CR 94-39

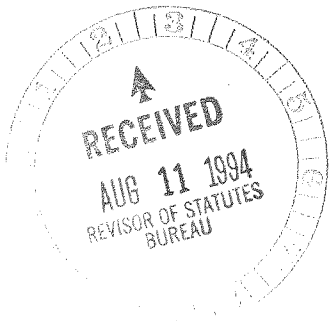
CERTIFICATE

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 10th day of August, 1994.

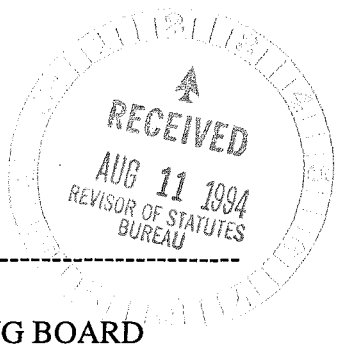
I further certify that said copy has been compared by me with the original on file in this office and that the same is a true copy thereof, and of the whole of such original.



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 10th day of August, 1994.

Patrick D. Braatz, Director
Medical Examining Board, Department of Regulation and Licensing

10-1-94



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 94-39)

ORDER

An order of the Pharmacy Examining Board to create Phar 1.02 (4m) and (15); to repeal Phar 8.07 (5); and to amend Phar 8.07 (3), (4) (intro.) and (4) (a) relating to the partial dispensing of schedule II controlled substances to the terminally ill.

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), Stats.

Statutes interpreted: s. 450.02 (3) (a), Stats.

In this proposed rule-making order, the Pharmacy Examining Board amends Phar 8.07 (3), (4) (intro.) and (4) (a), and repeals Phar 8.07 (5), in order to permit the partial dispensing of schedule II controlled substances to the terminally ill. It also defines the terms "long term care facility" and "terminal illness" in Phar 1.02, in order to clarify the settings and context in which partial dispensing of schedule II controlled substances may occur.

Under the current rules, a pharmacist is not permitted to partially dispense a prescription order written for a schedule II controlled substance on behalf of a terminally ill patient; but rather, is required to dispense the entire quantity set forth on the prescription order. One consequence of dispensing the entire amount prescribed can be an increased risk of theft or diversion of the unused medications when a terminally ill patient dies. This can also result in significant economic loss and disposal problems, since the medications may not be returned to the dispensing pharmacy.

The regulations of the Drug Enforcement Administration permit the partial dispensing of schedule II controlled substances for terminally ill patients, as set forth in 21 C.F.R. s. 1306.13 (b) and (c). In order to permit the partial dispensing of schedule II controlled substances consistent with federal regulations respecting the terminally ill, language has been added to Phar 8.07 (3), (4) (intro.) and (4) (a). Additionally, Phar 8.07 (5), which had limited partial dispensing to instances involving long term parenteral pain therapy, is no longer necessary in light of the modification of the rules to include all terminally ill patients, and is accordingly deleted.

TEXT OF RULE

SECTION 1. Phar 1.02 (4m) and (15) are created to read:

Phar 1.02 (4m) "Long term care facility" means a facility for the developmentally disabled or other nursing home.

(15) "Terminal illness" means an incurable condition caused by injury or illness that reasonable medical judgment finds would cause death.

SECTION 2. Phar 8.07 (3), (4) (intro.) and (4) (a) are amended to read:

Phar 8.07 (3) Prescription orders for schedule II controlled substances written for patients in long term care facilities (LTCF) or for patients with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities to include individual dosage units. The prescribing practitioner may document a terminal illness by writing upon the face of the prescription order the phrase "terminal illness" or words of similar meaning. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescribing practitioner prior to partially dispensing the prescription. Documentation of a terminal illness, whether substantiated by the presence of an appropriate phrase written upon the face of the prescription order or through pharmacist contact with the prescribing practitioner, shall be placed within the individual medication profile record maintained under s. Phar 7.07. The pharmacist shall record on the prescription order whether the patient is "terminally ill" or an "LTCF patient." A prescription order that is partially dispensed and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been dispensed in violation of this section. 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. Subsequent partial dispensing is not permitted under this section if the patient becomes deceased, or is no longer diagnosed as terminally ill, or no longer resides within an LTCF. The total quantity of a schedule II controlled substance dispensed by partial dispensing may not exceed the total quantity prescribed. ~~Schedule II prescription~~ Prescription orders for schedule II controlled substances for patients in an LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless ~~sooner~~ terminated earlier by the ~~discontinuous~~ discontinuance of medication.

(4) (intro.) Information pertaining to current ~~schedule II~~ prescription orders for schedule II controlled substances for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness 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~~ name and address of the LTCF or name and address of the hospital or residence of

the patient; ~~identifications~~ 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)~~ (3).

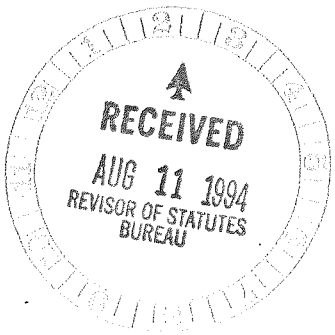
SECTION 3. Phar 8.07 (5) is repealed.

(END OF TEXT OF RULE)

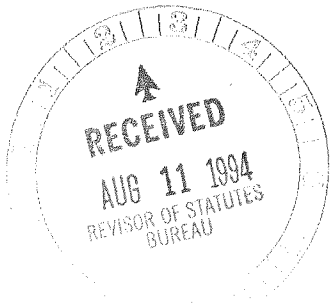
The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register pursuant to s. 227.22 (2) (intro.), Stats.

Dated 8/10/94 Agency

Chairperson
Pharmacy Examining Board



CORRESPONDENCE/MEMORANDUM **STATE OF WISCONSIN**



DATE: August 11, 1994

TO: Gary Poulson
Assistant Revisor of Statutes

FROM: Pamela A. Haack, Administrative Assistant
Department of Regulation and Licensing
Office of Administrative Rules

SUBJECT: Final Rule-Making Order

Agency: PHARMACY EXAMINING BOARD

Clearinghouse Rule: 94-39

Attached is a copy and a certified copy of a final order adopting rules. Would you please publish these rules in the code.

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

Thank you.