01-075
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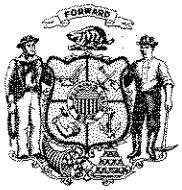
WISCONSIN STATE SENATE



Carol Roessler
STATE SENATOR

To: Members of the Senate Committee on Health, Children, Families, Aging and Long Term Care

From: Senator Carol Roessler, Chair

Date: July 17, 2003

Re: Clearinghouse Rule 01-075, relating to requirements for a central fill system

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CR 01-075 has been referred to the Senate Health, Children, Families, Aging and Long Term Care Committee. This rule specifies 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 the rule 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. The clearinghouse rule is enclosed for your review.

If you would like the committee to hold a hearing on CR 01-075, please contact my office at 266-5300. The committee has jurisdiction over this rule until Friday, August 15, 2003.

CAPITOL ADDRESS: State Capitol • P.O. Box 7882, Madison, WI 53707-7882 • **PHONE:** 608-266-5300 • **FAX:** 608-266-0423
HOME: 1506 Jackson Street, Oshkosh, WI 54901 • **TOLL-FREE:** 1-888-736-8720
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STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	**PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 01-075)**

TO: Alan J. Lasee
President of the Senate
Room 219 South, State Capitol
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the PHARMACY EXAMINING BOARD submitting in final draft form rules relating to the requirements for a central fill pharmacy.

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 PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	REPORT TO THE LEGISLATURE ON CLEARINGHOUSE 01-075 (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:

See attached.

IV. STATEMENT EXPLAINING NEED:

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.

V. NOTICE OF PUBLIC HEARING:

The Pharmacy Examining Board held a public hearing on these rules on eld on September 11, 2001. Susan Kleppin, Madison, WI, appeared in support of the proposed rules. Written comments were received from Diane Darvey, Director of State Pharmacy Affairs, National Association of Chain Drug Stores, Alexandria, VA, who also supports the proposed rules.

Following submission of the rule to the legislature, the Pharmacy Examining Board determined that the rule should be reexamined in light of the uncertain state of federal privacy law regaring confidential medical information under proposed HIPAA rules that had not yet been finalized. Subsequently, the new federal HIPAA privacy rules became effective on April 14, 2003. (45 C.F.R. parts 160-164)

As a result the rule was modified related to recordkeeping, filling protocols, prescription label information and obtaining appropriate patient consent under both federal and state law. A second public hearing was held on May 14, 2003, to allow interested parties the opportunity to comment on the board's modifications. There were no appearances at the May 14, 2003 hearing and no written comments were received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 4.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."

Response: The term "processing functions" as used in s. Phar 7.12 (3) (e) is further defined in that section by seven delineated activities.

Comment 4.b. Section Phar 7.12 (3) (f), (g) and (h) all refer to various recordkeeping 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.

Response: The cross-references state and federal law suggested for explicit inclusion in s. Phar 7.12 (3) (f). (g) and (h) are too numerous for repetition in these sections. The intent of these sections is to reinforce that the records already required to be kept are still kept in the central fill context. For all recordkeeping requirements for each specific type of record, the current provisions of chs. Phar 7 and 8 continue to apply.

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

VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

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

2003 Session

FISCAL ESTIMATE
DOA-2048 N(R10/94)

☑ ORIGINAL ☐ UPDATED
☐ CORRECTED ☐ SUPPLEMENTAL

LRB or Bill No/Adm. Rule No.
CR-01-075

Amendment No. If Applicable

Subject
Central Fill Pharmacies

Fiscal Effect

State: ☐ No State Fiscal Effect

Check columns below only if bill makes a direct appropriation or affects a sum certain appropriation

☐ Increase Existing Appropriation
☐ Decrease Existing Appropriation
☐ Create New Appropriation
☐ Increase Existing Revenues
☐ Decrease Existing Revenues

☑ Increase Costs - May be possible to Absorb Within Agency's Budget ☐ Yes ☐ No
☐ Decrease Costs

Local: ☐ No local government costs

1. ☐ Increase Costs ☐ Permissive ☐ Mandatory
2. ☐ Decrease Costs ☐ Permissive ☐ Mandatory
3. ☐ Increase Revenues ☐ Permissive ☐ Mandatory
4. ☐ Decrease Revenues ☐ Permissive ☐ Mandatory
5. Types of Local Governmental Units Affected:
☐ Towns ☐ Village ☐ Cities
☐ Counties ☐ Others _____
☐ School Districts ☐ WTCS Districts

Fund Sources Affected
☐ GPR ☐ FED ☑ PRO ☐ PRS ☐ SEG ☐ SEG-S

Affected Ch. 20 Appropriations
s. 20.165 (1)(g)

Assumptions Used in Arriving at Fiscal Estimate

The Department of Regulation and Licensing will revise and reprint books of Administrative Code

$500 worth of a Program Assistant time will be needed to prepare revised code books.

There may also be an indeterminate cost for investigators to review the written protocols.

Long-Range Fiscal Implications

Agency/Prepared by: (Name & Phone No.)	Authorized Signature/Telephone No.	Date
Department of Regulation and Licensing Elizabeth Reinwald 266-0746	266-0746	

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 01-075)

PROPOSED 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 filled 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 _____

Chairperson
Pharmacy Examining Board

FISCAL ESTIMATE

See attached.

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.

g:\rules\phm22.doc
7/14/03

LCRC FORM 2

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 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

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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

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Clearinghouse Director

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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.

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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.