

**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 January, 1996.*

*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 January, 1996.**



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

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD

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IN THE MATTER OF RULE-MAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 95-135)

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ORDER

An order of the Pharmacy Examining Board to amend Phar 8.05 (4); and to create Phar 6.02 (1m) and 13.02 (11) (f) relating to licensing outpatient hospital pharmacies; to the time in which a controlled substance listed in schedule II must be dispensed; and to exempting certain pharmacies from the distributor licensing requirements when selling prescription drugs to practitioners for office dispensing.

Analysis prepared by the Department of Regulation and Licensing.

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ANALYSIS

Statutes authorizing promulgation: ss. 15.08 (5) (b), 227.11 (2), 450.02 (3) (a), (d) and (e) and 450.07 (4) (a), Stats.

Statutes interpreted: ss. 450.01 (8), 450.06 (1), 450.07 (2) and (4) (a) and 450.11 (1) and (4), Stats.

In this proposed rule-making order the Pharmacy Examining Board makes changes to its administrative rules to clarify and modify provisions relating to the licensing of outpatient hospital pharmacies, the time period in which prescriptions for schedule II controlled substances must be dispensed, and circumstances in which a pharmacy will not be required to obtain a distributor's license when selling prescription drugs to practitioners for office dispensing.

SECTION 1 clarifies the requirement that a hospital operating a pharmacy in its facility for the dispensing of medications on an outpatient basis, which is physically separate from and in addition to a pharmacy on the premises to respond to inpatient medication needs, must have a pharmacy license for the separate, outpatient dispensing location. Pursuant to s. 450.06 (1), Stats., each location from which a pharmacist dispenses medication must be licensed by the Pharmacy Examining Board as a pharmacy. Hospitals which dispense from separate locations within the institution serving separate classes of patients, need separate licenses. This is to assure that the separate records required for outpatient as opposed to inpatient dispensing are recognized and maintained. For example, pharmacy dispensing to inpatients may be performed "consistent with accepted inpatient institutional drug distribution systems;" whereas the dispensing requirements applicable to all pharmacies apply "to any institutional pharmacy dispensing to outpatients, including prescriptions for discharged patients." See, s. Phar 7.01 (2), Wis. Adm. Code. The proposal would formally require that a second pharmacy license be

obtained when a separate location is set aside within a hospital to specifically dispense outpatient medications, due to the separate record keeping and dispensing requirements, greater public access to the outpatient pharmacy, the need for increased security for the pharmaceutical area, and the existence of a physical separation between the outpatient and inpatient pharmacy locations within such hospitals.

SECTION 2 relates to situations in which a patient receives a prescription order for a schedule II controlled substance which is presented at a pharmacy for dispensing which the prescriber does not desire to be immediately dispensed. Under the current rule, all prescription orders for a schedule II controlled substance must be presented to the pharmacy within 7 days after having been prepared by the prescriber. However, although the prescription order must be presented shortly after issuance, there are situations in which the prescriber may not desire that the prescribed medication be immediately dispensed; for example, where the patient has an adequate supply of the medication to meet his or her needs for a couple weeks and the prescriber does not desire the patient to have possession of a large quantity of schedule II medications.

Also, under s. Phar 8.05 (5), no more than a 34-day supply of a controlled substance may be dispensed at one time. Furthermore, s. Phar 8.06 (1), prohibits a prescription order for a schedule II controlled substance from being renewed. The effect of these provisions is to require a patient receiving schedule II medications to visit the prescriber on a monthly basis in order to obtain new prescription orders for needed medication. In some situations, requiring visits upon such a frequent basis solely in order to obtain a new prescription order is medically unnecessary, as well as unduly costly and inconvenient for both the prescriber and patient. The proposal would permit a prescription order to be dispensed within 60 days after the date that it was written. This may be accommodated by a prescriber, for example, providing a notation upon the face of a prescription order written on February 1: "Do Not dispense Until March 1." The proposed rule would make it clear that such prescription orders are valid and may be dispensed at the time specifically directed as long as the schedule II medication is dispensed within 60 days from the date on the face of the prescription order, and the prescription order was presented to and filed by the pharmacy within 7 days following the date on the face of the prescription order.

SECTION 3 relates to the exceptions provided in s. Phar 13.01 (11), from the general requirement in s. 450.07 (2), Stats., that persons who engage in the sale or distribution at wholesale of prescription drugs obtain a distributor's license. The proposal would permit pharmacies to make sales of relatively small quantities of prescription drugs to practitioners for office dispensing to their patients without being required to obtain a distributor's license. The language in the proposal, as well as the exception itself, is taken from the similar exclusion provided by the Drug Enforcement Administration from federal registration as a distributor of controlled substances for licensed pharmacies under 21 CFR § 1307.11(a)(4). The proposal would exempt pharmacies from the distributor licensing requirements if the sales of controlled substances and all prescription drugs to practitioners for patient office dispensing do not exceed 5% of all such medications distributed and dispensed by the pharmacy during the calendar year. The board has historically interpreted the incidental distribution of drugs by a pharmacist as constituting the "coincident distribution of drugs" within the meaning of the "practice of pharmacy" under s. 450.01 (16) (b), Stats. Therefore, it has not required a pharmacist to obtain

an additional license as a wholesale distributor under such limited circumstances. This interpretation is intended to be formalized and made more specific through rule-making.

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TEXT OF RULE

SECTION 1. Phar 6.02 (1m) is created to read:

Phar 6.02 (1m) A hospital which has a pharmacy area providing outpatient pharmacy services which is physically separate from, and not contiguous to the area from which inpatient pharmacy services are provided, shall have a pharmacy license for the outpatient pharmacy in addition to a license for the inpatient pharmacy.

SECTION 2. Phar 8.05 (4) is amended to read:

Phar 8.05 (4) A prescription containing a controlled substance listed in schedule II may be dispensed only pursuant to a written order signed by the prescribing individual practitioner, except in emergency situations. No prescription containing a controlled substance listed in schedule II shall be dispensed unless the order is presented for dispensing within 7 days following the date of its issue. A prescription for a controlled substance listed in schedule II may not be dispensed more than 60 days after the date of issue on the prescription order.

SECTION 3. Phar 13.02 (11) (f) is created to read:

Phar 13.02 (11) (f) Distributions to a practitioner for the purpose of general dispensing by the practitioner to his or her patients if all of the following apply:

1. The total number of dosage units of all prescription drugs distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of the total number of dosage units of all prescription drugs distributed and dispensed by the pharmacy during the same calendar year.

2. The total number of dosage units of all controlled substances distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of the total number of dosage units of all controlled substances distributed and dispensed by the pharmacy during the same calendar year.

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(END OF TEXT OF RULE)

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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 01/10/96

Agency George F. Chutkan, M.D.  
Chairperson  
Pharmacy Examining Board

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1/2/96

**CORRESPONDENCE/MEMORANDUM**

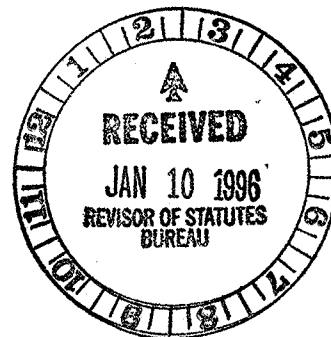
**STATE OF WISCONSIN**

**DATE:** January 10, 1996

**TO:** Gary Poulson  
Assistant Revisor of Statutes

**FROM:** Pamela A. Haack, Rules Center Coordinator  
Department of Regulation and Licensing  
Office of Administrative Rules

**SUBJECT:** Final Order Adopting Rules



**Agency: PHARMACY EXAMINING BOARD**

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

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

Thank you.