CR 81-240

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CERTIFICATE

STATE OF WISCONSIN)
) SS
PHARMACY EXAMINING BOARD)

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Bud L. Nelson, secretary of the Pharmacy Examining Board, and custodian of the official records of said board do hereby certify that the annexed rules relating to authority and definitions; pharmacist licensure by examination; pharmacist licensure by reciprocity; examinations; biennial renewal; pharmacy permits and equipment; pharmacy practice; requirements for controlled substances; pharmaceutical services requirements in nursing homes; standards of professional conduct; and, procedures for hearings, were duly approved and adopted by this board on October 13, 1982.

I further certify that said copy has been compared by me with the original on file in this board and that the same is a true copy thereof, and of the whole of such original.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the board at 1400 East Washington Avenue, Madison, Wisconsin, this 13th day of October, A.D. 1982.

Meredith L. "Bud" Nelson, R.Ph.

Bud L. Nelson, Secretary
Pharmacy Examining Board

STATE OF WISCONSIN
BEFORE THE
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	ORDER OF THE PHARMACY EXAMINING BOARD REPEALING, AMENDING OR ADOPTING RULES

ORDER

Pursuant to authority vested in the Pharmacy Examining Board in ss. 15.08(5), 227.014 and Chapter 450, Stats., the Pharmacy Examining Board hereby repeals and recreates and adopts rules, interpreting ss. 440.03(1), 450.02, 450.04 and 450.14, Stats., as follows:

SECTION 1. Chapters Phar 1, 2 and 3 of the Wisconsin Administrative Code are repealed and recreated to read:

Chapter Phar 1

AUTHORITY AND DEFINITIONS

Phar 1.01 AUTHORITY. Rules in Chapters Phar 1 to 11 are adopted under authority of ss. 15.08(5), 161.31, 227.014, Stats. and Chapter 450, Stats.

Phar 1.02 DEFINITIONS. As used in chs. Phar 1 to 11:

(1) "Board" means the pharmacy examining board.

[NOTE: The board office is located at 1400 East Washington Avenue, Madison, Wisconsin 53702, telephone (608) 266-8794.]

(2) "Managing pharmacist" means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

(3) "NABPLEX" means the national association of boards of pharmacy licensing examination.

(4) "Pharmacist" means a person licensed by the board under ch. 450, Stats., and chs. Phar 1 to 11.

(5) "Pharmacist-in-charge" means a pharmacist who is physically present in the licensed facility and responsible for the routine operation of a pharmacy for the period of time specified by the managing pharmacist.

(6) "Pharmacy" means any place in which prescription drugs, as defined in s. 450.07(1)(a), Stats., are compounded or dispensed.

(7) "Pharmacy owner" means a person or entity to whom a pharmacy permit is issued.

(8) "Practice of pharmacy" means any of the following: interpreting prescription orders; compounding, packaging, labeling, dispensing, and distributing drugs and devices; monitoring drug therapy and use; initiating, modifying or administering drug therapy in accordance with written guidelines or procedures previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; participation in drug utilization reviews and drug product substitution as authorized in ch. 450, Stats.; proper and safe storage and distribution of drugs and devices and maintenance of proper records of drugs and devices; providing information on prescription and non-prescription drugs and devices which may include, but is not limited to, advice on therapeutic values, hazards and the uses of drugs and devices, and performing those acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy.

(9) "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, Stats., and ch. CSB 2, Wis. Adm. Code, are available, or where patients are consulted.

Chapter Phar 2

PHARMACIST LICENSURE BY EXAMINATION

Phar 2.01 QUALIFICATIONS. An applicant for licensure as a pharmacist may be admitted to examination under ch. 450, Stats., if the applicant:

(1) Has been graduated from a school or college of pharmacy approved by the board. Deficiencies may be removed by satisfactory completion of the required program of study in a school or college of pharmacy approved by the board.

(2) Has completed an internship program approved by the pharmacy internship board consisting of practical experience directly related to pharmacy under the direct supervision of a pharmacist for at least 365 days, on a days-elapsed basis, commencing no earlier than the date of completion by an applicant of all but 2 years of an approved pharmacy curriculum.

Phar 2.02 APPLICATION PROCEDURE. (1) Each applicant shall submit a completed notarized application no later than 30 days prior to the examination date on forms provided by the board. The application shall include:

(a) The signature of the applicant.

(b) A statement from the dean of the school of pharmacy or the academic records office of the respective educational institution that the applicant has graduated from the pharmacy school.

(c) A recent notarized photograph.

(d) The fee specified under s. 440.05(1), Stats..

(2) Any change of name made prior to admission to examination shall be supported by an affidavit satisfactory to the board.

Phar 2.03 EXAMINATIONS. (1) An applicant for licensure as a pharmacist is required to take the NABPLEX, a jurisprudence examination and a laboratory practice examination.

(2) The coverage and conduct of examinations administered by the board are specified in ch. Phar 4, Wis. Adm. Code.

(3) An applicant may request to take the NABPLEX examination in another licensing jurisdiction at the time the applicant is eligible to take the NABPLEX in Wisconsin if the board is notified in writing not less than 30 days in advance of the exam and authorizes the transfer of those grades to the board.

Chapter Phar 3

PHARMACIST LICENSURE BY RECIPROCITY

Phar 3.01 QUALIFICATIONS. A pharmacist holding a license to practice pharmacy in another state may become licensed in Wisconsin if the applicant:

(1) Has been graduated from a school or college of pharmacy approved by the board.

(2) Has passed the required examinations administered by the board.

Phar 3.02 APPLICATION PROCEDURE. (1) Each applicant shall file with the board, no later than 30 days prior to the examinations, the following:

(a) Completed application form.

(b) The fee specified under s. 440.05(1), Stats.

(2) Verification of license shall be forwarded from the original state of licensure by examination.

(3) Credentials received in a name other than that on the original application shall be supported by a change of name affidavit satisfactory to the board.

Phar 3.03 INELIGIBILITY OF LICENSEES FROM FOREIGN COUNTRIES. Any applicant who is licensed in a foreign country, but who is not licensed in any state of the United States, shall not be eligible for licensure under this chapter.

Phar 3.04 EXAMINATIONS. (1) ACTIVE PRACTICE. An applicant licensed as a pharmacist in another state who is engaged in the active practice of pharmacy, shall take the jurisprudence examination described in s. Phar 4.02(2). 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.

(a) In this section, "active practice of pharmacy" means having engaged in at least 2,000 hours of the practice of pharmacy within the 12 months preceding application for licensure in Wisconsin or at least 2,000 hours of the practice of pharmacy comprised of no less than 500 hours in each of 3 of the 4 12-month periods preceding application for licensure in Wisconsin.

(2) EQUIVALENCY EXAMINATION. Any applicant who has not engaged in the active practice of pharmacy shall take a jurisprudence examination under s. Phar 4.02(2), a laboratory practical examination under s. Phar 4.02(3) and practice of pharmacy examination under s. Phar 4.02(4).

(3) COVERAGE AND CONDUCT. The coverage and conduct of examinations administered by the board are specified in ch. Phar 4, Wis. Adm. Code.

Section 2. Chapter Phar 4 of the Wisconsin Administrative Code is created to read:

Chapter Phar 4

EXAMINATIONS

Phar 4.01 ADMINISTRATION. (1) Examinations may be written, oral, or practical.

(2) Examinations are conducted in the English language only.

(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 photograph which is a duplicate of that filed with the application for licensure.

(4) A number shall be assigned to each applicant. Rules of conduct shall be provided at the beginning of the examination.

(5) An applicant found by the board to have violated rules of the examination may be denied licensure by the board.

Phar 4.02 COMPETENCIES TESTED. (1) Competencies tested are the basic principles of the practice of pharmacy.

(2) The jurisprudence examination shall determine an applicant's familiarity with Wisconsin laws and rules and federal laws and regulations governing the practice of pharmacy.

(3) The laboratory practical examination shall determine an applicant's proficiency in compounding and dispensing medications.

(4) The practice of pharmacy examination shall determine an applicant's familiarity with the basic principles of the practice of pharmacy.

(5) NABPLEX tests in 5 areas.

[Note: The 5 different areas tested are: Chemistry, mathematics, pharmacology, pharmacy and practice of pharmacy. Competency statements on the NABPLEX portion of the exam are available from the National Association of Boards of Pharmacy, 1 E. Wacker Drive, Chicago, Illinois 60601.]

Phar 4.03 PASSING SCORES. (1) The passing scores set by the board represent the minimum competency required to protect public health and safety.

(2) Each exam is scored separately and an applicant shall earn passing scores on each required examination to qualify for licensure.

(3) The board requires a minimum average score of 75.0 in the chemistry, mathematics, pharmacology, and pharmacy sections of NABPLEX, with no score less than 60.0 on any of the four sections. A minimum score of 75.0 on the practice of pharmacy section of NABPLEX is required.

(4) A minimum score of 75.0 is required in jurisprudence.

(5) A minimum score of 75.0 is required in the laboratory practical examination.

(6) A minimum score of 75.0 is required in the practice of pharmacy examination.

Phar 4.04 SCORING. (1) The board shall send written notification of results to applicants.

(2) An applicant shall be offered the opportunity to make written comments and objections within 30 days after notification of the examination results.

(3) Any unsuccessful applicant may request in writing that his or her answer sheet be rescored by hand to verify the accuracy of scoring.

(4) The cost of rescoring shall be paid by the applicant.

Phar 4.05 FAILURE AND RE-EXAMINATION. (1) An applicant who has not obtained a 75.0 average, subject to s. Phar 4.03, with no grade less than 60.0 of NABPLEX sections on chemistry, mathematics, pharmacology and pharmacy shall repeat the section or sections with a grade less than 75.0, subject to sub. (3). Any applicant earning a 75.0 average on these four sections of NABPLEX with one or more sections less than 60.0 shall repeat only those sections less than 60.0, subject to sub. (3). All applicants have the option to retake all sections of NABPLEX in lieu of only those sections with grades below 75.0 or 60.0.

(2) An applicant who fails to earn a passing score in jurisprudence, laboratory practice or practice of pharmacy may repeat the failed examination subject to sub. (3).

(3) An applicant who fails to earn a passing score in any examination for licensure may be re-examined, but not earlier than the next scheduled test date.

(4) Application for re-examination shall be made on forms provided for that purpose by the board. For each re-examination the applicant shall file the re-examination fee specified in ch. RL 4, Wis. Adm. Code.

(5) Any unsuccessful applicant may request in writing to meet with the board to discuss any grievance concerning the examination.

SECTION 3. Section Phar 5.02(4) of the Wisconsin Administrative Code is repealed.

SECTION 4. Chapter Phar 5 of the Wisconsin Administrative Code is renumbered to Chapter Phar 10.

SECTION 5. Chapter Phar 5 of the Wisconsin Administrative Code is created to read:

Chapter Phar 5

LICENSE RENEWAL

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

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

(3) No pharmacy, manufacturer or distributor may operate without a current license.

Phar 5.02 CHANGE OF NAME OR ADDRESS. (1) A pharmacist shall notify the board in writing when his or her name has been legally changed.

(2) A pharmacist shall notify the board of his or her current address.

Phar 5.03 DISPLAY OF LICENSES. A pharmacist who engages in the practice of pharmacy shall display his or her license in a manner conspicuous to the public view. Biennial renewal cards shall be placed in the lower right hand corner of the license and shall be posted when received. Only current renewal cards may be posted. A pharmacist may not display his or her license in any place other than the pharmacy where he or she engages in the practice of pharmacy.

Phar 5.04 RENEWAL PROHIBITED; RE-LICENSURE. 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 may renew his or her license upon completion of a renewal form and filing of the required renewal fee.

SECTION 6. Chapter Phar 6 of the Wisconsin Administrative Code is repealed and recreated to read:

Chapter Phar 6

PHARMACY PERMITS AND EQUIPMENT

Phar 6.01 PERMITS; APPLICATION. Requirements and procedures for applying for a pharmacy permit are specified in s. 450.02(9), Stats. Approved application forms are available from the board. Appointments for the required pharmacy inspection may be made by telephoning the board office. A permit application and fee shall be on file with the board at least 30 days prior to the granting of the pharmacy permit. A pharmacy may not operate unless a pharmacy permit has been granted.

Phar 6.02 PERMITS; CHANGE OF LOCATION OR OWNERSHIP. (1) A pharmacy permit authorizes a pharmacy to operate only at the location designated on the permit. Permits may not be transferred to another location.

(2) Any change in pharmacy ownership shall be reported to the board office and the pharmacy permit of the former owner returned. A pharmacy permit shall be granted to the new pharmacy owner before the pharmacy may operate.

Phar 6.03 CHANGES IN MANAGING PHARMACIST. The pharmacy owner shall report to the board any change of managing pharmacist within 5 days following the change.

[Note: Forms may be obtained upon request from the board office located at 1400 East Washington Avenue, Madison, Wisconsin 53702]

Phar 6.04 FLOOR DESIGN. (1) PROFESSIONAL SERVICE AREA. The professional service area of a pharmacy shall not be less than 250 sq. ft. No more than 20% of the space may be used for storage of bulk pharmaceuticals. If the pharmacy is open at any time solely as a non-prescription or sundry outlet, without a pharmacist present, the professional service area shall be secured as specified in sub. (3). A variance to the 250 sq. ft. professional service area requirement may be authorized by the board upon submission of a specific plan describing the manner in which the proposed professional service area plan varies from the requirement.

(2) PRESCRIPTION COUNTER SPACE. A pharmacy shall have a prescription counter with a free working surface of 18 or more inches in width and at least 12 square feet in area. This free-working surface must be used only for the compounding and dispensing of prescriptions.

(3) PROFESSIONAL SERVICE AREA REQUIREMENTS WHERE PHARMACIST IS ABSENT. (a) A pharmacy may convert to a non-prescription or sundry outlet without a pharmacist present if the following requirements of the professional service area are met:

1. A secured, physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by unlicensed personnel. The secured barrier may be constructed of other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

2. The barrier is locked in the absence of the pharmacist.

3. A patient's telephone request to renew a certain prescription may be accepted, but a telephone message from a practitioner giving a new prescription order or renewal authority may not be accepted.

4. Inside signs indicating "pharmacy", "drug store", "prescriptions", etc. and outdoor signs advertising drugs and prescriptions are not illuminated.

5. Signs of reasonable size are posted at the entrance of the building and the professional service area prominently displaying the hours the pharmacist will be on duty.

6. The manner in which the telephone is answered does not imply that the location is, at that time, operating as a pharmacy.

7. The pharmacy examining board office is notified of the hours during which the establishment is operated as a sundry outlet.

(b) The managing pharmacist is responsible for compliance with all professional service area security requirements.

Phar 6.05 SANITATION. The professional service area of a pharmacy shall have a sink convenient and suitable for cleaning pharmaceutical equipment and supplied with hot and cold running water. Detergent and a waste disposal container also shall be provided in the professional service area.

Phar 6.06 EQUIPMENT. The professional service area of a pharmacy shall have the following equipment:

(1) A prescription balance capable of weighing substances of 100 milligrams or less.

(2) One set of accurate metric weights capable of weighing substances of 50 mg. to 50 gm..

(3) A supply of transparent graduates in metric scale capable of measuring one ml. to 100 ml.

(4) A supply of Wedgewood and glass mortars and pestles.

(5) Stainless steel spatulas in assorted sizes and at least one non-metallic spatula.

(6) An assortment of acid/base and solvent-resistant funnels.

(7) A heating device.

Phar 6.07 STORAGE. (1) The professional service area shall have a refrigerator adequate for the storage of biological and other drugs requiring refrigeration.

(2) The professional service area shall have sufficient shelf, drawer or cabinet space for the proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment.

(3) Controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory of non-controlled substances in a manner that obstructs theft.

SECTION 7. Chapters Phar 7, 8, 9 and 11 of the Wisconsin Administrative Code are created to read:

Chapter Phar 7

PHARMACY PRACTICE

Phar 7.01 MINIMUM PROCEDURES FOR COMPOUNDING AND DISPENSING. (1) Except as provided in sub. (4), a pharmacist who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist shall:

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

(b) Read and interpret a prescriber's directions for use for the purpose of accurately transferring the instructions to the prescription label.

(c) Select, compound, mix, combine, measure, count and otherwise prepare drugs needed to dispense a prescription except that an agent of the pharmacist may procure, measure or count prefabricated dosage forms if a pharmacist verifies accuracy of the agent's action.

(d) Make a final check on the accuracy and correctness of the prescription. For all original and renewed prescriptions, the prescription order shall identify the pharmacist responsible for the prescription.

(e) Transfer the prescription to the patient or agent of the patient and 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.

(f) Obtain, when required by law and standard professional practice, permission to renew from authorized prescribers, and note on the reverse side of the prescription order or a medication profile record the following data:

1. Date renewed.

2. Name of practitioner authorizing renewal, if different from the original prescriber.

3. Quantity of drug dispensed.

4. Identification of the pharmacist renewing the prescription.

(2) Sub. (1)(d) and (e) does not prohibit institutional pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. Sub. (1) applies to any institutional pharmacy dispensing to outpatients, including prescriptions for discharged patients.

(3) A pharmacist may supervise no more than one pharmacy intern and one non-pharmacist engaged in compounding and dispensing activities as described in sub. (1), 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.

(4) A system for compounding and dispensing not in conformance with subs. (1) to (3) may be used if reviewed and approved by the board.

Phar 7.02 PRESCRIPTION LABEL; NAME OF DRUG OR DRUG PRODUCT DISPENSED. No prescription drug may be dispensed unless the prescription label discloses the generic or brand name of the drug or drug product dispensed. If the product dispensed is not the brand prescribed, the label may include the statement, "substituted for prescribed brand".

Phar 7.03 PRESCRIPTION RENEWAL LIMITATIONS. A prescription order for any drug other than controlled substances, which bears renewal authorization permitting the pharmacist to renew the prescription as needed by the patient, may not be renewed beyond one year from the date originally prescribed. If additional medication is needed, the original prescription order shall be voided and a new one obtained after the one-year period. No prescription order containing either specific or pro re nata renewal authorization is valid after the patient-physician relationship has ceased.

Phar 7.04 RETURN OF DRUGS PROHIBITED. No drugs, medicines, or items of personal hygiene, after taken from a pharmacy where sold, distributed or dispensed, may be returned except a health care facility may return them to the pharmacy provided they are in their original containers and the pharmacist determines the contents are unadulterated and uncontaminated.

Phar 7.05 PRESCRIPTION RECORDS. (1) A record of prescriptions dispensed shall be maintained for a period of 5 years after the date of the last renewal.

(2) A record of all prescriptions renewed shall be maintained by indicating on the original prescription order or on a readily retrievable medication profile record the date and amount of the renewal.

(3)(a) The transfer of original prescription information for the purpose of refill dispensing is permissible between two pharmacies on a one-time basis pursuant to the following requirements:

1. The transfer is communicated directly between two pharmacists and the pharmacist making the transfer records the following information:

a. The word "VOID" is written on the face of the invalidated prescription.

b. The name and address of the pharmacy to which it is transferred, the name of the pharmacist receiving the prescription, the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription.

(b) The pharmacist receiving the transferred prescription information shall record in writing the following:

1. The word "TRANSFER" on the face of the transferred prescription.

2. The date of issuance of the original prescription order.

3. The original number of refills authorized on the original prescription.

4. The date the prescription was dispensed originally.

5. The number of valid refills remaining and the date of the last refill.

6. The pharmacy's name, address, the original prescription number from which the prescription information was transferred.

7. The name of the pharmacist making the transfer.

(c) The original and transferred prescription order shall be maintained for a period of five years from the date of the last refill.

(4) A written copy of any prescription order for a prescription drug provided by a pharmacist shall be identified in writing as "COPY - FOR INFORMATION ONLY". No prescription drug may be dispensed based on an information copy.

Phar 7.06 COMPLETE PHARMACEUTICAL SERVICE. Complete pharmaceutical service, including compounded prescriptions, shall be available to the public normally served by the pharmacy.

Chapter Phar 8

REQUIREMENTS FOR CONTROLLED SUBSTANCES

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

Phar 8.02 RECORDS. (1) Any pharmacy, practitioner, or other federal drug enforcement administration registrant, as referenced in ch. 161, 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, 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, Stats. and ch. CSB 2, Wis. Adm. Code, on hand shall be made in conformance with all applicable federal and state laws.

(3) Required records shall be maintained as follows:

(a) Records of schedule II controlled substances, other than prescription orders, shall be maintained separately from all other records.

(b) Records of schedule III, IV and V controlled substances shall be maintained either separately or in such form that the information required is readily retrievable from the registrant's ordinary records.

(c) The official drug enforcement administration order forms, DEA form 222, used in the procurement and distribution of schedule II substances shall be maintained at the locations from which the drug was distributed and where it is received.

(d) Any person authorized to manufacture, distribute or dispense controlled substances shall maintain complete and accurate records with the following information:

1. The name of the substance.

2. The dosage form, strength and quantity of the substance.

3. The quantity and date of distribution as well as the name, address and DEA registration number of the person to whom distributed.

4. The number of units and date of receipt as well as the name, address and DEA registration number of the person from whom received.

5. The name and address of the person for whom dispensed, date of dispensing, quantity dispensed and name or initials of the individual who dispensed the substance.

(e) Records for dispensed schedule V substances shall be maintained as follows:

1. If a schedule V drug is dispensed pursuant to the prescription order of a practitioner, the prescription shall be labeled properly and the order filed in accordance with the requirements for schedule III and IV orders.

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, Stats., in a bound controlled substance V register at the time of the transaction.

(f) Any pharmacy, practitioner or other drug enforcement administration registrant authorized to possess controlled substances shall notify the regional office of the drug enforcement administration, the local police, and the pharmacy examining board of the theft or significant loss of any controlled substances upon discovery of such theft or loss.

[NOTE: The Drug Enforcement Administration regional office is at 1800 Dirksen Federal Building, 219 S. Dearborn, Chicago, Illinois 60604.]

(4)(a) Any registrant authorized under ch. 161, Stats., to dispense controlled substances shall establish and maintain a prescription profile record system for all schedule II controlled substances dispensed directly for outpatient use. The required profile record shall be kept either as part of the dispenser's uniformly maintained composite medication record system or as a separate profile record for schedule II controlled substances. The profile records shall be retained for 2 years and include at least the following information:

1. Identification of the patient.

2. The patient's drug allergies.

3. The date the prescription is dispensed.

4. The prescription number.

5. The name of the prescribing practitioner.

6. The name of the drug product dispensed including its dosage form and strength.

7. The daily dosage.

8. The quantity of the drug product dispensed.

(b) Computerized profile record systems and institutional outpatient records shall be deemed to comply with the requirements of this subsection if they contain the information specified in subdivisions 1. to 8.

Phar 8.03 FILING PRESCRIPTION ORDERS. (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, Stats.

(2) Schedule II prescription orders may be filed separately from all other prescription orders or they may be filed with those for schedule III, IV and V drugs provided all orders in the file 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 prescription order. Under no circumstances may schedule II prescription orders be filed together with those for non-controlled drugs.

(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 prescription order or orders for schedule III, IV and V substances may be filed separately.

Phar 8.04 PURPOSE OF ISSUE OF PRESCRIPTION. (1) A prescription order for a controlled substance to be effective shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her 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 issued not 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. 450.07(1)(f) and 161.38, Stats. The person knowingly dispensing pursuant to such a purported prescription, 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.

(2) A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing to patients by the practitioner is not valid.

Phar 8.05 DISPENSING. (1) All controlled substance prescription orders shall be dated as of, and signed on, the day issued and shall contain the full name and address of the patient, the name, address and registration number of the practitioner, the name and quantity of the drug prescribed, and the directions for use. Prescription orders shall be written with ink or indelible pencil or be typewritten and shall be signed by the practitioner. An order for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe controlled substances by the jurisdiction in which he or she is licensed to practice and registered or exempt from registration under the federal controlled substance act.

(2) A pharmacist may dispense directly 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, as defined in s. 161.16, 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.

(3) An individual practitioner may dispense directly a controlled substance listed in schedule II, III or IV provided that the prescription container is labeled and records are maintained in accordance with the requirements of this code. An individual practitioner may not delegate

to an employee or agent other than a pharmacist any of the functions involved in directly dispensing a controlled substance to a patient in the course of his or her professional practice.

(4) A prescription containing a controlled substance listed in schedule II may be dispensed only pursuant to a written order signed by the prescribing individual practitioner, except in emergency situations. No prescription containing a controlled substance listed in schedule II shall be dispensed unless the order is presented for dispensing within 7 days following the date of its issue.

(5) No pharmacy, individual practitioner or other DEA registered dispenser may dispense at any one time, and no individual practitioner may prescribe for dispensing at any one time, a controlled substance in any quantity exceeding a 34-day supply or 120 dosage units, whichever is less, except that up to a 90 day supply of any schedule III or IV anticonvulsant substance, as determined by the directed dosage and frequency of dosage, may be prescribed and dispensed at one time.

Phar 8.06 RENEWING PRESCRIPTIONS. (1) No prescription containing a schedule II substance may be renewed.

(2) No prescription containing a substance listed in schedule III or IV may be dispensed originally or renewed more than 6 months after the date on which the prescription order was issued and no such prescription authorized to be renewed may be renewed more than 5 times. Each renewal of a prescription shall be recorded on the prescription order or readily retrievable medication profile, including the date, quantity dispensed and identity of the pharmacist. Additional quantities of drugs listed in schedules III and IV may be authorized only by a prescribing practitioner through issuance of a new and separate prescription order.

(3) A prescription containing a drug listed in schedule V may be renewed only as expressly authorized by the practitioner.

Phar 8.07 PARTIAL DISPENSING. The partial dispensing of a prescription containing a controlled substance listed in schedule III, IV or V is permissible.

Phar 8.08 LABELING PRESCRIPTIONS. (1) The pharmacist dispensing a prescription containing a controlled substance shall affix to the immediate container a label showing the date of dispensing; the pharmacy name and address; serial number of the prescription; name of the patient; name of the prescribing practitioner; directions for use; and cautionary statements, contained in the prescription order or required by law.

(2) Practitioners who personally dispense any controlled substance to patients in the course of their professional practice other than by prescribing or administering shall affix to the immediate container a label showing the date of dispensing; the practitioner's name and address; the name of the patient; the directions for use; and cautionary statements contained in the prescription order or required by law.

Phar 8.09 EMERGENCY DISPENSING. (1) For the purpose of authorizing an oral prescription order for a schedule II controlled substance, the term "emergency" means those situations in which the prescribing practitioner determines that:

(a) Immediate administration of the controlled substance is necessary for proper treatment of the patient.

(b) No appropriate alternative treatment is available, including the administration of a drug which is not a schedule II controlled substance.

(c) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing.

(2) In an emergency a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a practitioner if:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

(b) The prescription order is immediately reduced to writing by the pharmacist and contains all information required in s. Phar 8.05, except for the signature of the practitioner.

(3) If the practitioner is not known to the pharmacist, he or she shall make a reasonable effort to determine that the oral authorization came from an authorized practitioner, which may include a call back to the prescribing practitioner using his or her phone number as listed in the telephone directory and other good faith efforts to insure his or her identity.

(4) Within 72 hours after authorizing an emergency oral prescription, the practitioner shall cause a written prescription 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 prescription order shall contain on its face "authorization for emergency dispensing" and the date of the oral order. The written prescription 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 period. Upon receipt, the dispensing pharmacist shall attach this prescription order to the oral emergency prescription 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 prescription order. Failure of the pharmacist to provide notification shall void the authority conferred by this section to dispense without a written prescription order of a practitioner.

CHAPTER PHAR 9

PHARMACEUTICAL SERVICES REQUIREMENTS

IN NURSING HOMES

Phar 9.01 PHARMACEUTICAL SERVICES REQUIREMENTS IN NURSING HOMES. Requirements for pharmaceutical services provided in nursing homes are specified in ch. H 32, Wis. Adm. Code (1977).

CHAPTER PHAR 11

PROCEDURE FOR HEARINGS

Phar 11.01 PROCEDURE FOR DISCIPLINARY PROCEEDINGS. Procedures for disciplinary proceedings before the board are set forth in ch. RL 2, Wis. Adm. Code.

The rules contained in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.026, Stats.

Dated this 13th day of October, 1982.

By: Paul Bjerke
Paul Bjerke, Chairman
Pharmacy Examining Board

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