CERTIFICATE

STATE OF WISCONSIN DEPARTMENT OF REGULATION AND LICENSING

TO ALL WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Patrick D. 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 12th day of December, 1995.

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.

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REVISOR OF STATUTES

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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 12th day of December, 1995.

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

STATE OF WISCONSIN PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD ORDER OF THE PHARMACY EXAMINING BO

ADOPTING RULES (CLEARINGHOUSE RULE 95-022)

ORDER

An order of the Pharmacy Examining Board to repeal Phar 6.04 (3) (a) 4 and 7.06; to amend Phar 2.01 (1), 3.01 (1), 3.04 (1), 4.02 (4), 7.01 (1) (e) and 7.02; and to create Phar 8.05 (7) relating to licensure of graduates of a foreign pharmacy school or college; patient consultation portion of the laboratory practical examination; display of pharmacists' licenses in a pharmacy; illumination of pharmacy signs; patient consultation; drug names on prescription labels; providing pharmaceutical services; and missing information on prescription orders for controlled substances.

Analysis prepared by the Department of Regulation and Licensing.

<u>ANALYSIS</u>

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

Statutes interpreted: ss. 450.04 (1) and (3) (a), 450.05, 450.09 (5) and 450.11 (1) and (4), Stats.

This proposed rule-making order of the Pharmacy Examining Board makes changes to its administrative rules to clarify and modify provisions relating to pharmacy practice and licensure.

SECTIONS 1 and 2 address the professional pharmacy education necessary for an individual to qualify to take the required examinations leading to licensure as a pharmacist in this state. Section 1 pertains to the rule relating to persons seeking an original pharmacist license in Wisconsin, and Section 2 pertains to persons seeking licensure through reciprocity of a license held in another state.

The current rules require that applicants for a pharmacist license must have graduated from a school or college of pharmacy approved by the board. The board does not have the capability of independently evaluating the individual educational programs of foreign pharmacy schools. Accordingly, in the past a graduate of a pharmacy school located other than in the United States has been referred to an approved school of pharmacy for an evaluation of the course work taken and completed at the foreign institution. The purpose of the evaluation was to determine whether additional education was necessary in order for the candidate to obtain the substantial equivalent

of the professional education provided within domestic schools of pharmacy. This evaluation, however, is difficult and burdensome upon the schools and is unnecessary given the existence of the Foreign Pharmacy Graduate Equivalency Examination which performs the same function. Accordingly, the proposed rules would accept successful completion of the Foreign Pharmacy Graduate Equivalency Examination as establishing that a candidate has received a satisfactory pharmacy education within a foreign school of pharmacy.

SECTION 3 relates to the examination which is required under s. Phar 3.04 for a pharmacist holding a license in another state to become licensed in Wisconsin through reciprocity. The current rule requires that an applicant successfully complete a written examination upon the laws pertaining to the practice of pharmacy in this state. The proposed amendment would require that an applicant for a license by reciprocity also successfully complete the patient consultation portion of the examination required for candidates for an original license. Direct consultation with patients on such matters as medication usage, drug interactions and adverse reactions has become an increasingly important part of the practice of pharmacy. Consultation is an important mechanism for assuring that patients are provided with essential information regarding the medications they are taking to help reduce inadvertent misuse or inappropriate drug utilization. Accordingly, the board believes that all candidates for a license to practice pharmacy in this state should be required to demonstrate an ability to adequately counsel patients regarding medications.

SECTION 4 amends the description of the required laboratory practical examination in s. Phar 4.02 (4), to specifically refer to the patient consultation segment as comprising a part of that examination.

SECTION 5 modifies the current requirement in s. Phar 5.03 relating to the display of a pharmacist's license in a pharmacy. The current rule dictates that the cards which are received by a pharmacist as indicia of the biennial renewal of their license must be placed "in the lower right hand corner" of the wall license previously received. The board believes that it is not necessary to require that the renewal card be placed in a precise location respecting the license, and that such a requirement appears over-regulatory in nature. Accordingly, the rule is modified to specify that the biennial renewal card be displayed "with the license."

The proposed rule also addresses the location at which a pharmacist is required to display his or her license in situations where the pharmacist is employed at more than one pharmacy. The current rule, read literally, could be viewed as necessitating the pharmacist either to obtain additional copies of his or her license and biennial renewal card for posting at different pharmacies or to physically transport his or her license for display while working at each location. The board believes that the rule should be amended to require that the license need only be displayed in the pharmacy at which the pharmacist works most of the time.

SECTION 6 repeals s. Phar 6.04 (3) (a) 4, prohibiting any indoor or outside signs indicating "pharmacy," "drug store," or otherwise advertising drugs and prescriptions from being illuminated when the pharmacy is not open. The board does not believe the current restriction serves any valid public protection purpose. In fact, under some circumstances the lack of

illumination of pharmacy premises during non-operating hours may serve to render the pharmacy a more vulnerable target for theft or burglary. Accordingly, the proposal would repeal the "illuminated sign" provision.

SECTION 7 pertains to the patient consultation requirement in s. Phar 7.01 (1) (e). The rule is modified to make it clear that the duty to provide consultation to patients regarding medications applies both at the time of initial dispensing under a new prescription order, as well as at the time of each renewal. Furthermore, the rule is clarified to indicate that merely inquiring whether a patient desires consultation does not meet the intent of the requirement; but rather, that the pharmacist is required to at least attempt to provide or solicit relevant patient information upon each occasion of dispensing medication.

SECTION 8 relates to the name of the drug which is placed on the label of the medication container upon dispensing pursuant to s. Phar 7.02. Section 452.13, Stats., authorizes pharmacists to dispense a drug product other than that named upon a prescription order in limited situations. Prior language in s. Phar 7.02 had permitted pharmacists to place a phrase on the label of the medication container which stated both the name of the drug actually dispensed, as well as that originally prescribed (e.g., "X substituted for Y"). However, the listing of two different drugs upon the label often confused patients as to which medication had been dispensed. Accordingly, the language in s. Phar 7.02 permitting the label to refer to a drug not actually dispensed was repealed, with the intent of prohibiting the practice. However, the result was that the rule is technically silent on the question. The board, accordingly, proposes additional language to s. Phar 7.02 to specifically indicate that a pharmacist may not place the name of any drug upon a medication container label which has not actually been dispensed.

SECTION 9 repeals s. Phar 7.06 which requires that all pharmacies have the capability of compounding prescriptions. Many pharmacies do not serve patients which require the utilization of compounding services. Accordingly, the requirement places an unnecessary requirement and burden upon those pharmacies.

SECTION 10 creates s. Phar 8.05 (7) to address situations in which a pharmacist receives a written prescription order for a controlled substances which fails to contain all of the necessary information required under s. Phar 8.05 (1). The board believes that an inadvertent failure by a prescriber to provide all of the information on the written prescription order should not automatically prevent the prescription order from being honored by the pharmacist, especially in circumstances where the missing information is otherwise available to the pharmacist from records maintained in the pharmacy. For example, a prescription order missing the patient's home address should not be rejected, thereby resulting in unnecessary inconvenience to the patient in obtaining another prescription order, where the pharmacist is able to verify the actual address of the patient from his or her own pharmacy records. The proposed rule details the missing items which may be supplied by a pharmacist, as well as the circumstances under which they may be supplied.

3

TEXT OF RULE

SECTION 1. Phar 2.01 (1) is amended to read:

Phar 2.01 (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 or has taken and passed the foreign pharmacy graduate equivalency examination given by the foreign pharmacy graduate examination commission.

SECTION 2. Phar 3.01 (1) is amended to read:

Phar 3.01 (1) Has been graduated from a school or college of pharmacy approved by the board, or has taken and passed the foreign pharmacy graduate equivalency examination given by the foreign pharmacy graduate examination commission.

SECTION 3. 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 state law examination described in s. Phar 4.02 (2), 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.

SECTION 4. Phar 4.02 (4) is amended to read:

Phar 4.02 (4) The laboratory practical examination shall determine an applicant's competence in compounding and dispensing medications, which includes consultation of patients.

SECTION 5. Phar 5.03 is amended to read:

Phar 5.03 <u>DISPLAY OF LICENSES</u>. 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 displayed with the license when received. Only current renewal cards may be posted displayed. 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. A pharmacist who engages in the practice of pharmacy at more than one pharmacy shall display his or her license and renewal card in the pharmacy at which he or she practices most.

SECTION 6. Phar 6.04 (3) (a) 4 is repealed.

SECTION 7. Phar 7.01 (1) (e) is amended to read:

Phar 7.01 (1) (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. 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 8. Phar 7.02 is amended to read:

Phar 7.02 PRESCRIPTION LABEL; NAME OF DRUG OR DRUG PRODUCT DISPENSED. No prescription drug may be dispensed unless the prescription label discloses the 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. The prescription label shall not contain the brand or generic name of any drug or drug product other than that actually dispensed.

SECTION 9. Phar 7.06 is repealed.

SECTION 10. Phar 8.05 (7) is created to read:

Phar 8.05 (7) Except as provided in this subsection, a prescription order for a controlled substance may not be dispensed unless the prescription order contains all of the information required in sub. (1). A pharmacist may supply any information missing from a prescription order for a schedule III, IV or V controlled substance that is verifiable and retrievable from information maintained by the pharmacist or that is obtained through consultation with a practitioner, with the exception of the practitioner's signature. A pharmacist may supply the address of the patient and the registration number of the practitioner missing from a prescription order for a schedule II controlled substance if that information is verifiable and retrievable from information maintained by the pharmacist or is obtained through consultation with the practitioner.

(END OF TEXT OF RULE)

The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register pursuant to s. 227.22 (2) (intro.), Stats.

Dated <u>December</u> 12, 1995

Chairperson

Pharmacy Examining Board