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 14th day of September, 1999.

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 14th day of September, 1999.

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

98-090

Filed 9/15/99 3:45pm

11-1-99

STATE OF WISCONSIN PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING

ORDER OF THE

PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD

PHARMACY EXAMINING BOARD

ADOPTING RULES

(CLEARINGHOUSE RULE 98-090)

ORDER

An order of the Pharmacy Examining Board to *amend* Phar 7.01 (1) (a), 8.06 (2) (intro.) and (a) (intro.), 8.07 (2), 8.09 (1) (intro.), (2) (intro.), (3) and (4); and to *create* Phar 7.08, relating to the transmission and receipt of electronic prescription orders.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 15.08 (5) (b), 227.11 (2) and 450.02 (3) (a), (b), (d) and (e), Stats., and s. 961.38 (2), as amended by 1997 Wisconsin Act 27.

Statutes interpreted: ss. 450.01 (21), 450.11 (1m) and (5) and 961.38 (2), Stats.

This order of the Pharmacy Examining Board is in response to 1997 Wisconsin Act 27 (the "Act") which amended several sections of Chapter 450, Stats., to specifically authorize the electronic transmission of prescription orders from prescribers to pharmacies. Prior to the new law, the statutes alluded specifically only to oral or written prescription orders. The objective of the proposed rules is to assure the appropriate use of electronic transmission systems in conveying prescription orders, and to provide guidance to the profession in adopting procedures and systems assuring the validity, accuracy and security of prescription orders received electronically from prescribers.

SECTION 1 amends s. Phar 7.01 (1) (a), to provide that pharmacists are required to review all electronically transmitted prescription orders for therapeutic compatibility and legality, as is currently required for oral and written prescription orders they receive.

SECTION 2 creates s. Phar 7.08, setting forth the requirements that must be met to authorize a pharmacist to dispense pursuant to an electronically transmitted prescription order. Among these are requirements that the electronic prescription orders must be sent only at the option of the patient and to the pharmacy chosen by the patient; they must contain identifying information regarding the sender and contain language to the effect that the prescription order is being "Electronically Transmitted"; contain all the information required for a valid prescription order under law (e.g., patient name, prescriber name, medication name, directions for use, etc.); and contain either the prescriber's electronic signature or other secure method of validating the order as coming from a prescriber. Additionally, pharmacists are required to adopt measures assuring

the security, integrity and confidentiality of the information received by electronic transmission of prescription orders.

SECTIONS 3, 4 and 5 make technical amendments to existing rules consistent with the intent of the Act, by specifically authorizing the renewal of schedule III and IV controlled substance orders by electronic transmission and permitting the emergency and partial dispensing of schedule II controlled substances pursuant to electronically transmitted prescription orders.

TEXT OF RULE

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

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

SECTION 2. Phar 7.08 is created to read:

Phar 7.08 Prescription orders transmitted electronically. (1) Except as provided in s. 453.068 (1) (c) 4., Stats., and as otherwise prohibited by law, prescription orders may be accepted and dispensed if they have been transmitted electronically from a practitioner or his or her designated agent to a pharmacy via computer modem or other similar electronic device. Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

Note: Prescription orders for schedule II controlled substances may not be transmitted electronically except as emergency orders, subject to the same requirements for oral emergency orders for schedule II controlled substances. See s. 961.38 (1r) and (2), Stats., and s. Phar 8.09.

- (2) A pharmacist may dispense a prescription pursuant to a prescription order transmitted electronically, if the pharmacist assures the prescription order does all of the following:
- (a) Was sent only to the pharmacy of the patient's choice and only at the option of the patient, with no intervening person or third party having access to the prescription order other than to forward it to the pharmacy.
- (b) Identifies the individual sender's name and telephone number for oral confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission.
- (c) Is designated "electronically transmitted prescription", or with similar words or abbreviations to that effect.

- (d) Contains all other information that is required in a prescription order.
- (3) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided with a prescription order electronically transmitted via computer modem or other similar electronic device.
- (4) Any visual or electronic document received in connection with an electronically transmitted prescription order shall be accessible only within the professional service area of the pharmacy to protect patient confidentiality and assure security.
- (5) A pharmacist who receives a prescription order electronically shall ensure the security, integrity and confidentiality of the prescription order and any information contained in the order. To maintain the confidentiality of patient records, the electronic system shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the prescription has been dispensed, any alterations in prescription order drug data shall be documented including the identification of the pharmacist responsible for the alteration.
- (6) Access to the electronic mail system for the receipt of prescription orders electronically may only be acquired by use of a password or passwords, known only to individuals authorized to access the system.
- (7) A pharmacist may not use any electronic device to circumvent his or her responsibilities with regard to documenting, authenticating and verifying prescription orders or in order to circumvent other pharmacy laws.
 - SECTION 3. Phar 8.06 (2) (intro.) and (2) (a) (intro.) are amended to read:
- Phar 8.06 (2) (intro.) The prescribing practitioner may authorize renewals of schedule III or IV controlled substances on the original prescription order or through a verbal an electronic or oral renewal authorization transmitted to the pharmacist. The following conditions must be met:
- (a) (intro.) The pharmacist obtaining the <u>verbal</u> <u>electronic or oral</u> authorization shall note on the prescription order, medication profile record or readily retrievable and uniformly maintained document the following information:
 - SECTION 4. Phar 8.07 (2) is amended to read:
- Phar 8.07 (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 electronic or oral 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 electronic or oral 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.

SECTION 5. Phar 8.09 (1) (intro.), (2) (intro.), (3) and (4) are amended to read:

Phar 8.09 (1) (intro.) For the purpose of authorizing an <u>electronic or</u> oral prescription order for a schedule II controlled substance, the term "emergency" means those situations in which the prescribing practitioner determines that:

- (2) (intro.) In an emergency a pharmacist may dispense a controlled substance listed in schedule II upon receiving electronic or oral authorization of a practitioner if:
- (3) If the practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the <u>electronic or</u> oral authorization came from an authorized practitioner, which may include a call back to the prescribing practitioner using the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure the practitioner's identity.
- (4) Within 72 hours 7 days after authorizing an emergency electronic or oral prescription order, the practitioner shall cause a written order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of s. Phar 8.05, the order shall contain on its face "authorization for emergency dispensing" and the date of the electronic or oral order. The written order may be delivered to the pharmacist in person or by mail, but if delivered by mail it shall be postmarked within the 72 hour 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription order to the electronic or oral emergency order reduced to writing under sub. (2) (b). The pharmacist shall notify the board or department of regulation and licensing if the practitioner fails to deliver the written order. Failure of the pharmacist to provide notification shall void the authority conferred by this section to dispense without a written order of a practitioner.

(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 9/14/99

Agency

Chairperson

Pharmacy Examining Board



State of Wisconsin DEPARTMENT OF REGULATION AND LICENSING

CORRESPONDENCE/MEMORANDUM

DATE:

September 15, 1999

TO:

Gary Poulson

Assistant Revisor of Statutes

FROM:

Pamela A. Haack, Paralegal

Department of Regulation and Licensing

Office of Administrative Rules

SUBJECT:

Final Order Adopting Rules

Agency: PHARMACY EXAMINING BOARD Clearinghouse Rule 98-090

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

Please stamp or sign a copy of this letter to acknowledge receipt.

Thank you.

