiederholt, Ph.D., Professor of Pharmacy Administration, School of Pharmacy, University of Wisconsin-Madison, Madison, WI

Steve Rough, M.S., R.Ph., Director, Pharmacy Service Organization, University of Wisconsin Hospital and Clinics, Madison, WI

Tom Thielke, M.S., F.A.S.H.P., Director of Pharmacy, University of Wisconsin Hospital and Clinics, Clinical Professor, University of Wisconsin, School of Pharmacy, Madison, WI

Tom Engels, Director of Government Affairs, Pharmacy Society of Wisconsin, Madison, WI

Paul G. Rosowski, M.S., R.Ph., Director of Pharmacy Internship, University of Wisconsin-Madison, School of Pharmacy, Madison, WI; and Chair of the Exam Task Force

Kenneth R. Schaefer, R.Ph.

Tom Reilly, Director, Government Affairs, Aurora Health Care, Milwaukee, WI

Prati Agarwal, M.S., Manager, Aurora Health Care, Pharmaceutical Services, Milwaukee, WI

Chris Klink, R.Ph., Beloit Memorial Hospital, Beloit, WI

George F. Christiansen, R.Ph., Past Member and Chair of the Wisconsin Pharmacy Examining Board, West Salem, WI

Betty Chewing, Ph.D., Associate Professor, Director Sonderegger Research Center,
School of Pharmacy, University of Wisconsin-Madison, Madison, WI
David H. Kreling, Ph.D., Associate Professor of Social & Administrative Pharmacy,
University of Wisconsin-Madison, Madison, WI
Christopher T. Ehlenbach, Wauwatosa, WI
Doug and Kay Palmer
Kim T. Kass, R.Ph.
Thomas J. Lausten, Pharmacy Director, St. Francis Hospital
Roger A. Gottschalk, R.Ph.
Clyde Birringer, Pharm D, Meriter Hospital, Madison, WI
Mark Zwaska, R.Ph.
Teri Luebbering, R.Ph., CGP
Ronn Teri
Mike Moses, R.Ph., Director of Pharmacy & Inpatient Support, Waukesha Memorial
Hospital, Waukesha, WI
Beth A. Martin, R.Ph., Madison, WI

VI. EXPLANATORY SUMMARY:

As originally drafted, Sections 3, 4 and 5 of the proposed rule-making were intended to delete entirely the requirement for an applicant for licensure to take and pass the consultation portion of the laboratory practical examination contained in s. Phar 4.02 (4). Upon further review by the board following the public hearing for the proposed rule, it was decided that the consultation portion of the laboratory practical examination would be retained for all applicants for original licensure under s. Phar 2.03, and for persons licensed in another state who were not engaged in the active practice of pharmacy under s. Phar 2.06 (2). The proposed rule has been modified to reflect the board's decision to maintain the consultation examination under these circumstances. Accordingly, ss. Phar 2.06 and 4.02 have undergone revision to remove references to examinations no longer offered, and provide for consistent nomenclature for the state practical examination, which includes the consultation of patients.

VII. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 1. 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.

Response: The rule as proposed mirrors the wording of s. Psy 4.02 (1).

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

VIII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

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

g:\rules\phm18aleg.doc
1/10/02

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 00-157)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 2.06 (1) (title), (3) (a) and 4.02 (3); to renumber Phar 2.06 (3) (c) and 4.02 (5) and (6); to renumber and amend Phar 2.06 (3) (b) and 4.02 (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), 450.04 (1), 450.05 and 450.085, 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) and 2.06 (1) is to require the patient consultation portion of the laboratory practical examination for all applicants for original licensure and as part of an equivalency examination for persons licensed in another state who have not been engaged in the active practice of pharmacy as defined in the rules. The objective of the proposed amendment of s. Phar 16.02 is to provide that the board may require that not more than 6 continuing education hours in each 2-year period be acquired within specified topic areas. Currently, the rules require that an applicant for original licensure in this state and pharmacists licensed in another state seeking licensure in this state who have not engaged in the active practice of pharmacy successfully pass the laboratory practical examination. The laboratory practical examination currently consists solely of an examination testing competence in the consultation of patients, and does not otherwise test compounding and dispensing competence. Currently, the rules do not allow the board to require any portion of continuing education to be acquired within specified topic areas.

The objective of the proposed repeal of ss. Phar 2.06 (3) (a) and 4.02 (3) and the relettering of s. Phar 2.06 (3) (b) and (c), and the renumbering and amending of s. Phar 4.02 (4) and the renumbering of s. Phar 4.02 (5) and (6) are to provide consistent examination references for applicants licensed in another state and residents of this state seeking original licensure. The objective of amending ss. Phar 2.06 (3) (b) and 4.02 (4) is to provide consistent nomenclature between those sections for the practical examination. The current examination requirements for original licensure are set forth in s. Phar 4.02 and include the multi-state pharmacy jurisprudence examination, the state practice of pharmacy examination, the laboratory practical examination,

and the NAPLEX. The current examination requirements set forth in s. Phar 2.06 (3) for an applicant licensed in another state who has not engaged in the active practice of pharmacy include the state practice of pharmacy examination, the laboratory practical examination, and the multi-state pharmacy jurisprudence examination. The use of the NAPLEX national examination is determined by the board to adequately safeguard the health, safety and welfare of the citizens of this state. Therefore, to provide clarity and consistency between chapters, the references to the state practice of pharmacy examination are being deleted from current ss. Phar 2.06 (3) (b) and 4.02 (4). The multi-state pharmacy jurisprudence examination will be retained as a requirement of all applicants. Section Phar 2.03 (1) is amended to provide consistency with the other amended rules.

Sections Phar 12.03 (2) (d) and (e), and 13.05 (2) are amended to remove dates which are no longer applicable.

As originally drafted, Sections 3, 4 and 5 of the proposed rule-making were intended to delete entirely the requirement for an applicant for licensure to take and pass the consultation portion of the laboratory practical examination contained in s. Phar 4.02 (4). Upon further review by the board following the public hearing for the proposed rule, it was decided that the consultation portion of the laboratory practical examination would be retained for all applicants for original licensure under s. Phar 2.03, and for persons licensed in another state who were not engaged in the active practice of pharmacy under s. Phar 2.06 (2). The proposed rule has been modified to reflect the board's decision to maintain the consultation examination under these circumstances. Accordingly, ss. Phar 2.06 and 4.02 have undergone revision to remove references to examinations no longer offered, and provide for consistent nomenclature for the state practical examination, which includes the consultation of patients.

At a duly noticed meeting of the Pharmacy Examining Board on December 11, 2001, the board considered and approved a modification to this rule. Based upon public comment offered at the public hearing on this rule before the Senate Committee on Health, Utilities, Veterans and Military Affairs on May 23, 2001, the board became aware of concerns of the Pharmacy Society of Wisconsin relating to the proposed continuing education requirements contained in the rule. Clearinghouse Rule 00-157, as modified, is resubmitted for legislative committee review.

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) and (3).

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~~ may review requests for reciprocity.

SECTION 4. Phar 2.06 (3) (a) is repealed.

SECTION 5. Phar 2.06 (3) (b) is renumbered Phar 2.06 (3) (a) and amended to read:

Phar 2.06 (3) (a) ~~Laboratory practice~~ Practical examination.

SECTION 6. Phar 2.06 (3) (c) is renumbered Phar 2.06 (3) (b).

SECTION 7. Phar 4.02 (3) is repealed.

SECTION 8. Phar 4.02 (4), (5) and (6) are renumbered Phar 4.02 (2), (3) and (4) and as renumbered Phar 4.02 (2) is amended to read:

Phar 4.02 (2) The ~~laboratory~~ practical examination shall determine an applicant's competence in compounding and dispensing medications, which includes consultation of patients.

SECTION 9. 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 10. 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 ss. Phar 13.08 to 13.11, 21 USC 351 and 352 ~~(1990)~~ and 21 CFR 211.142 (b) ~~(1991)~~.

SECTION 11. 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 6 continuing education 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)

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.

g:\rules\phm18a.doc
1/10/02

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

Decrease Existing Appropriation

Create New Appropriation

Increase Existing Revenues

Decrease Existing Revenues

Increase Costs - May be possible to absorb

within agency's budget Yes No

Decrease Costs

Local: No local government costs

1. Increase Costs
 Permissive Mandatory

2. Decrease Costs
 Permissive Mandatory

3. Increase Revenue
 Permissive Mandatory

3. Decrease Revenue
 Permissive Mandatory

5. Types of local government units affected:

Towns Villages Cities

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

FISCAL ESTIMATE WORKSHEET

Detailed Estimate of Annual Fiscal Effect

- ORIGINAL UPDATE
 CORRECTED SUPPLEMENTAL

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.

I. One-time Costs or Revenue Impacts for State and/or Local Government (do not include in annualized fiscal effect):

II. Annualized Costs:	Annualized Fiscal impact on State funds from:	
A. State Costs by Category	Increased Costs	Decreased Costs
State Operations - Salaries and Fringes	\$	\$ -
(FTE Position Changes)	(FTE)	(- FTE)
State Operations - Other Costs		-5,870
Local Assistance		-
Aids to Individuals or Organizations		-
TOTAL State Costs by Category	\$	\$ -5,870
B. State Costs by Source of Funds	Increased Costs	Decreased Costs
GPR	\$	\$ -
FED		-
PRO/PRS		-5,870
SEG/SEG-S		-
III. State Revenues - Complete this only when proposal will increase or decrease state revenues (e.g., tax increase, decrease in license fee, etc.)	Increased Costs	Decreased Costs
GPR Taxes	\$	\$ -
GPR Earned		\$ 7,235
FED		-
PRO/PRS		\$72,352
SEG/SEG-S		-
TOTAL State Revenues	\$	\$ \$79,587

NET ANNUALIZED FISCAL IMPACT

	<u>STATE</u>	<u>LOCAL</u>
NET CHANGE IN COSTS	\$ (5,870)	
NET CHANGE IN REVENUES	\$ (\$79,587)	

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
---	---	-------------------