

JUL 27 2001

LCRC
FORM 2



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Ronald Sklansky
Clearinghouse Director

Terry C. Anderson
Legislative Council Director

Richard Sweet
Clearinghouse Assistant Director

Laura D. Rose
Legislative Council Deputy Director

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 01-075

AN ORDER to create Phar 7.12, relating to the requirements for an approved central fill system.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

06-27-01 RECEIVED BY LEGISLATIVE COUNCIL.

07-26-01 REPORT SENT TO AGENCY.

RS:RJC;jal;tlu

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



WISCONSIN LEGISLATIVE COUNCIL

RULES CLEARINGHOUSE

Ronald Sklansky
Clearinghouse Director

Richard Sweet
Clearinghouse Assistant Director

Terry C. Anderson
Legislative Council Director

Laura D. Rose
Legislative Council Deputy Director

CLEARINGHOUSE RULE 01-075

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 September 1998.]

2. Form, Style and Placement in Administrative Code

Section Phar 7.12 (1) and (2) should be consolidated into one subsection as follows:

Phar 7.12 (1) In this section: (a) "Central fill pharmacy" means . . .

(b) "Originating pharmacy" means . . .

If this change is made, sub. (3) should be renumbered as sub. (2).

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

a. Section Phar 7.12 (3) (e) makes reference to various processing functions that a central fill pharmacy may not perform in certain situations. This appears to refer to functions required by other rule provisions or statutes. An appropriate cross-reference to the existing rules or statutes for these functions should be provided to clarify the term "processing functions."

b. Section Phar 7.12 (3) (f), (g) and (h) all refer to various record keeping requirements under state and federal law. A cross-reference should be provided in these paragraphs to the appropriate record keeping requirements of state and federal law that are being referred to.

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

a. In s. Phar 7.12 (3) (a), the use of the word “accountabilities” is unclear. The American Heritage Dictionary defines the word “accountable” to mean “answerable or capable of being explained.”

b. In s. Phar 7.12 (3) (c), it appears that the word “and” after the reference to ch. Phar 7 should be deleted or that the reference “ch. Phar 7” should be replaced by the phrase “this chapter and ch. Par 8.” [See also the cross-reference in sub. (3) (b).] In addition, the reference to ch. Phar 7, if it is the sole reference, should be changed to “this chapter.”

c. It appears that the first phrase of s. Phar 7.12 (3) (d) is redundant. Because the remainder of the provision provides that an originating pharmacy shall remain solely responsible for certain functions, the phrase “the central fill pharmacy shall not assume and” can be deleted. If it is necessary to retain this phrase in the rule, it should be added as a second sentence which provides, essentially, that the functions for which the originating pharmacy must remain solely responsible may not be delegated to the central fill pharmacy.

d. In s. Phar 7.12 (3) (e), a comma should be inserted after the second occurrence of the word “pharmacy” and the comma after the word “as” should be deleted.

e. In s. Phar 7.12 (3) (h), the central fill pharmacy and originating pharmacy are required to maintain “duplicate records.” Does this mean that each record that the pharmacies keep must be maintained in duplicate or must each pharmacy maintain copies of certain records of the other pharmacy? The rule should be clarified.

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 01-)

PROPOSED ORDER

An order of the Pharmacy Examining Board to create Phar 7.12 relating to the requirements for an approved 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 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, responsibilities and accountabilities of each pharmacy. 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 proposed rule provides that the originating pharmacy shall still 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, claims adjudication, refill authorizations, interventions, drug interactions and selection of drug product equivalents. 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 duplicate records to identify each pharmacist 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 this section. The label of any prescription drug container dispensed is also required to contain an additional label encoding either electronically or in printed form the name and address of the central fill pharmacy, the name of the pharmacist who filled the prescription order, and the date of filling.

TEXT OF RULE

SECTION 1. Phar 7.12 is created to read:

Phar 7.12 **Central fill pharmacy.** (1) ^{(a) "Central"} As used in this section, "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) "Orig."} (2) ~~As used in this section,~~ "originating pharmacy" means a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order.

⁽²⁾ (3) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription 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 contract with the originating pharmacy outlining the services to be provided and the responsibilities and accountabilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law.

(b) 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 chs. Phar 7 and 8.

(c) The originating pharmacy shall remain responsible for compliance with the prescription drug compounding and dispensing requirements of ch. Phar 7 and which are not assumed in writing by the central fill pharmacy pursuant to such protocol. 5.

(d) ~~The central fill pharmacy shall not assume and~~ 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) in instances where the prescription is not delivered by an agent of the pharmacist to a patient's residence. } ok. 5.

(e) 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 utilization review, claims adjudication, refill authorizations, interventions, drug interactions and selection of drug product equivalents. } X 5 } (cross ref) to early rules

(f) 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. - X - ref 4

(g) 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. - X - ref 4

5. (h) In addition to meeting the other recordkeeping requirements required by state and federal law, the central fill pharmacy and originating pharmacy shall maintain duplicate records to identify each pharmacist 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.

(i) 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.

(j) In addition to meeting the requirements of s. 450.11 (4), Stats., every container of a prescription drug dispensed pursuant to this section shall contain an additional label encoding either electronically or in printed form the name and address of the central fill pharmacy, the name of the pharmacist who filled the prescription order, and the date of filling.

(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.

INITIAL REGULATORY FLEXIBILITY ANALYSIS

These proposed rules will be reviewed by the department through its Small Business Review Advisory Committee to determine whether there will be an economic impact on a substantial number of small businesses, as defined in s. 227.114 (1) (a), Stats.

g:\rules\phm22.doc
6/27/01