

WISCONSIN LEGISLATIVE COUNCIL STAFF



RULES CLEARINGHOUSE

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CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE 98-090

AN ORDER to amend Phar 7.01 (1) (a), 8.06 (2) (intro.) and (a) (intro.), 8.07 (2) and 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.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

06-26-98 RECEIVED BY LEGISLATIVE COUNCIL.

07-24-98 REPORT SENT TO AGENCY.

RNS:DD:kjf;jt

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]

Comment Attached YES NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached YES NO

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CLEARINGHOUSE RULE 98-090

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated October 1994.]

2. Form, Style and Placement in Administrative Code

- a. The department's analysis should add s. 961.38 (2), Stats., to both the list of statutes authorizing promulgation and the list of statutes interpreted.
- b. The analysis fails to note and discuss the amendment of s. Phar 8.09 (4), which revises the current 72-hour period to a seven-day period.
- c. In s. Phar 7.08 (3), "a" should replace the second "the."
- d. In s. Phar 7.08 (4), it is suggested that "in connection with an electronically transmitted prescription order" follow "received" and that "only" be relocated to follow "accessible."
- e. In s. Phar 7.08 (5), first sentence, "a" should replace the first two occurrences of "any." In addition, "therein" should be replaced by "in the order."
- f. It is suggested that the Note following s. Phar 7.08 (7) be relocated to follow sub. (1).

4. Adequacy of References to Related Statutes, Rules and Forms

- a. If possible, the phrase "(e)xcept as otherwise prohibited by law" in s. Phar 7.08 (1) should be replaced by specific cross-references to pertinent statutes and rules.

b. The reference to "under law" in s. Phar 7.08 (2) (d) should be replaced by specific cross-references to pertinent statutes or rules.

c. Can the references in s. Phar 7.08 (7) to a pharmacist's "responsibilities" and to "other pharmacy laws" be made more specific?

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

a. In s. Phar 7.01 (1) (a), the comma that follows the second "oral" in the current text of the rule is not included.

b. Section Phar 7.08 (2) (a) requires that a pharmacist "assures" that an electronically transmitted prescription order 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. Is it possible for a pharmacist to assure that no intervening person or third party had access to the prescription? Can more guidance be given, either in the rule or in a note, as to how this requirement can be accomplished? See, also, comment d. below.

c. Consideration should be given to including in a note following s. Phar 7.08 (2) (c) examples of "similar words or abbreviations."

d. Section Phar 7.08 (5) requires the system for transmitting prescriptions electronically to "have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records." Does the requirement apply to both ends of the system? Can more guidance be given as to what constitutes "adequate" security and system safeguards? For example, do adequate safeguards require:

- (1) That, during a message's transit from sender to receiver, not only can no observer obtain access to the content of the data, but no observer can identify the sender and receiver?
- (2) That data cannot be lost or changed during transmission?
- (3) That the sender can be sure that the message reaches only the intended recipient?
- (4) That the recipient can be sure that the message came from the sender and not an imposter?

e. Section Phar 7.08 (6) appears only to apply to access to the system at the receiving end. Is that intended?

JUL 08 REC'D

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 98-090)

TO: Senator Judy Robson, Senate Co-Chairperson
Joint Committee for the Review of Administrative Rules
Room 15 South, State Capitol
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the PHARMACY EXAMINING BOARD is submitting in final draft form proposed rules relating to the transmission and receipt of electronic prescription orders.

Please stamp or sign a copy of this letter to acknowledge receipt. If you have any questions concerning the final draft form or desire additional information, please contact Pamela Haack at 266-0495.

**STATE OF WISCONSIN
PHARMACY EXAMINING BOARD**

IN THE MATTER OF RULE-MAKING :	REPORT TO THE LEGISLATURE
PROCEEDINGS BEFORE THE :	ON CLEARINGHOUSE 98-090
PHARMACY EXAMINING BOARD :	(s. 227.19 (3), Stats.)

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS:

No new or revised forms are required by these rules.

III. FISCAL ESTIMATES:

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

IV. STATEMENT EXPLAINING NEED:

This proposed 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.

V. PUBLIC HEARING ATTENDEES AND WRITTEN COMMENTS:

A public hearing was held on August 12, 1998.

A list of attendees:

- 1) Karen Mesca-Beaty, Madison, WI, representing the University of Wisconsin Hospital and Clinic, Department of Pharmacy.
- 2) Steve Maike, Franklin, WI, representing the Blue Cross Blue Shield of Wisconsin, CompCare Health Services.
- 3) Michael Boushon, Beaver Dam, WI
- 4) Lynnae Mahaney, Middleton, WI.

Written comments were received from:

1) Dick Nerbun, Ph.D., Director of Pharmacy, Cumberland Memorial Hospital, Extended Care Unit, Inc., Cumberland, WI.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

With respect to Clearinghouse Comment 2.b., s. Phar 8.09 (4), the requirement for preparing a written order following an emergency oral prescription order is changed from a 72-hour period to a seven-day period.

With respect to Clearinghouse Comment 5.b., the rule, in s. DE 7.08 (2), identifies the responsibility of the pharmacist to assure that a prescription order transmitted electronically was sent with no intervening person or third party having access to the prescription order other than to forward it to the pharmacy. The rule does not identify the means to be used by the pharmacist to meet this responsibility. A pharmacist would be expected to establish a system for receiving electronically transmitted prescription orders that would enable the pharmacist to meet this responsibility. The rule does not identify the means to be used by the pharmacist to meet this requirement.

With respect to Clearinghouse Comment 5.d., the rule, in s. DE 7.08 (5), refers to the responsibility of a pharmacist who receives a prescription order sent electronically and not to the security of transmission. Transmission requirements are in s. DE 7.08 (2).

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

VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

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

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 98-090)

PROPOSED 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.

The proposed 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 electronic, oral or written prescription orders of a prescriber, review all original and renewal prescription orders, whether electronic, 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., 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 ~~verbal~~ electronic or oral 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 electronic or 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 electronic or 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 _____

Agency _____

Chairperson
Pharmacy Examining Board

FISCAL ESTIMATE

1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is: \$0.00.
2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: \$0.00.
3. The projected net annualized fiscal impact on state funds of the proposed rule is: \$0.00.

FINAL REGULATORY FLEXIBILITY ANALYSIS

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

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