

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 01-075)

ORDER

An order of the Pharmacy Examining Board to create Phar 7.12 relating to the requirements for a central fill system.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

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

Statutes interpreted: ss. 450.01 (7) and (16) (b), 450.02 (2) and (3) and 450.09, Stats.

The objective of this proposed rule-making order is to specify the requirements for an approved central fill system. Integrated health systems, business entities comprising common ownership of multiple pharmacies and pharmacies desiring to enter contractual relationships with outside vendors have an interest in increasing patient convenience and lowering cost of service based upon the central filling of prescription orders for dispensing. The intent of such rules is to preserve the integrity of the dispensing process by addressing the issues of ownership of inventory, patient confidentiality, consultation, security, accuracy and accountability which must be maintained in any approved central fill system.

A “central fill pharmacy” is defined as a pharmacy licensed in this state acting as an agent of an originating pharmacy to fill or refill a prescription order. The “originating pharmacy” is a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order for purposes of dispensing by the originating pharmacy.

The central fill pharmacy and originating pharmacy may only process a request for the filling or refilling of a prescription received by an originating pharmacy when the requirements of this section are met. The central fill pharmacy must either have the same owner as the originating pharmacy or a contract with the originating pharmacy outlining the services and responsibilities. The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number, for which it processes a request for the filling or refilling of a prescription order received by the originating pharmacy. The record shall be made available upon request for inspection by the board or its agent. Also, both pharmacies must maintain a written protocol delineating each pharmacy’s assumption of responsibility for compliance with the prescription drug compounding and dispensing requirements of chs. Phar 7 and 8. The

originating pharmacy shall remain responsible for compliance with the prescription drug compounding and dispensing requirements of chs. Phar 7 and 8 which are not assumed in writing by the central fill pharmacy pursuant to a filling protocol. The originating pharmacy will always remain solely responsible for the patient consultation and transfer requirements of s. Phar 7.01 (1) (e) and (em) where the prescription drug is not delivered by an agent of the pharmacist to a patient's residence. Certain functions in the dispensing process may not be performed by the central fill pharmacy unless it shares a common central processing unit with the originating pharmacy. These functions are the medication profile record review of the patient, drug utilization review, refill authorizations, interventions and drug interactions. The prescription label attached to the container of all dispensed drugs shall contain the name and address of the originating pharmacy as the licensed facility from which the prescribed drug or device was dispensed for purposes of s. 450.11 (4) (a) 1., Stats. The date on which the prescription was dispensed for purposes of s. 450.11 (4) (a) 2., Stats., shall be the date on which the central fill pharmacy filled the prescription order.

The originating pharmacy remains responsible for original recordkeeping of all prescription orders as required by state and federal law. All original and refill requests received by the central fill pharmacy are required to be treated as prescription orders for purposes of filing and recordkeeping as required by state and federal law. Each pharmacy is required to maintain records to identify each of its pharmacists responsible for receiving and reviewing prescription orders and compounding and dispensing pursuant to a prescription order and to track the prescription order during each step in the dispensing process. Both pharmacies are required to adopt a joint written quality assurance program to monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and insure compliance with the central fill rule. The originating pharmacy shall provide the patient with the name and address of the central fill pharmacy and obtain consent as required by applicable state and federal law. A system for using a central fill pharmacy not otherwise in conformance with this rule may be permitted if reviewed and approved by the board.

TEXT OF RULE

SECTION 1. Phar 7.12 is created to read:

Phar 7.12 Central fill pharmacy. (1) In this section: (a) "Central fill pharmacy" means a pharmacy licensed in this state acting as an agent of an originating pharmacy to fill or refill a prescription.

(b) "Originating pharmacy" means a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order.

(2) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription order received by an originating pharmacy only pursuant to the following requirements:

(a) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law.

(b) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number, for which it processes a request for the filling or refilling of a prescription order received by the originating pharmacy. The record shall be made available upon request for inspection by the board or its agent.

(c) The central fill pharmacy and originating pharmacy maintain a written filling protocol delineating each pharmacy's assumption of responsibility for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8.

(d) The originating pharmacy shall remain responsible for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8, and which are not assumed in writing by the central fill pharmacy pursuant to a written filling protocol.

(e) The originating pharmacy shall at all times remain solely responsible to perform and comply with the requirements of s. Phar 7.01 (1) (e) and (em).

(f) Unless the central fill pharmacy shares a common central processing unit with the originating pharmacy, it may not perform processing functions such as the medication profile record review of the patient, drug initialization review, refill authorizations, interventions and drug interactions.

(g) The prescription label attached to the container shall contain the name and address of the originating pharmacy as the licensed facility from which the prescribed drug or device was dispensed for purposes of s. 450.11 (4) (a) 1., Stats. The date on which the prescription was dispensed for purposes of s. 450.11 (4) (s) 2., Stats., shall be the date on which the central fill pharmacy filed the prescription order.

(h) The originating pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.

(i) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription orders for purposes of filing and recordkeeping as required by state and federal law.

(j) In addition to meeting the other recordkeeping requirements required by state and federal law, the central fill pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for receiving and reviewing prescription orders and compounding and dispensing pursuant to a prescription order and track the prescription order during each step in the dispensing process.

(k) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and insure compliance with this section.

(l) The originating pharmacy shall provide the patient with the name and address of the central fill pharmacy and obtain consent as required by applicable state and federal law.

(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 _____
Susan L. Sutter, R.Ph. Chairperson
Pharmacy Examining Board

FISCAL ESTIMATE

The Department of Regulation and Licensing will incur \$500 in costs to print and distribute the rule change.

FINAL REGULATORY FLEXIBILITY ANALYSIS

These rules will have no significant economic impact on a substantial number of small businesses, as defined in s. 227.114 (1) (a), Wis. Stat.

PHAR 7.12 CR01-075 (Central Fill) Final 9-2-03