

1997-98 SESSION  
COMMITTEE HEARING  
RECORDS

Committee Name:

*Joint Committee For  
Review of Administrative  
Rules (JCR-AR)*

Sample:

Record of Comm. Proceedings ... RCP

- 05hrAC-EdR\_RCP\_pt01a
- 05hrAC-EdR\_RCP\_pt01b
- 05hrAC-EdR\_RCP\_pt02

➤ Appointments ... Appt

➤ \*\*

➤ Clearinghouse Rules ... CRule

➤ 97hrJCR-AR\_Crule\_98-016

➤ Committee Hearings ... CH

➤ \*\*

➤ Committee Reports ... CR

➤ \*\*

➤ Executive Sessions ... ES

➤ \*\*

➤ Hearing Records ... HR

➤ \*\*

➤ Miscellaneous ... Misc

➤ \*\*

➤ Record of Comm. Proceedings ... RCP

➤ \*\*

98-016-PHAR1-14-PHARMACIST

PHARM. REGS.

**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 98-016)**

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TO: Senator Richard Grobschmidt, Senate Co-Chairperson  
Joint Committee for the Review of Administrative Rules  
100 North Hamilton Street  
Room 404  
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the PHARMACY EXAMINING BOARD is submitting in final draft form proposed rules relating to pharmacists and pharmacies.

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.

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State of Wisconsin \ DEPARTMENT OF REGULATION & LICENSING

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Governor

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# **Administrative Rules in Final Draft Form**

## **Pharmacy Examining Board**

### **Rule: Chs. Phar 1 to Phar 14**

### **Relating to: Pharmacists and Pharmacies**

### **Clearinghouse Rule: No. 98-016**

Regulatory Boards

Accounting; Architects; Landscape Architects; Professional Geologists; Professional Engineers; Designers and Land Surveyors; Auctioneer; Barbering and Cosmetology; Chiropractic; Dentistry; Dietitians; Funeral Directors; Hearing and Speech; Medical; Nursing; Nursing Home Administrator; Optometry; Pharmacy; Physical Therapists; Psychology; Real Estate; Real Estate Appraisers; Social Workers; Marriage and Family Therapists and Professional Counselors; and Veterinary

Committed to Equal Opportunity in Employment and Licensing

**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 98-016  
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:**

These rules will have no significant impact upon state or local units of government.

**IV. STATEMENT EXPLAINING NEED:**

The changes being recommended relate to such technical matters as amending form, style, grammar or punctuation in order to improve readability, eliminate outdated provisions, and update citations to statutes for accuracy. A provision is created referencing the provision of reasonable accommodations required under the American With Disabilities Act.

More specifically, outdated transition provisions are repealed; specific types of examinations, passing scores, examination review procedures and cheating on examinations are created; a provision for renewing a license after five years of nonrenewal is created; language for consistency with statutory authority is modified; and the list of actions deemed to constitute unprofessional conduct is updated.

**V. NOTICE OF PUBLIC HEARING:**

A public hearing was held on March 11, 1998. Carol Petersen, Madison and Jamie Statz, Verona, appeared at the public hearing. Joe Wiederholt, Ph.D., Professor of Pharmacy Administration, University of Wisconsin-Madison appeared at the public hearing and also submitted written comments. Written comments were also received from Doug Johnson, Sr. Vice President/General Counsel, Wisconsin Merchants Federation, Madison and Karen Disharoon, Manager, State Government Affairs, National Association of Chain Drug Stores, Madison; and Arthur Thexton, attorney, Department of Regulation and Licensing. In general, the comments were in support of the proposed rules. The main issue dealt with was should the proposal that a consultation not be required to occur at the

transfer of the medication be deleted. It is the board's opinion that they, the board, should not mandate when consultations are given or how the pharmacist should practice.

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

Comment 2.f. Section Phar 5.05 (2) (c) authorizes the board to prescribe the examinations or educational requirements, or both, which must be successfully completed by an applicant for reinstatement of a license five years or more after the renewal date. Could these requirements be set forth in the rule? If these rules are not set forth in the rule, how will they be made available to the public?

Response: No, these requirements cannot adequately be set forth in the rule. They are determined on a case-by-case basis. Some may have practiced in other states and some have not. Some have taken continuing education and some have not. Every case is different.

Comment 5.e. If it is found under s. Phar 4.046 that there is an error in an examination which has been administered by the board, should the board be required to take any action, such as reviewing the examination scores of all persons who took that examination to determine if the error in the examination would, if corrected, result in the passing of the examination by an applicant who was considered to have failed?

Response: The board employs this review process as a matter of fairness and due process considerations. The board does not believe it is necessary to state the fundamental proposition in a rule.

Comment 5.f. Should s. Phar 5.01 (2) specify that a person who is practicing under an original license is not required to have a current renewal certificate?

Response: No, the board believes it is sufficiently clear that the receipt of the original license permits a person to practice.

Comment 5.g. Is the address referred to in s. Phar 5.02 (2) the home or business address of the pharmacist?

Response: It could be either. That is left up to the pharmacist.

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

## **VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:**

The proposed 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 98-016)

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PROPOSED ORDER

An order of the Pharmacy Examining Board to **repeal** Phar 2.03 (3), ch. Phar (3) (title), 3.03, 4.02 (2), 4.05 (1) and (4), the Note following 6.03, and ch. Phar 14; to **renumber and amend** Phar 3.01, 3.02 and 3.04; to **amend** Phar 1.01, 1.02 (7), (8), (11) and (14), ch. Phar 2 (title), 2.01 (title) and (intro.), 2.02 (title), (1) (intro.) and (d), 2.03 (title), (1), (4) and (5), 4.01 (3), 4.02 (1) and (5), 5.01 (1) and (2), 5.02 (1) and (2), 5.04, 6.01, 6.06 (1) (j) 3., 7.01 (1) (a), (e), (f) (intro.) and (3), 7.07 (1), 8.01, 8.02 (1), (2) and (3) (e) 2., 8.03 (1) and (3), 8.04 (1), 8.05 (2), 8.09 (4), 10.02 (1), (2) and (3), 12.03 (2) (intro.), (a), (b), (c), (d) and (5), 13.02 (3) and 13.07; to **repeal and recreate** Phar 4.03 (3) and 7.04; to **create** a Note following Phar 2.01 (2), 4.02 (6), 4.035, 4.045, 4.046, 5.05, 6.08, 7.01 (3m), 7.065, 8.12 and 10.03 (7m) and (19), relating to pharmacists and pharmacies.

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), 440.08 (3) (b), 450.02 (3) and 961.31, Stats.

Statutes interpreted: ss. 450.04, 450.05, 450.06, 450.07, 450.08, 450.09 and 450.10, Stats.

This proposed rule-making order of the Pharmacy Examining Board contains many amendments of a housekeeping nature that relate to the definitions; the statutory authority; and the form, style, placement, clarity, grammar, punctuation and plain language of the current rules.

The following sections contain changes of a more substantive nature:

SECTIONS 8, 13 and 15 amend provisions alluding to separate state and federal law examinations for pharmacist licensure to reflect the fact that they have been combined into a single examination called the "multi-state pharmacy jurisprudence examination."

SECTIONS 9 through 13 serve to transfer the requirements for reciprocal pharmacist licensure from Chapter Phar 3 into Chapter Phar 2, in order to place the requirements for both original pharmacist licensure in Wisconsin, as well as by reciprocity upon pharmacist licensure in another state under the same chapter.

SECTIONS 19, 20 and 21 amend provisions relating to the prelicense examinations and make the provisions similar to other rules of the department and boards in the department. These provisions relate to the determination of the passing score on the pharmacist examinations, cheating on the examinations and procedures for reviewing failed examinations administered by the board.

SECTION 26 creates the requirements for renewing a license that has expired, depending upon whether the application for renewal is made less than 5 years, or 5 years or more, after the renewal date.

SECTION 30 is created to require that all pharmacies have an alarm system that is monitored from a central location.

SECTION 33 raises from one to two the number of non-pharmacists that may engage in aspects of the dispensing function under the supervision of a pharmacist.

SECTION 34 clarifies the circumstances under which a pharmacy may or may not accept the return of dispensed items after they have left the pharmacy.

SECTION 35 sets forth the board's current interpretation that a pharmacist may not accept prescription orders received by telephone answering machines.

SECTIONS 39, 42 and 43 bring the rules into conformity with regulations regarding controlled substances adopted by the federal Drug Enforcement Administration. Section 39 waives the requirement to mark hard copy prescription orders for a controlled substance with a red "C", if a pharmacy utilizes a computerized recordkeeping system. Section 42 extends to 7 days the time period in which a prescriber has to provide a written order to a pharmacy for a schedule II controlled substance previously authorized by emergency oral order. Section 43 adopts the federal requirements for prescription orders transmitted to pharmacies by facsimile machine.

SECTION 45 creates rules clarifying current board interpretations that it is unprofessional conduct to practice without a current license, and that the board must be informed by a licensee when a prescription is dispensed that could likely cause substantial harm to a person.

SECTION 49 repeals Chapter Phar 14 providing a procedure for assessing forfeitures without the issuance of a formal disciplinary complaint. The procedure has never been utilized since its creation in 1989. Although the procedure provides for a hearing to contest the forfeiture assessed, the board believes the process to be highly questionable, from both a legal and public policy perspective.

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TEXT OF RULE

SECTION 1. Phar 1.01 is amended to read:

Phar 1.01 AUTHORITY. Rules in chs. Phar 1 to ~~14~~ 13 are adopted under authority of ss. 15.08 (5) ~~(b)~~, ~~161.31~~, 227.11 (2), Stats., and ch. 450, Stats.

SECTION 2. Phar 1.02 (7), (8), (11) and (14) are amended to read:

Phar 1.02 (7) ~~“NABPLEX”~~ “NAPLEX” means the ~~national association of boards of north American pharmacy~~ licensing examination.

(8) “Pharmacist” ~~means a person licensed by the board under ch. 450, has the meaning given in s. 450.01 (15), Stats.~~

(11) “Pharmacy owner” means a person or entity to whom a pharmacy ~~permit~~ license is issued.

(14) “Professional service area” means the area of a pharmacy in which prescriptions are compounded or dispensed, hypodermic needles, syringes, poisons and schedule V controlled substances as listed in s. ~~161.22~~ 961.22, Stats., and ch. CSB 2, ~~Wis. Adm. Code~~, are available, or where patients are consulted.

SECTION 3. Chapter Phar 2 (title), 2.01 (title) and 2.01 (intro.) are amended to read:

Chapter Phar 2 (title)

APPLICATION FOR PHARMACIST  
LICENSURE BY EXAMINATION LICENSE

Phar 2.01 (title) QUALIFICATIONS FOR ORIGINAL LICENSURE. (intro.) An applicant for original licensure as a pharmacist may be admitted to examination under ch. 450, Stats., if the applicant:

SECTION 4. A Note following Phar 2.01 (2) is created to read:

Note: The Pharmacy Internship Board is located at 425 North Charter Street, Madison, Wisconsin 53706.

SECTION 5. Phar 2.02 (title), (1) (intro.) and (d) are amended to read:

Phar 2.02 (title) APPLICATION PROCEDURE FOR ORIGINAL LICENSURE. (1) (intro.) Each applicant for original licensure as a pharmacist shall submit a completed notarized application no later than ~~30~~ 45 days prior to the examination date on forms provided by the board. The application shall include all of the following:

(d) The fees ~~specified~~ required under s. 440.05 (1), Stats.

Note: Applications are available upon request to the board office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

SECTION 6. Phar 2.03 (title) and (1) are amended to read:

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

SECTION 7. Phar 2.03 (3) is repealed.

SECTION 8. Phar 2.03 (4) and (5) are amended to read:

Phar 2.03 (4) An applicant for licensure as a pharmacist may not be admitted to the ~~NABPLEX NAPLEX~~ or the ~~federal law~~ multi-state pharmacy jurisprudence examination before that ~~uniform designated~~ test date which is immediately before completion of the applicant's internship. Except as provided in sub. (5), an applicant may not be admitted to the ~~state law examination or the~~ laboratory practical examination before the test date which immediately follows completion of the applicant's internship.

(5) An applicant may make a written request for early admittance to the ~~state law examination and~~ laboratory practical examination if the applicant's internship completion date is within 15 days of the scheduled examination date. However, an applicant shall successfully complete an approved internship program and all other requirements before a license to practice may be issued.

SECTION 9. Chapter Phar 3 (title) is repealed.

SECTION 10. Phar 3.01 is renumbered Phar 2.04 and as renumbered Phar 2.04 (title) is amended to read:

Phar 2.04 (title) QUALIFICATIONS FOR PERSONS LICENSED IN ANOTHER STATE.

SECTION 11. Phar 3.02 is renumbered Phar 2.05 and as renumbered Phar 2.05 (title) and (1) (intro.) are amended to read:

Phar 2.05 (title) APPLICATION PROCEDURE FOR PERSONS LICENSED IN ANOTHER STATE. (1) (intro.) Each applicant licensed as a pharmacist in another state shall file with the board, no later than 30 days prior to the examinations, the following:

SECTION 12. Phar 3.03 is repealed.

SECTION 13. Phar 3.04 is renumbered Phar 2.06 and as renumbered Phar 2.06 (title), (1), (3) (intro.), (a), (b) and (c) are amended to read:

Phar 2.06 (title) EXAMINATIONS FOR PERSONS LICENSED IN ANOTHER STATE. (1) ACTIVE PRACTICE. An applicant licensed as a pharmacist in another state who is engaged in the active practice of pharmacy, shall take the ~~state law~~ multi-state pharmacy jurisprudence examination described in s. Phar 4.02 (2) (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 review requests for reciprocity.

(3) EQUIVALENCY EXAMINATION. (intro.) Any applicant who has not engaged in the active practice of pharmacy shall take and pass each of the following examinations ~~by a minimum score of 75.0:~~

- (a) State practice of pharmacy;
- (b) Laboratory practice; ~~and,~~
- (c) ~~State law examination~~ Multi-state pharmacy jurisprudence.

SECTION 14. Phar 4.01 (3) is amended to read:

Phar 4.01 (3) At least 10 days prior to the examination, the applicant shall be mailed an admission card and that card shall be presented at the door of the examination room, with a driver's license or passport photograph ~~which is a duplicate of that filed with the application for licensure.~~

SECTION 15. Phar 4.02 (1) is amended to read:

Phar 4.02 (1) The ~~federal law~~ multi-state pharmacy jurisprudence examination shall determine an applicant's competence to practice within federal laws and regulations and Wisconsin laws and rules governing the practice of pharmacy.

SECTION 16. Phar 4.02 (2) is repealed.

SECTION 17. Phar 4.02 (5) is amended to read:

Phar 4.02 (5) ~~NABPLEX~~ NAPLEX shall determine an applicant's competence in the basic principles and professional areas within the practice of pharmacy.

SECTION 18. Phar 4.02 (6) is created to read:

Phar 4.02 (6) An otherwise qualified applicant shall be provided with reasonable accommodations, as required by the Americans with disabilities act.

SECTION 19. Phar 4.03 (3) is repealed and recreated to read:

Phar 4.03 (3) The score required to pass an examination shall be based on the board's determination of the level of examination performance required for minimum acceptable competence in the profession. The board shall make the determination after consultation with experts in the subject matter of the examination who have reviewed a representative sample of the examination questions and available candidate performance statistics, and shall set the passing score for the examination at that point which represents minimum acceptable competence in the profession.

SECTION 20. Phar 4.035 is created to read:

Phar 4.035 UNAUTHORIZED ASSISTANCE. An applicant may not give or receive unauthorized assistance during the examination. The action taken by the board when unauthorized assistance occurs shall be related to the seriousness of the offense. These actions may include withholding the score of the applicant, entering a failing grade for the applicant, and suspending the ability of the applicant to sit for the next scheduled examination after the examination in which the unauthorized assistance occurred.

SECTION 21. Phar 4.045 and 4.046 are created to read:

Phar 4.045 EXAMINATION REVIEW. (1) An applicant who fails an examination administered by the board may request a review by the applicant of that examination by filing a written request to the board within 45 days after the date on which the examination results were mailed to the applicant.

(2) An examination review shall be conducted under the following conditions:

- (a) The time for review shall be limited to one hour.
- (b) The examination shall be reviewed only by the applicant and in the presence of a proctor.
- (c) The proctor may not respond to inquiries by the applicant regarding allegations of examination error.
- (d) An applicant shall be permitted only one review of the failed examination each time it is taken and failed.

Phar 4.046 CLAIM OF EXAMINATION ERROR. (1) An applicant wishing to claim an error regarding specific questions or procedures on an examination administered by the board shall file a written request on a form provided for this purpose in the board office within 30 days after the date the examination was reviewed. The request shall include:

- (a) The applicant's name and address.
- (b) The type of registration applied for.
- (c) A description of the alleged error, including reference text citations or other supporting evidence for the applicant's claim.

(2) The request shall be reviewed by the board in consultation with an expert in the subject matter of the examination. The applicant shall be notified in writing of the board's decision.

SECTION 22. Phar 4.05 (1) and (4) are repealed.

SECTION 23. Phar 5.01 (1) and (2) are amended to read:

Phar 5.01 (1) Pharmacists, pharmacies, manufacturers and distributors licensed under ch. 450, Stats., and otherwise qualified for renewal, may continue to be licensed biennially by applying for renewal and paying the fee specified in s. 440.05 ~~(3)~~ 440.08 (2), Stats.

(2) No one without a current renewal ~~and certificate~~ certificate may engage in the practice of pharmacy, nor hold ~~him-~~ himself or herself out to be a pharmacist nor use the title or letters "Pharmacist" or "Registered Pharmacist" or "R.Ph."

SECTION 24. Phar 5.02 (1) and (2) are amended to read:

Phar 5.02 CHANGE OF NAME AND ADDRESS. (1) A pharmacist shall notify the board in writing when his or her name has been legally changed, within 30 days of the change.

(2) A pharmacist shall notify the board ~~of his or her current address in writing~~ when his or her address has changed, within 30 days of the change.

SECTION 25. Phar 5.04 is amended to read:

Phar 5.04 RENEWAL PROHIBITED; RELICENSURE. Any person whose license is currently suspended or revoked may not renew his or her license. A person whose license has been suspended or revoked and subsequently reinstated by the board, and who is otherwise qualified for renewal, may renew his or her license upon completion of a renewal form and filing of the required renewal fee.

SECTION 26. Phar 5.05 is created to read:

Phar 5.05 REQUIREMENTS FOR LATE RENEWAL; REINSTATEMENT. (1) An individual who files an application for renewal of a license within 5 years after the renewal date may be reinstated by filing with the board all of the following:

(a) An application for renewal on a form prescribed by the department.

(b) The fee required under s. 440.08 (2), Stats., plus the applicable late renewal fee required under s. 440.08 (3), Stats.

(2) An individual who files an application for renewal of a license 5 years or more after the renewal date may be reinstated by filing with the board all of the following:

(a) An application for renewal on a form prescribed by the department.

(b) The fee required under s. 440.08 (2), Stats., plus the applicable late renewal fee required under s. 440.08 (3), Stats.

(c) Verification of successful completion of examinations or educational requirements, or both, as the board may prescribe, provided that the examination or education requirements may not be more extensive than those required to obtain an initial license.

SECTION 27. Phar 6.01 is amended to read:

Phar 6.01 LICENSES; APPLICATION. Requirements and procedures for applying for a pharmacy license are specified in s. 450.06, Stats. Approved application forms are available from the board. Appointments for the required pharmacy inspection may be made by contacting the board office. A license application and fee shall be on file with the board at least 30 days prior to the granting of the pharmacy license. A pharmacy may not operate unless a pharmacy license has been granted. Board action shall be taken within ~~90~~ 60 business days of receipt of a completed pharmacy application, as provided in s. RL 4.03.

Note: Applications are available upon request to the board office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708.

SECTION 28. The Note following Phar 6.03 is repealed.

SECTION 29. Phar 6.06 (1) (j) 3. is amended to read:

Phar 6.06 (1) (j) 3. Wisconsin controlled substances act, ch. ~~161~~ 961, Stats.

SECTION 30. Phar 6.08 is created to read:

Phar 6.08 SECURITY. Effective January 1, 2000, a pharmacy shall have a centrally monitored alarm system in the pharmacy or the immediate physical structure within which the pharmacy is located.

SECTION 31. Phar 7.01 (1) (a) and (e) are amended to read:

Phar 7.01 (1) (a) Receive oral ~~or written~~ prescription orders of a prescriber, review all original and renewal prescription orders, written or oral, determine therapeutic compatibility and legality of the prescription order. The review shall include, when indicated or appropriate, consultation with the prescriber.

(e) ~~Transfer the prescription to the patient or agent of the patient and give~~ Give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a patient's residence if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a patient's residence, is not satisfied by only offering to provide consultation.

SECTION 32. Phar 7.01 (em) is created to read:

Phar 7.01 (em) Transfer the prescription to the patient or agent of the patient.

SECTION 33. Phar 7.01 (1) (f) (intro.) and (3) are amended to read:

Phar 7.01 (1) (f) (intro.) ~~Obtain~~ Receive, when required by law and standard professional practice, permission to renew from authorized prescribers, and note on the prescription order, medication profile record or uniformly maintained and readily retrievable document the following information:

(3) A pharmacist may supervise no more than one pharmacy intern and ~~one non-pharmacist~~ 2 non-pharmacists engaged in compounding and dispensing activities as described in sub. (1) (c), except a higher ratio may be authorized by the board upon request to and approval by the board of a specific plan describing the manner in which additional interns or non-pharmacists shall be supervised.

SECTION 34. Phar 7.04 is repealed and recreated to read:

Phar 7.04 RETURN OR EXCHANGE OF HEALTH ITEMS. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug, medicines, or items of personal hygiene.

(b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community-based residential facilities, jails or prison facilities.

(2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned, except for any of the following:

(a) From an inpatient health care facility, provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.

(b) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed beyond their expiration date.

(c) When in the professional judgment of the pharmacist substantial harm could result to the public or a patient if they were to remain in the possession of the patient, patient's family or agent, or other person.

(3) Health items returned to a pharmacy pursuant to sub. (2), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

(4) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device for the same patient's use.

Note: The DEA does not permit the return of controlled substances to a pharmacy under any circumstances.

SECTION 35. Phar 7.065 is created to read:

Phar 7.065 ANSWERING MACHINES IN PHARMACIES. Oral prescription orders may be received at a pharmacy via a telephone answering device and dispensed by the pharmacist if the voice of the physician or physician's agent is known to the pharmacist, and provided other requirements of reducing the prescription order to writing, labeling and filing are met.

SECTION 36. Phar 7.07 (1) is amended to read:

Phar 7.07 (1) ~~Within 3 years of February 1, 1989, an~~ An individual medication profile record system shall be maintained in all pharmacies for persons for whom prescriptions, original or renewal, are dispensed for outpatient use. The system shall be capable of permitting the retrieval of information. The system need not be limited to individual medication profile records.



SECTION 37. Phar 8.01 is amended to read:

Phar 8.01 SCOPE. Procedures governing the manufacture, distribution and dispensing of controlled substances pursuant to ch. ~~161~~ 961, Stats., are set forth generally by that chapter and specifically by sections of this chapter and chs. Phar 12 and 13.

SECTION 38. Phar 8.02 (1), (2) and (3) (e) 2. are amended to read:

Phar 8.02 (1) Any pharmacy, practitioner, or other federal drug enforcement administration registrant, as referenced in ch. ~~161~~ 961, Stats., shall maintain complete and accurate records of each controlled substance received, manufactured, distributed, dispensed or disposed of in any other manner.

(2) Records required by the federal controlled substances act and ch. ~~161~~ 961, Stats., shall be maintained at the location where the drug is received, manufactured, distributed or dispensed, and be available for inspection by authorized persons for at least 5 years from the date of such record. Financial and shipping records such as invoices and packing slips, but not executed order forms, may be kept at a central location. A complete and accurate biennial physical inventory of all schedule II, III, IV and V controlled substances pursuant to ss. ~~161.16, 161.18, 161.20 and 161.22~~ 961.16, 961.18, 961.20 and 961.22, Stats., and ch. CSB 2, ~~Wis. Adm. Code~~, on hand shall be made in conformance with all applicable federal and state laws.

(3) (e) 2. If a schedule V drug is dispensed other than pursuant to a prescription order, the dispenser shall make the record required by s. ~~161.23~~ 961.23, Stats., in a bound controlled substance V register at the time of the transaction.

SECTION 39. Phar 8.03 (1) and (3) are amended to read:

Phar 8.03 (1) All controlled substance prescription orders shall be maintained on file, in chronological order, for a period of at least 5 years. The orders shall be readily accessible to enforcement personnel authorized by s. ~~161.51~~ 961.51, Stats.

(3) Schedule III, IV and V prescription orders may be filed with those for non-controlled drugs provided that orders for schedule III, IV and V drugs are stamped in red ink with the letter "C" one inch in height in the lower right hand corner of the order or orders for schedule III, IV and V substances may be filed separately. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescription orders which permits identification by prescription order number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription order with a red "C" is waived.

SECTION 40. Phar 8.04 (1) is amended to read:

Phar 8.04 (1) Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription order within the meaning and intent of ss. 450.01 (21) and ~~161.38~~ 961.38, Stats. The person knowingly dispensing pursuant to such a purported order, as well as the person issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

SECTION 41. Phar 8.05 (2) is amended to read:

Phar 8.05 (2) A pharmacist may dispense a controlled substance listed in schedule II, III or IV only pursuant to a prescription order issued by an individual practitioner. The order shall be initialed and dated by the dispensing pharmacist as of the date the prescription is dispensed. If the person accepting the medication pursuant to any prescription order for a schedule II controlled substance, specified in s. ~~161.16~~ 961.16, Stats., is not personally known to the pharmacist, there shall be written in ink, on the reverse side, the printed name, signature and address of the person.

SECTION 42. Phar 8.09 (4) is amended to read:

Phar 8.09 (4) Within ~~72 hours~~ 7 days after authorizing an emergency oral prescription order, the practitioner shall cause a written order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of s. Phar 8.05, the order shall contain on its face "authorization for emergency dispensing" and the date of the oral order. The written order may be delivered to the pharmacist in person or by mail, but if delivered by mail it shall be postmarked within the ~~72-hour~~ 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription order to the oral emergency order reduced to writing under sub. (2) (b). The pharmacist shall notify the board or department of regulation and licensing if the practitioner fails to deliver the written order. Failure of the pharmacist to provide notification shall void the authority conferred by this section to dispense without a written order of a practitioner.

SECTION 43. Phar 8.12 is created to read:

Phar 8.12 PRESCRIPTION ORDERS TRANSMITTED BY FACSIMILE MACHINE.  
(1) PRESCRIPTION DRUGS OTHER THAN SCHEDULE II CONTROLLED SUBSTANCES. A pharmacist may dispense a prescription drug, other than a schedule II controlled substance, pursuant to a prescription order transmitted by a facsimile machine from the practitioner or the practitioner's agent to the dispensing pharmacy if all of the following conditions are met:

(a) The transmitted facsimile prescription order shall contain all of the information required for a valid written prescription order. The order shall also contain the time and date of the transmission, as well as the telephone number and name of the transmitter.

(b) Unless the facsimile paper is non-fading, the facsimile prescription order received shall be duplicated by copy machine or other similar device and the copy must be physically attached to the order received.

(2) SCHEDULE II CONTROLLED SUBSTANCES. A pharmacist may not dispense a schedule II controlled substance pursuant to a prescription order transmitted by a facsimile machine unless all of the conditions stated in sub. (1) are satisfied, and any of the following conditions are met:

(a) The prescription order is written for a schedule II controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(b) The prescription order is written for a schedule II controlled substance for a patient in a long term care facility, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(c) The prescription order is written for a schedule II controlled substance for a patient residing in a hospice certified by medicare under Title XVIII or licensed by this state, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(3) PRESCRIPTION ORDERS TRANSMITTED BY FACSIMILE CONSIDERED WRITTEN ORDERS. For all purposes under chs. 450 and 961, Stats., and the rules of the board, a prescription order transmitted by facsimile machine shall be considered the original written prescription order.

SECTION 44. Phar 10.02 (1), (2) and (3) are amended to read:

Phar 10.02 DEFINITIONS. In this chapter:

(1) "Dispense" ~~means to select, compound, mix, combine, measure, count, or otherwise prepare a drug or drugs for delivery to the patient, or to deliver a drug or drugs to the patient~~ has the meaning given in s. 450.01 (7), Stats.

(2) "Drug" has the meaning ~~defined in s. 450.06~~ given in s. 450.01 (10), Stats.

(3) "Patient" ~~means the individual for whom drugs are prescribed or to whom prescription drugs are administered~~ has the meaning given in s. 450.01 (14), Stats.

SECTION 45. Phar 10.03 (7m) and (19) are created to read:

Phar 10.03 (7m) Failing to report to the board information that reasonably suggests there is a probability that a prescription drug or device dispensed by a pharmacist has caused or contributed to the substantial bodily injury or death of a customer or patient.

(19) Practicing without a current license.

SECTION 46. Phar 12.03 (2) (intro.), (a), (b), (c), (d) and (5) are amended to read:

Phar 12.03 (2) (intro.) To obtain a license a person shall do all of the following:

(a) Submit an application on a form provided by the board;

(b) Pay the fee specified in s. 440.05 ~~(8)~~ (1), Stats.;

(c) Meet the inspection requirement under s. Phar 12.04;

(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); ~~and,~~

(5) The board shall act on the application for a license within 60 business days after receiving the completed application, as provided in s. RL 4.03.

SECTION 47. Phar 13.02 (3) is amended to read:

Phar 13.02 (3) "Controlled substance" has the meaning set forth in s. ~~161.01(4)~~ 961.01(4), Stats.

SECTION 48. Phar 13.07 is amended to read:

Phar 13.07 APPLICATION REVIEW. The board shall act upon an application for a license within 60 business days after receiving the completed application, as provided in s. RL 4.03. If the license is denied, the applicant may request a hearing pursuant to ch. RL 1.

SECTION 49. Chapter Phar 14 is repealed.

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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

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.

FINAL REGULATORY FLEXIBILITY ANALYSIS

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

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5/4/98

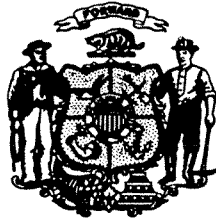
WISCONSIN LEGISLATIVE COUNCIL STAFF

LCRC  
FORM 2

***RULES CLEARINGHOUSE***

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**CLEARINGHOUSE REPORT TO AGENCY**

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[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 98-016**

AN ORDER to repeal Phar 2.03 (3), chapter Phar (3) (title), 3.03, 4.02 (2), 4.05 (1) and (4), the Note following 6.03 and chapter Phar 14; to renumber and amend Phar 3.01, 3.02 and 3.04; to amend Phar 1.01, 1.02 (7), (8), (11) and (14), chapter Phar 2 (title), 2.01 (title) and (intro.), 2.02 (title) and (1) (intro.) and (d), 2.03 (title), (1), (4) and (5), 4.01 (3), 4.02 (1) and (5), 5.01 (1) and (2), 5.02 (1) and (2), 5.04, 6.01, 6.06 (1) (j) 3., 7.01 (1) (a), (e) and (f) (intro.) and (3), 7.07 (1), 8.01, 8.02 (1), (2) and (3) (e) 2., 8.03 (1) and (3), 8.04 (1), 8.05 (2), 8.09 (4), 10.02 (1), (2) and (3), 12.03 (2) (intro.), (a), (b), (c) and (d) and (5), 13.02 (3) and 13.07; to repeal and recreate Phar 4.03 (3) and 7.04; and to create a Note following Phar 2.01 (2), 4.035, 4.045, 4.046, 5.05, 6.07 (4), 7.01 (3m), 7.065, 8.12 and 10.03 (7m) and (19), relating to pharmacists and pharmacies.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

02-09-98 RECEIVED BY LEGISLATIVE COUNCIL.  
03-09-98 REPORT SENT TO AGENCY.

RNS:MM:jt:ksm

**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)]

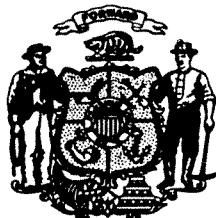
Comment Attached      YES       NO

# WISCONSIN LEGISLATIVE COUNCIL STAFF

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## CLEARINGHOUSE RULE 98-016

### 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 1994.]**

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

- a. In the second sentence of the last paragraph of the analysis, "The procedures have" should be changed to "The procedure has."
- b. In s. Phar 1.01 (14), ", Wis. Adm. Code," should be deleted.
- c. The Note following s. Phar 4.02 (5) appears to be substantive, as does the first part of the Note following s. Phar 7.04. They should be incorporated into the text of the rule.
- d. It appears that ss. Phar 4.045 (2) (d) and Phar 4.046 contain essentially the same information, that is, the procedure which should be followed by a person who claims that there is an error in an examination administered by the board. Section Phar 4.046 appears to provide a more thorough procedure to be followed; however, that section does not address claims of error regarding *procedures* followed in the examination, as does s. Phar 4.045 (2) (d). Should s. Phar 4.045 (2) (d) be deleted and s. Phar 4.046 be expanded to include claims of error regarding procedures followed in examinations administered by the board? In addition, in s. Phar 4.046 (1) (c), should "perceived" be replaced with "alleged"?
- e. In several provisions of the rule, "shall" should replace "must." For example, see s. Phar 4.046 (1) (intro.).
- f. Section Phar 5.05 (2) (c) authorizes the board to prescribe the examinations or educational requirements, or both, which must be successfully completed by an applicant for



reinstatement of a license five years or more after the renewal date. Could these requirements be set forth in the rule? If these rules are not set forth in the rule, how will they be made available to the public?

g. Is it appropriate to place the requirement that a pharmacy have a centrally monitored alarm system, as set forth in s. Phar 6.07 (4), in the section of the rule titled "Storage"?

h. In s. Phar 7.04 (2) (c), should "or other person" be added to the end of the sentence?

i. The acronym "ADP" in s. Phar 8.03 (3) should be defined or spelled out.

j. In s. Phar 8.12 (2) (intro.), readability would be enhanced if "either" were replaced with "any of the following conditions are met." In pars. (a) and (b), a period should replace "; or,".

k. In s. Phar 8.12 (2) (a), should "home infusion pharmacy" be replaced with "dispensing pharmacy"?

l. The common terminology used when referring to a definition set forth in the statutes is the phrase "has the meaning given in." The definitions in ss. Phar 1.02 (8) and 10.02 could be rewritten to conform to this common terminology.

m. In s. Phar 10.03 (7m), should "dispensed by the pharmacist" be inserted after "device"?

n. In s. Phar 12.03 (5), "the license" should be replaced with "the application for a license."

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

a. What is a "subject matter expert" referred to in ss. Phar 4.03 (3), Phar 4.045 (2) (d) and Phar 4.046 (2)?

b. The last sentence in s. Phar 4.035 appears to be missing a phrase. Perhaps "or requiring the applicant" should be inserted after "applicant."

c. It appears that s. Phar 4.045 (1) should be clarified to specify that the review which may be requested is a review conducted by the applicant, rather than by the board. In addition, should that section specify what may be reviewed? For example, is the applicant permitted to review his or her examination answers or only the questions?

d. It is unclear to what "request" in the second sentence of s. Phar 4.045 (2) (d) refers.

e. If it is found under s. Phar 4.046 that there is an error in an examination which has been administered by the board, should the board be required to take any action, such as reviewing the examination scores of all persons who took that examination to determine if the error in the examination would, if corrected, result in the passing of the examination by an applicant who was considered to have failed?

f. Should s. Phar 5.01 (2) specify that a person who is practicing under an original license is not required to have a current renewal certificate?

g. Is the address referred to in s. Phar 5.02 (2) the home or business address of the pharmacist?