

CR 89-150

CERTIFICATE

STATE OF WISCONSIN

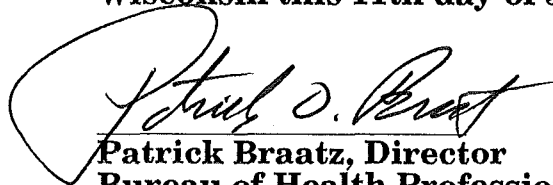
DEPARTMENT OF REGULATION AND LICENSING

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Patrick Braatz, Director, Bureau of Health Professions in the Wisconsin Department of Regulation and Licensing and custodian of the official records of the Pharmacy Examining Board, do hereby certify that the annexed rules were duly approved and adopted by the Pharmacy Examining Board on the 11th day of June, 1991.

I further certify that said copy has been compared by me with the original on file in this office 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 11th day of June, 1991.



Patrick Braatz, Director
Bureau of Health Professions
Department of Regulation and
Licensing

RECEIVED

JUN 12 1991
4:00 pm
Revisor of Statutes
Bureau

9-1-91

DRAFT OF MARCH 26, 1991

JUN 12 1991

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARDRevisor of Statutes
Bureau

IN THE MATTER OF RULE-MAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 89-150)

ORDER

An order of the Pharmacy Examining Board to repeal Phar 8.02 (4) (a) and (b) and 10.03 (1), (2), (7), (13) and (22); to renumber Phar 1.02 (2), (3), (5), (7) and (9), 3.04 (1) (a) and (3), 7.08, 8.06 (3) and 10.03 (3), (4), (5), (6), (8), (9), (10), (11), (12), (14), (15), (16), (17), (18), (19), (20) and (21); to renumber and amend Phar 1.02 (4), (6) and (8), 3.04 (2), 7.05 (5) and 8.06 (2); to amend Phar 1.01, 1.02 (intro.), 2.01 (2), 2.03 (1) and (3), 3.02 (1) (b), 3.04 (1), 4.02 (1) and (2), 4.05 (2), ch. Phar 6 (title), 6.01 (title) and 6.01, 6.02 (title) and (1) and (2), 7.01 (1) (intro.) and (d) and (f) (intro.), 7.02, 7.03, 7.04, 7.05 (1), 7.05 (3) (a) (intro.), 1.a. and b., (b) (intro.), 1., 3., 5., 6., (c) and (4), 8.01, 8.02 (3) (f), 8.03 (2) and (3), 8.04 (title), (1) and (2), 8.05 (1), (2), (3) and (5), 8.08 (1) and (2), 8.09 (3) and (4), 10.03 (intro.), and 12.02 (3); to repeal and recreate Phar 7.05 (2) and 8.07; and to create Phar 1.02 (2), (3), (4), (5) and (13), 2.03 (4) and (5), 6.04 (4), 7.05 (5), 8.05 (6), 8.06 (2), 8.10 and 8.11 of the administrative code relating to technical and remedial changes to rules, disclosure of suspicious orders of controlled substances, controlled substances in emergency kits for long term care facilities.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 15.08 (5) (b), 227.11 (2) (a), 450.02 (2), (3) and (4), 450.09, 450.11 (8) (a), Stats.

Statutes interpreted: ss. 450.02 (2) and (3), 450.07 (4) (b), 450.09 (1), (3) and (6), Stats.

This proposed order of the Pharmacy Examining Board makes minor substantive changes to the board's rules, as well as changes to clarify the language in existing rules, and changes needed to conform the rules to changes in chapter 450, Stats., made by 1985 Wisconsin Act 146.

The definitions in section Phar 1.02 of "practice of pharmacy," "pharmacist," "pharmacy," "community pharmacy," and "institutional pharmacy" are modified or created to reflect the changes in chapter 450, Stats., and current usage.

Other sections of the rules make changes in terminology for the purposes of consistency and clarification. For example, the term "refill" is replaced by the term "renewal."

Section Phar 2.01 (2) is amended to reference the requirements of the internship program approved by the pharmacy internship board to those specified in s. 450.045, Stats.

Sections Phar 2.03 (4) and (5) set forth the times when an applicant for Wisconsin original licensure may be admitted to the various examinations required.

The terms describing the examinations on federal and state laws and rules governing the practice of pharmacy are changed in the relevant sections of chapters 2, 3 and 4 of the rules from federal and state "jurisprudence" examinations to "law" examinations.

Section Phar 4.05 (2) is amended to require that applicants who fail an examination two times is not eligible for further examination until after completing additional preparation directed and approved by the board.

Sections Phar 6.01 and 6.02 change the term "permit" to "license" in order to be consistent with the statutory designation.

Phar 6.04 (4) is created to require approval of a pharmacy floor plan if any structural or physical changes are planned in the professional service area of a pharmacy.

Section Phar 7.01 (1) (intro.) is amended to clearly state that pharmacist-interns may engage in compounding and dispensing under the direction and supervision of a pharmacist.

The prescription labelling requirements in section Phar 7.02 are revised to require that the label disclose the strength of the brand name drug dispensed, or if the drug dispensed is generic, that both the strength and name of the manufacturer or distributor is listed in order to facilitate. This requirement will provide often important treatment and tracing information in the event of adverse patient reactions to drugs dispensed. The revision also repeals the provision regarding the use of the statement "substituted for prescribed brand" because of substantial confusion that the rule made such statement mandatory, rather than permissive.

Section Phar 7.05 (2) itemizes the information which must be maintained by pharmacies regarding the dispensing of prescriptions.

Section Phar 7.05 (5) is created to permit patients to renew their prescriptions at any pharmacy which has access to a shared computer system containing the original prescription information. Pharmacies with such shared systems must obtain approval from the board and, if the prescription involves controlled substances, the Drug Enforcement Administration.

The last sentence of section Phar 8.05 (3) which prohibited individual practitioners, such as physicians, from delegating to their health care employees or agents the dispensing of controlled substances is deleted, as it is in conflict with s. 450.11 (3), Stats.

Section 8.05 (5), which concerns the maximum amount of controlled substances which may be dispensed at one time, is amended to delete the reference to "dosage units." The term was subject to differing interpretations, and its deletion now provides a clear limit upon such dispensing.

The amendments to section Phar 8.06 (3) deletes redundant provisions of the rule which are now better specifically expressed and contained in ss. Phar 7.05 (2) and Phar 8.06 (2).

Section Phar 8.07 (1) is a restatement of the current provision which permits the partial dispensing of prescriptions for schedule III, IV and V controlled substances.

Section Phar 8.07 (2) permits the pharmacist to partially dispense a schedule II controlled substance in the event the full quantity prescribed is unavailable at the time of dispensing. That portion of the prescription not filled originally must be filled within 72 hours. If it cannot be, the pharmacist must contact the physician.

Section Phar 8.07 (3) to (5) set forth the specific dispensing and recordkeeping requirements which must be met when partially dispensing schedule II controlled substances to patients in long term care facilities or who are receiving long term parenteral pain therapy.

The specific labelling requirements for dispensing physicians in s. Phar 8.08 (2) are deleted due to the creation of such standards by the Medical Examining Board in ch. Med 17.

Section Phar 8.10 requires that manufacturers and distributors notify the board and the Drug Enforcement Administration of orders for controlled substances which are of unusual size, deviate substantially from a normal pattern, or are of unusual frequency.

Section Phar 8.11 sets forth the requirements for maintaining emergency supplies of controlled substances in long term care facilities. Such supplies are necessary in order to provide for emergency situations arising when a pharmacist is unavailable to dispense such drugs.

TEXT OF RULE

SECTION 1. Phar 1.01 and 1.02 (intro.) are amended to read:

Phar 1.01 AUTHORITY. Rules in chs. Phar 1 to ~~11~~ 14 are adopted under authority of ss. 15.08 (5), 161.31, ~~227.014~~ 227.11, Stats., and ch. 450, Stats.

Phar 1.02 DEFINITIONS. (intro.) As used in chs. Phar 1 to ~~11~~ 14:

SECTION 2. Phar 1.02 (2) and (3) are renumbered (6) and (7).

SECTION 3. Phar 1.02 (4) is renumbered (8) and amended to read:

Phar 1.02 (8) "Pharmacist" means a person licensed by the board under ch. 450, Stats., ~~and chs. Phar 1 to 11.~~

SECTION 4. Phar 1.02 (5) is renumbered (9).

SECTION 5. Phar 1.02 (6) is renumbered (10) and amended to read:

Phar 1.02 (10) "Pharmacy" means any place ~~in which prescription drugs, as defined in s. 450.07 (1) (a), Stats., are compounded or dispensed~~ of practice licensed by the board under s. 450.06, Stats.

SECTION 6. Phar 1.02 (7) is renumbered (11).

SECTION 7. Phar 1.02 (8) is renumbered (12) and amended to read:

Phar 1.02 (12) "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~~ has the meaning under s. 450.01 (16), Stats.

SECTION 8. Phar 1.02 (9) is renumbered (14).

SECTION 9. Phar 1.02 (2), (3), (4), (5) and (13) are created to read:

Phar 1.02 (2) "Community pharmacy" means practice in a licensed pharmacy providing pharmaceutical services primarily on an outpatient basis.

(3) "DEA" means the drug enforcement administration.

(4) "Institutional pharmacy" means practice in a licensed pharmacy providing pharmaceutical services primarily on an inpatient basis.

(5) "LTCF" means a long term care facility.

(13) "PRN" means renew as needed.

SECTION 10. Phar 2.01 (2) is amended to read:

Phar 2.01 (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~~ under s. 450.045, Stats.

SECTION 11. Phar 2.03 (1) and (3) are amended to read:

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

(3) An applicant may request to take the NABPLEX ~~examination~~ and federal law examinations 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~~ examinations and authorizes the transfer of those grades to the board.

SECTION 12. Phar 2.03 (4) and (5) are created to read:

Phar 2.03 (4) An applicant for licensure as a pharmacist may not be admitted to the NABPLEX or the federal law examination before that uniform 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 13. Phar 3.02 (1) (b) is amended to read:

Phar 3.02 (1) (b) The fee specified under s. ~~440.05-(1)~~ 440.05 (2), Stats.

SECTION 14. Phar 3.04 (1) is amended to read:

Phar 3.04 (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~~ state law 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.

SECTION 15. Phar 3.04 (1) (a) is renumbered (2).

SECTION 16. Phar 3.04 (2) is renumbered (3) and (3) (c) is amended to read:

Phar 3.04 (3) (c) ~~Jurisprudence,--related-to-state-and-federal-requirements~~ State law examination.

SECTION 17. Phar 3.04 (3) is renumbered (4).

SECTION 18. Phar 4.02 (1) and (2) are amended to read:

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

(2) The state ~~jurisprudence~~ law examination shall determine an applicant's competence to practice within Wisconsin laws and rules governing the practice of pharmacy.

SECTION 19. Phar 4.05 (2) is amended to read:

Phar 4.05 (2) An applicant who fails to achieve a passing score on any examination specified in s. Phar 4.02 is eligible for reexamination ~~at any subsequent examination scheduled by the board.~~ An applicant who twice fails any licensing examination specified in s. Phar 4.02 is not eligible for further examination until the applicant has satisfactorily completed additional preparation as directed and approved by the board. This condition on eligibility also applies to each third and subsequent failure.

SECTION 20. Chapter Phar 6 (title) is amended to read:

CHAPTER PHAR 6 (title)

PHARMACY ~~PERMITS~~ LICENSES AND EQUIPMENT

SECTION 21. Phar 6.01 (title), 6.01, 6.02 (title) and 6.02 (1) and (2) are amended to read:

Phar 6.01 (title) LICENSES; APPLICATION. Requirements and procedures for applying for a pharmacy ~~permit~~ 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 ~~telephoning~~ contacting the board office. A ~~permit~~ license application and fee shall be on file with the board at least 30 days prior to the granting of the pharmacy ~~permit~~ license. A pharmacy may not operate unless a pharmacy ~~permit~~ license has been granted. Board action shall be taken within 90 days of receipt of a completed pharmacy application.

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

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

SECTION 22. Phar 6.04 (4) is created to read:

Phar 6.04 (4) PROFESSIONAL SERVICE AREA REMODELING. Any modifications of the approved floor plan shall be submitted to and approved by the board or its designee. Board action must be taken within 60 days.

SECTION 23. Phar 7.01 (1) (intro.), (d) and (f) (intro.), 7.02, 7.03, 7.04 and 7.05 (1) are amended to read:

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

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

(f) (intro.) 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 or uniformly maintained and readily retrievable document the following data information:

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 and strength, or the generic name, strength, and manufacturer or distributor of the drug or drug product dispensed unless the prescribing practitioner requests omission of the above information. ~~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 (PRN) by the patient, ~~may~~ shall 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 ~~pre-re-nata~~ PRN renewal authorization is valid after the patient-physician relationship has ceased.

Phar 7.04 RETURN OR EXCHANGE 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~~ not adulterated or misbranded.

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

SECTION 24. Phar 7.05 (2) is repealed and recreated to read:

Phar 7.05 (2) All systems used for maintaining a record of any prescription dispensing shall include:

- (a) Patient's identification.
- (b) Name, strength and dosage form of the drug product dispensed.
- (c) Quantity dispensed.
- (d) Date of all instances of dispensing.
- (e) Practitioner's identification.
- (f) Pharmacist's identification.

(g) Retrieval designation.

SECTION 25. Phar 7.05 (3) (a) (intro.), 1.a. and b., (b) (intro.), 1., 3., 5., 6., (c) and (4) are amended to read:

Phar 7.05 (3) (a) (intro.) ~~The~~ Except as provided in sub. (5), the transfer of original prescription order information for the purpose of ~~refill~~ renewal dispensing is permissible between two pharmacies on a one-time basis pursuant to the following requirements:

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

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

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

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

3. The original number of ~~refills~~ renewals authorized on the original prescription order.

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

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

(c) The original and transferred prescription order shall be maintained for a period of 5 years from the date of the last ~~refill~~ renewal.

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

SECTION 26. Phar 7.05 (5) is renumbered (6) and (6) (intro.) is amended to read:

Phar 7.05 (6) (intro.) A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of original prescription order information for the purposes of renewal dispensing, ~~as required under this section,~~ if the system:

SECTION 27. Phar 7.05 (5) is created to read:

Phar 7.05 (5) Pharmacies having access to a common central processing unit are not limited in the transfer of original prescription order information for the purpose of renewal dispensing if prior written approval is received from the board.

Note: This procedure requires a variance from the federal drug enforcement administration (DEA) for controlled substances. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, D.C. 20537.

SECTION 28. Phar 7.08 is renumbered 7.07.

SECTION 29. Phar 8.01 and 8.02 (3) (f) are amended to read:

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 and chs. Phar 12 and 13.

Phar 8.02 (3) (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.

SECTION 30. Phar 8.02 (4) (a) and (b) are repealed.

SECTION 31. Phar 8.03 (2) and (3), 8.04 (title), (1) and (2), 8.05 (1), (2), (3) and (5) are amended to read:

Phar 8.03 (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 (title) PURPOSE OF ISSUE OF PRESCRIPTION ORDER. (1) A ~~prescription~~ Prescription order ~~orders~~ for a controlled ~~substance~~ substances ~~to-be-effective~~ shall be issued for a legitimate medical purpose by an individual ~~practitioner~~ practitioners acting in the usual course of ~~his-er-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 order not 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)~~ 450.01 (21) and 161.38, Stats. The person knowingly dispensing pursuant to such a purported ~~prescription 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.

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

Phar 8.05 (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~~ Orders for a controlled ~~substance~~ substances may be issued only by ~~an individual practitioner~~ practitioners who ~~is~~ are 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~~ substances 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~~ specified 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 employe 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.~~

(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.

SECTION 32. Phar 8.05 (6) is created to read:

Phar 8.05 (6) Prescription orders for all controlled substances shall specify dose and frequency of usage per day.

SECTION 33. Phar 8.06 (2) is renumbered (3) and amended to read:

Phar 8.06 (3) No prescription containing a controlled 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.~~

SECTION 34. Phar 8.06 (3) is renumbered (4).

SECTION 35. Phar 8.06 (2) is created to read:

Phar 8.06 (2) The prescribing practitioner may authorize renewals of schedule III or IV controlled substances on the original prescription order or through a verbal renewal authorization transmitted to the pharmacist. The following conditions must be met:

(a) The pharmacist obtaining the verbal authorization shall note on the prescription order, medication profile record or readily retrievable and uniformly maintained document the following information:

1. Date authorization is received.
2. Quantity of drug authorized.
3. Number of renewals.
4. Identification of practitioner authorizing the renewals if different from the original prescriber.
5. Identification of the pharmacist who received the authorization.

(b) The quantity of each renewal authorized is equal to or less than the quantity authorized for the initial dispensing of the original prescription.

SECTION 36. Phar 8.07 is repealed and recreated to read:

Phar 8.07 PARTIAL DISPENSING. (1) A pharmacist may partially dispense a prescription containing a controlled substance listed in schedule III, IV and V.

(2) The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency verbal prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written prescription order or written record of the emergency verbal prescription order. The remaining portion of the prescription may be dispensed within 72 hours of the first partial dispensing. If the remaining portion is not dispensed within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.

(3) Prescription orders for schedule II controlled substances written for patients in long term care facilities (LTCF) may be dispensed in partial quantities. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription order or on another appropriate

record, uniformly maintained and readily retrievable, the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. The total quantity of a schedule II controlled substance dispensed by partial dispensing may not exceed the total quantity prescribed. Schedule II prescription orders for patients in an LTCF shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(4) Information pertaining to current schedule II prescription orders for patients in an LTCF may be maintained in a computerized system if the system has the capability to permit:

(a) Display or printout of: the original prescription order designation; date of issue; identification of prescribing individual practitioner; identification of patient; identification of LTCF; identification of medication authorized, including dosage form, strength and quantity; listing of partial quantities that have been dispensed under each prescription order and the information required in sub. (4) (b).

(b) Immediate (real time) updating of the prescription order record each time there is partial dispensing of the prescription.

(c) Retrieval of partially dispensed schedule II prescription information identical to that required by s. Phar 7.05 (2) for all prescription renewal information.

(5) Prescription orders for schedule II controlled substances written for patients who are receiving long term parenteral pain therapy may be dispensed in partial quantities. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription order, or on another approved record uniformly maintained and readily retrievable, the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. The total quantity of schedule II controlled substances dispensed in all partial dispensing shall not exceed the total quantity prescribed and each partial dispensing shall not exceed a 14 day supply. Further dispensing of such substances shall be authorized by issuance of a new prescription order.

SECTION 37. Phar 8.08 (1) and (2) are amended to read:

Phar 8.08 (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; full 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~~ conform to ch. Med 17, standards for dispensing drugs.

SECTION 38. Phar 8.09 (3) and (4) are amended to read:

Phar 8.09 (3) If the practitioner is not known to the pharmacist, ~~he-or~~ she the pharmacist 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~~ the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure ~~his-or-her~~ the practitioner's identity.

(4) Within 72 hours after authorizing an emergency oral prescription order, 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.

SECTION 39. Phar 8.10 and 8.11 are created to read:

Phar 8.10 DISCLOSURE OF SUSPICIOUS ORDERS OF CONTROLLED SUBSTANCES. Manufacturers and distributors of controlled substances shall disclose suspicious orders of controlled substances. Suspicious orders include, without limitation because of enumeration, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. The licensee shall notify the regional office of the DEA and the board of all suspicious orders.

Phar 8.11 CONTROLLED SUBSTANCES IN EMERGENCY KITS FOR LONG TERM CARE FACILITIES. Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances:

(1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.

(2) The pharmaceutical services committee of the facility shall establish security safeguards for each emergency kit stored in the LTCF which shall include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

(3) A pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.

(4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.

(5) Noncompliance with this rule may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.

SECTION 40. Phar 10.03 (intro.) is amended to read:

Phar 10.03 UNPROFESSIONAL CONDUCT. (intro.) The following, without limitation because of enumeration, are violations of standards of professional conduct and constitute unprofessional conduct ~~under s. 450.02-(7)-(b)~~ in addition to those grounds specified under s. 450.10 (1), Stats.:

SECTION 41. Phar 10.03 (1), (2), (7), (13) and (22) are repealed.

SECTION 42. Phar 10.03 (3), (4), (5), (6), (8), (9), (10), (11), (12), (14), (15), (16), (17), (18), (19), (20), and (21) are renumbered (1) to (17).

SECTION 43. Phar 12.02 (3) is amended to read:

Phar 12.02 (3) "Establishment" means a place of business under one management at one general physical location.

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 June 11, 1991

Agency Don Reynolds RPh
Chairperson
Pharmacy Examining Board

RULES-195
3/26/91

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JUN 12 1991
Revisor of Statutes
Bureau

CORRESPONDENCE/MEMORANDUM

STATE OF WISCONSIN

DATE: June 12, 1991

TO: Gary Poulson
Assistant Revisor of Statutes

FROM: Pamela Haack, Administrative Assistant
Department of Regulation and Licensing

SUBJECT: Final Rulemaking Order

RECEIVED

JUN 12 1991
Revisor of Statutes
Bureau

Agency: PHARMACY EXAMINING BOARD

Clearinghouse Rule: 89-150

Attached is a copy and a certified copy of a final order adopting rules.

Would you please publish these rules in the code.

Thank you.